D3.1

Early Rapid Medical CCE/PPE Production Specifications & Eur3ka R3 Service Definition

D3.1 Early Rapid Medical CCE/PPE Production Specifications & Eur3ka R3 Service Definition

Work Package:	WP3 - Eur3ka Reliable Resilient Repurposing (R3) Cognitive Digital Twin Service Specification
Lead partner:	INTRASOFT International S.A (INTRASOFT)
Author(s):	John Soldatos (INTRASOFT), George Makantasis (INTRASOFT), Nikos Kefalakis (INTRASOFT) ETHZ, FHG-IOSB, UiO, SEAC, TNO, BRAIN, SIEMENS (SIEL & SIERO), INTELIMECH, POLIMI, VIS, ENG, INNOVALIA, IDSA, STAM, ENGINEERING, ATOS, SQS, UNP, SVM, DTI
Due date:	28/02/2021
Deliverable Type:	Report
Version number:	1.0 **Status:** Final

Project Number:	101016175 **Project Acronym:** Eur3ka
Project Title:	*EUropean Vital Medical Supplies and Equipment Resilient and Reliable Repurposing Manufacturing as a Service NetworK for Fast PAndemic Reaction*
Start date:	December 1st, 2020
Duration:	24 months
Call identifier:	H2020-SC1-PHE-CORONAVIRUS-2020-2-NMBP
Topic:	SC1-PHE-CORONAVIRUS-2020-2A Repurposing of manufacturing for vital medical supplies and equipment.
Instrument:	IA

Dissemination Level	
PU: Public	✓
PP: Restricted to other programme participants (including the Commission)	
RE: Restricted to a group specified by the consortium (including the Commission)	

CO: Confidential, only for members of the consortium (including the Commission)	

Revision History

Revision	Date	Who	Description
0.1	20 / 12 / 2020	INTRA	Table of Contents, Partners Responsibilities Following the WP3/D3.1 Telco
0.11	03 / 01 / 2021	INTRA	Introductory Section
0.12	04 / 01 / 2021	SEAC	Input on SEAC Repurposing Case
0.13	11 / 01 / 2021	ETHZ	Input on known Repurposing Case Studies
0.14	12 / 01 / 2021	UiO	Input on ZDM platforms and Semantics (Section 5) (background and specifications)
0.15	14 / 01 / 2021	IMECH	Inputs on Flexible Production Lines Specifications
0.16	14/01/2021	POLIMI	Inputs on Financial Impact Assessment
0.17	18 / 01 / 2021	FHG-IOSB	Inputs on Supply Chain Match Making / Smart Factory Web (Section 4)
0.18	19 / 01 / 2021	INTRASOFT	Various edits, formatting and quality control
0.19	20 / 01 / 2021	INNO, POLIMI, ENG INTRASOFT	Introduction of four transformation Scenarios (Section 3) and mapping of Eur3ka Components
0.20	22/01/2021	SQS	Inputs on the certification framework of Eur3ka
0.21	27/01/2021	ATOS	Inputs on the ZDM / Quality Management framework of Eur3ka
0.22	27/01/2021	ENG	Inputs on Situational awareness services and Eur3ka specifications
0.23	03/02/2021	INTRASOFT	Updates in Section 3, Inputs on Shifts Allocation in Section 7
0.24	05/02/2021	INTRASOFT	Initial Specification of Shift Allocations Solution
0.25	08/02/2021	INTRASOFT	Updates to Section 2, Various Edits
0.26	10/02/2021	IDSA, ATOS	Updates to Industrial Data Space Inputs (Section 4)

0.27	10/02/2021	INNO	Inputs on sections 4.1.5, 4.2.5, 5.1.1 & 5.2.1
0.28	11/02/2021	INTRASOFT	Updates to Shift Allocation Specifications
0.29	11/02/2021	TNO, BRAIN	Integration of Inputs on Supply Chain Management
0.30	15/02/2021	ETHZ	Updated Inputs on Case Studies (Section 2)
0.31	15/02/2021	POLIMI	Updated Inputs on Section 7
0.32	15/02/2021	INTRASOFT	Fine Tuning and Harmonization
0.33	16/02/2021	VC	Inputs on Robotic Cells and Remote Manufacturing Support
0.34	17/02/2021	INTRASOFT	Various Updates; Authoring of Section 8
0.35	19/02/2021	INTRASOFT	Updates to Section 1; Various Edits and Quality Control
0.36	19/02/2021	SIEMENS	Inputs on the SIEMENS AM Manufacturing Network (Section 4)
0.37	19/02/2021	INTRASOFT, UiO, FHG, STAM,	Enhancement of Inputs and Specifications of Eur3ka services; Provision of Specifications in Tabular Format
0.38	22/02/2021	INTRASOFT	Various updates; first version of the Executive Summary
0.39	22/02/2021	INTRASOFT	Various updates; Quality Control; First Version of Integration Concept (Section 3)
0.40	22/02/2021	INTRASOFT	Preparation of version for Quality Control
0.41	22/02/2021	IDSA, INTRASOFT	Updates to Sections 3 and 4
0.42	23/02/2021	SIEMENS	Updates to Sections 4 about the AMN
0.43	25/02/2021	INTRASOFT	Addressed Review Comments from ATOS
0.47	26/02/2021	INTRASOFT	Addressed Review Comments from FHG
0.99	27/02/2021	INTRASOFT	Fine tuning and preparation of version for final check by the coordinator
1.0	28/02/2021	ENG	Final coordinator review before submission

Quality Control

Role	Date	Who	Approved/Comment
Internal review	24/02/2021	ATOS	Provided Document with Track changes and Suggested Revisions
Internal review	24/02/2021	FHG	Provided Document with Track changes and Suggested Revisions

Disclaimer

Executive Summary

The main goal of Eur3ka is to implement and validate a Plug & Response (P&R) manufacturing platform that will enable manufacturers confront the main challenges arising from the COVID19 healthcare crises and related future events that could disrupt production operations. The platform will address the most important challenges faced by manufacturers since the COVID19 pandemic outbreak, including the need to operate their plants despite COVID19 measures and restrictions, the need to address disruptions in the Supply Chain, the need to design new products (e.g., marks and respirators), as well as the need to certify the products in-line with applicable regulatory requirements.

The present deliverable provides the initial definition and specification of the services of the Eur3ka platform. The definition of these services is driven by four manufacturing repurposing scenarios that align to the above-listed challenges faced by manufacturers in COVID19 times. The four scenarios are detailed in the document and address the following areas:

- Rapid reconfiguration and continuity of production line operations, despite COVID19 measures and restrictions.
- Reliable repurposing of production processes towards designing and producing new products (e.g., sanitizers, PPE/CCE products). Emphasis is paid in scenarios where certification requirements must be met, given that medical products for COVID19 are subject to stringent certification specifications.
- Resilient and trusted smart supply networks enabling manufacturers to address disruptions and changes in the supply chain.
- Robust on-demand remanufacturing networks enabling manufacturers to benefit from “manufacturing as a service” capabilities such as Additive Manufacturing networks.

The specification of these scenarios has been driven by the analysis of the state of the art of manufacturing during COVID19 times, as well as by the consideration of a rich set of manufacturing repurposing case studies. These case studies covered a wide array of different products such as visor holders for magnifying glass, face shields, face masks and medical gowns, face masks, mouth mask, respirators, and nanotechnology air filtration systems.

The analysis of case studies revealed the main challenges that should be addressed by the reference scenarios of the project. Likewise, the analysis of the reference scenarios led to the identification of the main services of the Eur3ka platform, including:

- The Eur3ka services for production line flexibility and adaptability to different conditions and resources.
- The Eur3ka Additive Manufacturing Network providing Manufacturing on demand capabilities for medical product.
- The Eur3ka Industrial Data Space which will provide the means for trusted data exchange among supply chain partners.

- The Eur3ka Smart Matchmaking Services for flexibility and resilience in the Supply Chain of medical products.
- The Eur3ka Semantic Interoperability which will boost semantic unification and interoperability for the data exchanged between the participants in the Eur3ka network and data space.
- The Eur3ka Zero Defect Manufacturing and Quality Management Services that will facilitate product design with high quality and short production ramp up times.
- The Eur3ka Certification Services that provides guidance and specification for the certifications at multiple levels, including site, equipment, process, and product certification.
- The Eur3ka Business Continuity Framework that provides a pool of services for plant and production continuity, including services that ensure the health and safety of employees. The framework comprises multiple services including services for plant risk assessment, shifts allocation, training and reskilling of employees, remote manufacturing support, as well as financial analysis and impact assessment at the business level.

The majority of the above-listed Eur3ka services will be built upon existing platforms and technologies of the consortium partners, which is the reason why these background technologies are also presented in this document. At later stages of the Eur3ka project, these services will be integrated in a cognitive digital twin for Plug and Response (P&R) manufacturing repurposing during COVID19 times and related healthcare crises. In the scope of the document an initial integration concepts will be provided, yet the detailed integration concept will be presented in other deliverables of the project (e.g., like the Eur3ka reference architecture deliverable in WP2).

This deliverable will serve as input to other technical specifications and integration activities of the project, notably to architecture specification activities in WP2 of the project and to platform integration activities in WP4. This is the main objective and function of the present document. The detailed and final specification of the Eur3ka services will be provided in an updated version of this deliverable, namely the second deliverable of WP3 of the project i.e., deliverable D3.2 (due M14 of the project), which has the same title as the present deliverable.

Table of Contents

List of figures

List of Tables

Definitions and acronyms

AAS	Asset Administration Shell
AI	Artificial Intelligence
AM	Additive Manufacturing
AMN	Additive Manufacturing Network
AOs	Application Ontologies
BCF	Business Continuity Framework
BFO	Basic Formal Ontology
BPM	Breaths Per Minute
CA	Consortium Agreement
CAD	Computer Aided Design
CCE	Clinical Care Equipment
CNC	Computer Numerical Control
CPPS	Cyber Physical Production Systems
CSV	Comma Separated Values
DDOs	Domain Dependent Ontologies
DIH	Digital Innovation Hub
DMP	Data Management Plan
GD&T	Geometries and Dimensional and geometric Tolerances
GMP	Good Manufacturing Practices
DE	Digital Enabler
DIROs	Domain Independent Reference Ontologies
DoA	Description of Action
DSROs	Domain Specific Reference Ontologies
EC	European Commission
EDI	Electronic Data Interchange
EU	European Union
Euratex	European textile and clothing industry
FF	Full Face
FO	Foundation Ontology
FTP	File Transfer Protocol
GA	Grant Agreement
I4.0	Industry 4.0
IDS	International Data Spaces
IDSA	International Data Space Association
IIC	Industrial Internet Consortium
IOF	Industry Ontology Foundry
IPP	Intermediate Product Properties
IRR	Internal Rate of Return
ISO	International Organization for Standardization
JSON	JavaScript Object Notation
LCA	Lifecycle Assessment
LCC	Life Cycle Costing
MAL	Manufacturing Autonomy Level
MES	Manufacturing Execution System
MILP	Mixed-Integer Linear Programming

MRT	Manufacturing Repurposing Transformations
NPV	Net Present Value
OEM	Original Equipment Manufacturer
PBT	Pay Back Time
PC	Personal Computer
PDF	Portable Document Format
PLM	Product Lifecycle Management
PP	Polypropylene
PPE	Personal Protection Equipment
PPS	Production Planning and Scheduling
P&R	Plug & Respond
QIF	Quality Information Framework
RA	Reference Architecture
RFQ	Request For Quote
ROI	Return on Investment
SCMP	Supply Chain Management Platforms
SCSN	Smart Connected Supplier Network
SFW	Smart Factory Web
SFWC	Smart Factory Web Connector
S-LCC	Social Life Cycle Costing
SMMA	Smart Matching/Mediation App
SROI	Social Return of Investments (SROI)
TC	Technical Coordinator
W3C	World Wide Web Consortium
WHO	World Health Organization
WP	Work Package
XSDL	XML Schema Definition Language
ZDM	Zero Defect Manufacturing

1 Introduction

1.1 Scope and Purpose

Since the beginning of 2020, the COVID19 pandemic outbreak has had a disruptive effective in production operations and supply chains. For a considerable amount of time during the 1st wave of the pandemic supply chains could not operate as planned, given that many companies were reliant on production and supplies in China while transportation and logistics were affected by COVID19 restrictions. Moreover, the demand for some products was significantly reduced because of measures for fighting against the pandemic. At the same time, there was a surge of demand for other products like face masks and sanitizers. In this context, many manufacturers had to repurpose their production. For instance, manufacturers of luxury perfumes repurposed their production to produce hand sanitizers[1], while some automotive companies evaluated options to producing urgently needed medical devices such as ventilators.

In this context, following the pandemic outbreak, manufacturers, industrial managers, and policy makers focused on the implementation of strategies for revamping production patterns and meet consumer demand for specific products, such as Clinical Care Equipment (CCE) and Personal Protection Equipment (PPE). Likewise, manufacturers and their suppliers started analysing supply chain operations to support the new requirements. Furthermore, it become apparent that production should become more agile and flexible against future disruptions. In this direction, digital manufacturing technologies and Cyber Physical Production Systems (CPPS) could play a key role through unlocking the flexibility potential of Industry 4.0 (I4.0).

Eur3ka is a joint effort of manufacturers and I4.0 experts to provide a Plug & Respond (P&R) framework for flexible manufacturing that could enable the rapid adaptation and repurposing of production in the scope of disruptive events such as the COVID19 healthcare crises. The Eur3ka P&R framework will empower manufacturers and other stakeholders in the manufacturing chain to react, adapt and set up crisis management mechanisms. It is motivated by the recent pandemic, but not limited to it: Eur3ka will boost the agility and flexibility stakeholders of the manufacturing chain towards enabling them to successfully respond to pandemics, trade wars, or even future restrictions stemming for national or global political interventions.

The Eur3ka P&R framework will be empowered by a range of digital manufacturing technologies, which will be integrated and will interact with each other in-line with an open, standardized, modular, digital manufacturing architecture. It will boost the flexibility of production lines inside manufacturing facilities, while at the same time boosting the agility of global supply chain capabilities with emphasis on the manufacturing chains of the CCE and PPE products.

The framework will therefore offer a pool of digital services at the level of the factory and across the supply chain. These digital services will collectively enable the development of a

[1] https://www.forbes.com/sites/richardkestenbaum/2020/03/15/lvmh-converting-its-perfume-factories-to-make-hand-sanitizer/?sh=14d10d5f4a9a

cognitive digital twin for supporting effective manufacturing P&R operations across the entire supply chain of medical products, which will facilitate manufacturers to rapidly respond to major crises. This cognitive twin will be tailored to support manufacturing flexibility in-line with requirements that emerged following the COVID19 pandemic outbreak, yet it will be able to support manufacturing resilience scenarios in future crises.

The present deliverable is destined to describe the services that comprise this cognitive twin, including services for:

- Flexible production lines that can rapidly adapt to different production recipes and schedules.
- Additive manufacturing services for printing products and parts in secure and resilient ways, and with the lowest latency possible.
- Supply chain adaptation services, including digital services for matching supply with demand in complex manufacturing chains.
- Adaptive and responsive Quality management and Zero Defect Manufacturing (ZDM) services, which safeguard the high quality of the products following the repurposing of a production line, while shortening ramp-up times.
- Certification services at the site, equipment, and processes level, including services that ensure compliance with COVID19 related production for CCE/PPE products.
- A rich set of business continuity services, including services that safeguard the safety of the employees and the proper operation of the plants, even in cases where COVID19 restrictions (e.g., site lock downs, teleworking for a significant percentage of the workers) are in place.

The deliverable provides specifications for the above listed services, including information on how background platforms and other Intellectual Property (IP) of the partner will be customized and used in Eur3ka. Nevertheless, it does not provide details on the architecture of the Eur3ka platform and does not specify the integration details of the various modules. The latter information (i.e., architecture and integration) are detailed in other deliverables of the project.

1.2 Methodology

The present deliverable is the first technical deliverable of the project's time plan. It is destined to set the scene for the detailed design and the implementation of the Eur3ka services. As such it is developed in a quite short time based on the following principles:

- **"Best Practices" Driven**: The specification of the Eur3ka services is strongly driven by international standards (e.g., IDSA (Industrial Data Spaces Association) standards for Data Spaces, Industry Ontology Foundry (IOF) standards for semantic modelling, ISO 13485 for quality management and certification), best practices, and documented experiences regarding how the manufacturing community responded to the 1st wave of the COVID19 pandemic. This is purposeful and aims at accelerating the Eur3ka requirements engineering process.

- **Reuse Driven**: Most of the Eur3ka services will be built on background platforms and projects of the partners. The latter platforms and projects will be reused and adapted to the Eur3ka requirements. This is part of the project's overall approach for accelerating the implementation of the Eur3ka P&R framework and for maximizing the project's value for money.
- **Standards and Blueprints based**: The services are specified in-line with applicable regulations and standards, which aims at boosting Eur3ka's wider adoption and technological longevity.

Along with the above-listed principles, the deliverable is developed based on the following methodological instruments:

- **Case Studies Analysis**: The deliverable presents various cases studies of manufacturing repurposing in response to the COVID19 pandemic outbreak. These cases studies provide insights on how different manufacturers ensured their production continuity and repurposed their production towards designing and manufacturing new products. The list of presented cases studies is very rich and includes both case studies within the consortium (e.g., the repurposing case study of partner SEAC) and case studies from third-party manufacturers i.e., manufacturers outside the consortium.
- **Direct Interaction with Stakeholders**: Some of the above-listed cases studies involved direct interactions with manufacturers. Specifically, interviews and face-to-face discussions took place towards collecting and documenting the information presented in the case studies.
- **Review of the State of the Art**: The deliverable reviews of the state of the art in manufacturing repurposing, towards defining the main repurposing transformations that will be supported by the project. Likewise, it also presents the state of the art in the technological areas that are directly linked to the Eur3ka services. For example, the state of the art is reviewed in areas like flexible production lines, trusted information exchange in the supply chain, digital quality management, zero defect manufacturing and more. Emphasis is paid on describing the partners' background IP that will be (re)used in the project. Leveraging on the description of such background IP, the deliverable specifies the Eur3ka services that will enable the project's manufacturing P&R (Plug n' Response) paradigm.
- **Software / Digital Components Description Templates:** The deliverable includes the specifications of Eur3ka services. In several cases these services are based on the implementation of digital components. In the scope of the deliverable some of the digital components to be implemented in the project are described in a structured way, based on a proper template for describing such components.

From a timing perspective, the deliverable was developed based on the following sequential phases-tasks:

- **Background IP Documentation and Review of the State of the art (M1)**: During the first month of the project's lifetime and following the Kick-Off Meeting of the project, the partners have put emphasis in providing detailed description of their background

technologies. The description of the background IP of the partners was a key prerequisite for specifying the Eur3ka services, given that in most cases these services were defined over background components and platforms of the partners.

- **Initial Services Specifications and Collection of Additional Requirements (M2):** The second month of the project's lifetime was devoted to an initial specification of the Eur3ka services, including a specification of their role in supporting the project's manufacturing repurposing scenarios.
- **Consolidation of Eur3ka Services Specifications and Alignment to other deliverables (M3):** During the third month of the project, the Eur3ka services specifications were further detailed and aligned to on-going work in other work packages (notably WP2 and WP4 of the project). Furthermore, some high-level integration concepts i.e., insights on how to integrate Eur3ka services were developed. The latter integration concepts are also reflected in the deliverable. Nevertheless, the need for detailing some aspects of the integration was identified as well. This is planned as future work that will be reported in deliverable D3.2, i.e., the second deliverable of this work package.

1.3 Relevance to Other Deliverables

The deliverable describes the main functionalities to be offered by the Eur3ka platform. As such it is relevant to most of the technical deliverables of the project, as most of them are dedicated to the detailed design and implementation of the services that are listed in D3.1. However, there are two deliverables with similar development timelines as D3.1, which are the most closely related to the present deliverable. Specifically:

- Deliverable D2.1 "Eur3ka Manufacturing Repurposing Reference Framework & Data Management Plan (DMP)" is the deliverable that specifies the reference architecture of the project. D3.1 should be generally aligned to D2.1 i.e., the services presented in this deliverable must be aligned to the structuring principles for the Eur3ka components that will be specified in D2.1.
- Deliverable D4.1 "Early Deployment of Eur3ka R3 Service Platforms and Infrastructure", which provides the integration specification of the Eur3ka platform. As such D4.1 specifies how the services described in the present deliverable will interact through the Eur3ka digital infrastructures such as cloud platforms and industrial data spaces.

Overall, the three deliverables listed above (i.e., D2.1, D3.1, D4.1) will provide a sound basis for implementing and integrating the Eur3ka framework. In this direction, it is very important to streamline the results of the three deliverables.

1.4 Structure of the Document

The rest of the deliverable is structured as follows:

- Section 2, following this introductory paragraph, presents the main requirements that drive the specification of the Eur3ka services. It aggregates requirements from many different sources, including review of state of the art on production requirements during COVID19, best practices and lessons learnt from successful cases of production repurposing, analysis of flexible production case studies, interviews with manufacturers and more.
- Section 3 specifies the main manufacturing repurposing scenarios that will be targeted in the Eur3ka project. These scenarios provide background and motivation for developing the Eur3ka services. Hence, the section outlines how different Eur3ka services address the needs and challenges of the introduced scenarios. Furthermore, Section 3 provides a high-level overview of the integration requirements of the various Eur3ka services. As such it provides a high-level overview of the structure of the cognitive digital twin for P&R production of PPE and CCE products.
- Section 4 illustrates the Eur3ka technologies that will be used to boost the flexibility of the production processes inside the plant. It also presents technologies for more flexible supply chains. The section specifies how different technologies of the project's partners will be customized to provide the above-mentioned flexibility.
- Section 5 specifies the Eur3ka services for quality management and ZDM. In this direction it introduces relevant background technologies and products of the partners, while illustrating their customization in-line with the manufacturing scenarios of Section 3.
- Section 6 is devoted to the specification of the Eur3ka certification services. It provides a checklist of requirements/specifications for certifying production sites, equipment, products, and processes. Furthermore, it clusters the requirements to different categories in-line with the objective of the certification process (e.g., whether the goal is the certification of a process or piece of equipment).
- Section 7 presents the Eur3ka business continuity framework, which is destined to safeguard the health, the safety and the capacity of the employees, while empowering plant operations under COVID19 restrictions. In this direction, it presents how Eur3ka will support processes like shifts allocation, employees' reskilling and training, remote manufacturing processes, and situation awareness. The framework also provides the means for COVID19 related financial impact assessment i.e., an assessment of the financial impacts of production repurposing and other P&R processes.
- Section 8 is the final and concluding section of the project. It draws main conclusions and provides an outlook for the future developments of WP3 that will lead to deliverable D3.2.

2 Industrial Production during the COVID19 Crises: Overview of Requirements and Lessons Learnt

2.1 COVID19 General Impact on Industrial Production and Manufacturing Supply Chains

During the first months of 2020, the COVID19 pandemic outbreak has a had a severe impact on industrial production. According to recent data by Eurostat[2] (Figure 2-1), which industrial production in the EU increased by 2.3 % in November 2020 after an increase of 2.0 % in October. However, we witnessed a strong production decline in March and April 2020. Nowadays, the total production level is very close to the level before the COVID19 crisis (99.4 %).

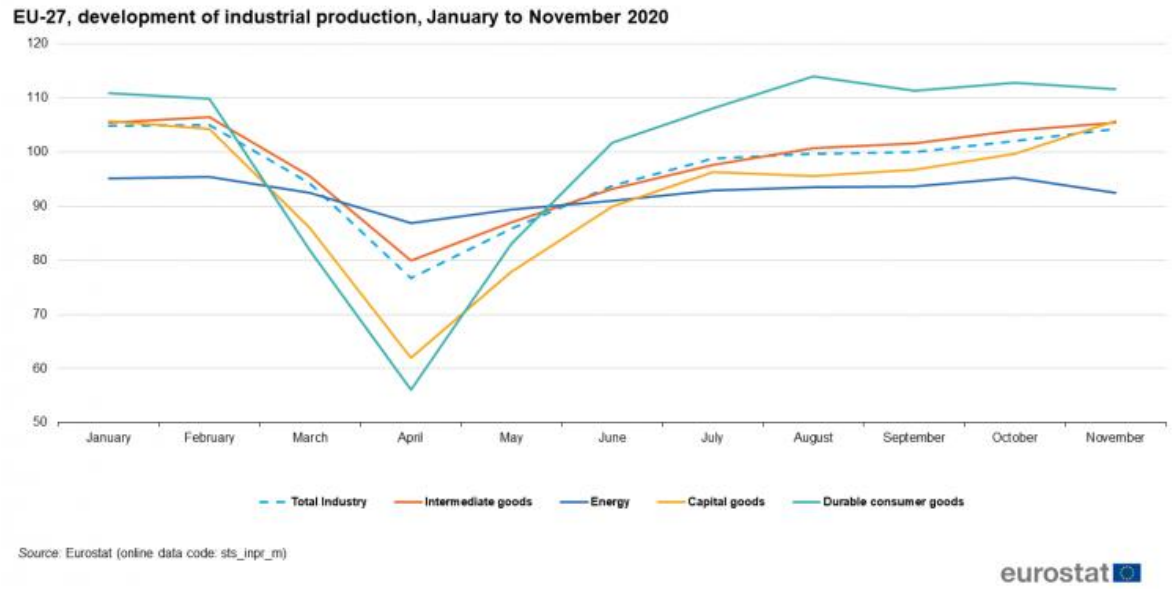


Figure 2-1: Development of industrial production, January to November 2020 (Source: Eurostat)

COVID19 did not only have an impact on the volume of the production. It also had some short- and medium-term effects, which illustrated the need for manufacturers to be more flexible, agile, and resilient, to confront this and other analogous crises. Specifically, the main impacts on COVID19 on industrial production, included:

- **Critical shortages in COVID19 related products like PPE**: This was a result of disruptions in the supply chain and of the surge in the demand for medical and healthcare related products.

[2] https://ec.europa.eu/eurostat/statistics-explained/index.php/Impact_of_Covid-19_crisis_on_industrial_production

- **Rapid repurposing of Supply Chains**: Manufacturers went on repurposing their supply chains towards confronting disruptions and increasing their resilience. Furthermore, it become apparent that more supply chain flexibility is needed towards responding to future crisis of similar nature.
- **Repurposing Manufacturing Capabilities and Develop New Products**: The pandemic led manufacturers to repurpose their capabilities and to develop new products. In several cases, they had to design new products that were very high in demand, such as sanitizers, face masks, N95 masks and other types of PPE and CCE products. The production of such products did not only aim at boosting the business results of the manufacturing enterprises during the pandemic. It was also deemed important to help societies deal with urgent challenges of the COVID19 period.
- **Impacts on the Health and Well-being of the Workforce**: Like in all sectors of the economy, some manufacturing workers got COVID19 infected, which compromised their ability to work on the shopfloor. In this context, manufacturers realized the importance of safeguarding the health and the safety of their workforce. Furthermore, they understood the importance of supporting their mental health and of implementing safe return to work policies for infected or affected workers.
- **Refocus of Supply Chains towards a Local Scope**: Several industrial enterprises had to refocus their supply chain strategies in directions that allocated resources to local communities. This was a result of supply chain disruptions, but also of political considerations.
- **Increased use of Digital Technologies to derive relevant insights and develop a Response to the Pandemic**: To achieve their ambitions goals in terms of production repurposing and new product design, manufacturers extensive use of digital manufacturing technologies developed as part of their Industry 4.0 strategies. They used digital tools such as digital twins, advanced analytics, and digital automation functions, towards increasing their agility and flexibility both inside their factories and across the supply chain. Furthermore, several manufacturers took advantage of novel manufacturing capabilities such as Additive Manufacturing (AM) and Manufacturing-as-a-Service.
- **Increased emphasis on Supply Chain Security**: The pandemic manifested the importance of exchanging accurate and timely digital information across the manufacturing chain as a means of increasing security and resilience. Therefore, supply chain security and trusted exchange of digital information become primary concerns for manufacturers during the pandemic. Trusted exchange of digital information also covered the need for exchanging assets (e.g., Intellectual Property (IP) like digital models for new products and parts).
- **Focus on Lessons Learnt and Continuous improvement**: Manufacturers underlined the importance of establishing continuous improvement processes, while capitalizing on lessons learnt from the 1st wave of the pandemic towards addressing the challenges of sub-sequent waves and of similar crisis in the future.

Eur3ka is motivated by these impacts and will provide technologies and services that will help manufacturers to address the described challenges. The project adopts a structured approach that builds on existing standards and blueprints. At the same time, it aims at enabling a holistic approach that addressed most of the manufacturing repurposing scenarios that related to the pandemic, including repurposing of production, design and

manufacturing of new products, support for resilient supply chain, as well as support of a new wave of novel, on-demand, manufacturing capabilities. Section 3 illustrates the main COVID19 manufacturing response scenarios that drive the project's work. Following paragraphs focus on requirements and lessons learnt stemming from tangible production scenarios (e.g., production transformation scenarios) that were materialized during the 1st wave of the pandemic.

2.2 Production Transformation Challenges and Requirements

2.2.1 Overview of COVID19 Impact on Production Transformation

COVID19 has brought upon an unprecedented change onto mankind impacting not only our daily lives but also businesses through disruptions in production and supply chain operations. Critical shortages of personal protective equipment (PPE) such as face masks as well as medical devices such as ventilators during the early stages of the COVID19 outbreak presented distinct challenges to many manufacturing industries and governmental institutions with this question: "What is the best approach to respond to skyrocketed demands of critical items during the early stages of a pandemic?"

While many governments enforced lock-down strategies that inevitably disrupted global supply networks, various enterprises with different sizes, research institutes, and service industries commenced new initiatives to help huge deficiencies of critical items desperately demanded by patients and healthcare workforces. Although several policy responses across the world have been observed to supplement the efforts of overcoming the shortages of critical items [Links20], there are little known about best practices to better respond to early stages of pandemics, future outbreaks and emergencies and prevent likely failures. A few examples worth highlighting here are attempts of car manufacturers such as Ford and General Motors to produce relatively complex products such as ventilators through collaboration with Ventec Life System [Sean20]. Although opponents challenged the effectiveness of such attempts in the long run and proposed to work around the resilience of existing global supply chains [Netland20] proponents argued that those initiatives and rapid responses by manufacturers—also termed as 'repurposing' [López-Gómez20] had a face value to supply PPE and medical devices.

2.2.2 Case Study 1: Requirement for Transformation from General Production towards Medical Production

2.2.2.1 Requirements Overview

The transformation from the general production towards a medical production presents different difficulties, and scenario. During the pandemic, we have seen different responds proposed by makers, industries, hospitals or just civilian. All this dynamic proved that EU could achieve great results, and being agile for producing missing items. However, at the

same time, these solutions encounter challenges to get in use due to the lack of medical certification.

To produce for the medical industry, there is a need to address several production requirements, which can be classified in the following very broad areas:

- **Product conformity with medical compliance**. The product cannot get on the market before it has been complying with the different regulation, if the Class I can get away with a self-certificate in EU all other Classes need an assessment by a Notified body for CE marking.
- **Risks Analysis based on the Standard for Risk Management of Medical devices ISO 14791**.
- **Quality system ISO 13485**. The implementation of a quality system requires many resources, and general changes in companies. It is most of all an updated quality system, more demanding than the ISO9001.
- Packaging, label, information.

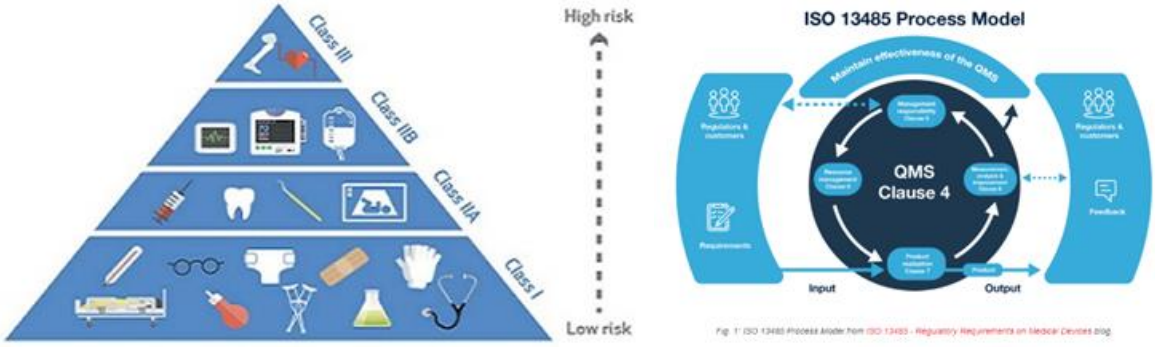


Figure 2-2: (a) (Left) Risk Analysis for Different Classes of Medical Devices; (b) (Right) ISO 13485 Quality System Process[3]

2.2.2.2 Transformation Solutions and Main Challenges

The transformation from a general production towards medical production will be only successful if we manage to help the company from their actual stage towards the medical. But the way can be quite long if you do not have any quality system at all, and also if you want to develop the product from scratch.

As an optimal solution, most of all from a simplicity point of view. As a medical company will "just" subcontract the production somewhere else and take the responsibility of the quality there, by auditing the subcontractors. They are paperwork to be done, but not as much as in a certification of a production. The product is already certified/CE marks, etc.

There are multiple challenges in this process, at different levels, including:

[3] ISO 13485:2016 Medical devices — Quality management systems — Requirements for regulatory purposes, https://www.iso.org/standard/59752.html

- **On the product**: Certification on higher product than Class I will need external and notified body help to the CE marking.
- **On the production**: Quality system is one thing, but respecting it need many resources and modifying the way of working. This can be difficult compared to pandemic restriction and lockdown situation as it already bringing changes in the “normal” working days.
- **On the company**: production regulation, and medical market encounter higher risks for the company. Resulting in possible changes of insurance (extra costs)
- **On the hospital**: They will need to trust non official sources, new productions, new products.
- **On official**: Each of the country as their own regulation/principle on top of it, making the generalisation of a solution difficult.

2.2.3 Lessons Learnt

The preliminary lessons learned from the various stakeholders can be categorized into 4 main categories namely: product design, regulatory, resources and supply chain, as follows:

- **Product Design**: Mainly, the product design impacts the ability and speed of repurposing. This is due to the complexity of the repurposed product where a more complex product required increased knowledge and know-how. For the more complex products, it is found that knowledge sharing, and collaboration is imperative between the new entrants with the experienced manufacturer.
- **Regulatory Implications**: Secondly, for the regulatory perspective, the speed at which this was carried out and information dissemination was also a vital component. Moreover, the involvement of regulatory bodies on the dissemination of information to provide the bridge between the customers and manufacturers was also identified as vital.
- **Resources**: Thirdly, from the resource’s standpoint, the key lessons learned were from the human resource and the financial resources. This is observed from the importance of know-how to ensure the speed and scale of delivery. Moreover, it is observed that funding played a vital role to secure the raw materials required for production.
- **Supply Chain**: Lastly, a key lesson learned was from the supply chain aspect where it is observed that the integration within and across supply chains was vital for effective results. It is important to coordinate across the various nodes to ensure a smooth delivery to meet the demands required.

2.3 Case Studies and Lessons Learnt from the 1st Wave of the COVID19 Pandemic

2.3.1 Eur3ka Partner Case Study: SEAC Full Face Mask

2.3.1.1 Supply chain operation during COVID19

One of SEAC's most representative product is the Full Face (FF) mask for snorkelling.

The company's reaction to the first pandemic wave in March/April 2020 was to make its skills, technology, and FF mask available to reconvert it and support who was fighting the pandemic.

It was something new for SEAC, and when you make something new, that is completely out from your area of application, it's necessary to start exploring a new world made of new rules, new definitions, new standards, new requirements, etc.

This is what SEAC did. Unfortunately, when the FF mask project was started, there was no cooperation, synchronization, and sharing opportunities between factories, even if the goal was the same.

Every company was working by itself, trying to design, in the shortest time possible, the best solution to help fighting the pandemic.

SEAC trusted that its FF mask had the best results in term of breathing performance and % of CO2 residual, so they understood it could be helpful to who was fighting the whole day against the virus. They just had to study the best way to make the mask completely compatible with the needs of the medical personnel.

Then, a connector was designed, to be able to install a filter in place of the snorkel, as shown in Figure 2-3. Using this filter, the user can always breath fresh and pure air.

In just three weeks SEAC was able to design the connector, make the mould, and produce it. During this challenge, the most important rule to get the best and fastest result has been working as a team, sharing knowledge, technology, results, equipment, data. That is the main reason for SEAC to participate to Eur3ka project, since the company is building a team to be ready to face together the next challenges and emergencies.

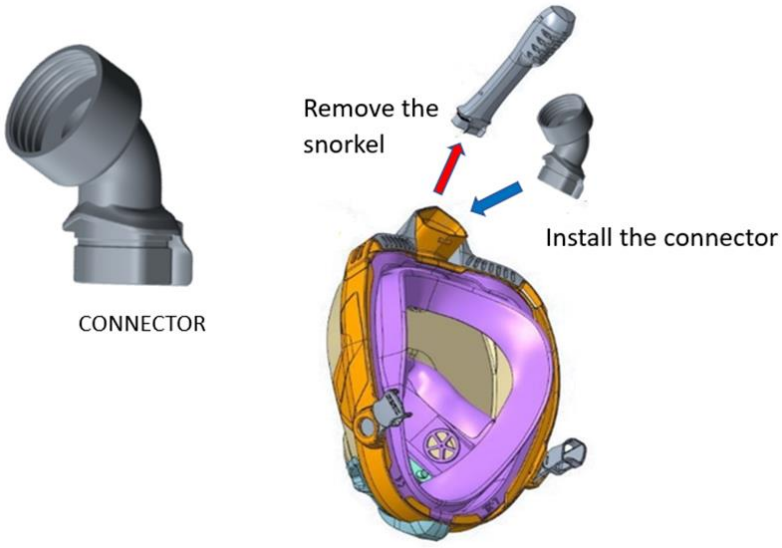


Figure 2-3: 3D models of FF mask, snorkel, and connector

2.3.1.2 Quality control testing procedures for PPE products

During the first wave of pandemic, SEAC was able to use the already existing test equipment for snorkeling FF masks to do quality control testing for the new product. The FF masks testing procedures were done according to the following list:

- All FF masks are subjected to visual examination. Visual examination shall be conducted prior to or during laboratory or practical tests.
- All FF masks are subjected to CO2 residual test (according to standard EN 136:2000): The mask is assembled on a Sheffield head connected to a breathing simulator.

Figure 2-4: FF mask, assembled on the Sheffield head

Through a CO2 analyzer is possible to set and inflate inside the system a gas mixture (atmospheric air + CO2) that contains 5% of CO2. A second CO2 analyzer checks the percentage of residual CO2 inside the FF masks during the breathing cycle. As per EN 136:2000 the percentage of residual CO2 must be lower than 1% with pneumatic lung set on 25 BPM (Breaths Per Minute) and 2.0 liters of tidal volume. CO2 machine is not connected to the PC, so the result of the test is a value available only through a display.

All FF masks are subjected to Breathing effort test: The mask must be assembled on a Sheffield head, connected to the ANSTI machine that measures the breathing effort, providing as a result inhalation and exhalation values.

Figure 2-5: FF mask, assembled on the Sheffield head connected to the ANSTI Machine

The right set up of the machine is 25 BPM (Breaths Per Minute) and 2 l tidal volume. The machine is operating through a PC that generates a test report. This test report is made by two parts: graphic and values expressed in numbers (mbar and Joule/l). In the report different parameters are available: test condition, breathing diagram, and all the breathing values in mbar and Joule. The results can be seen and read in the following diagrams.

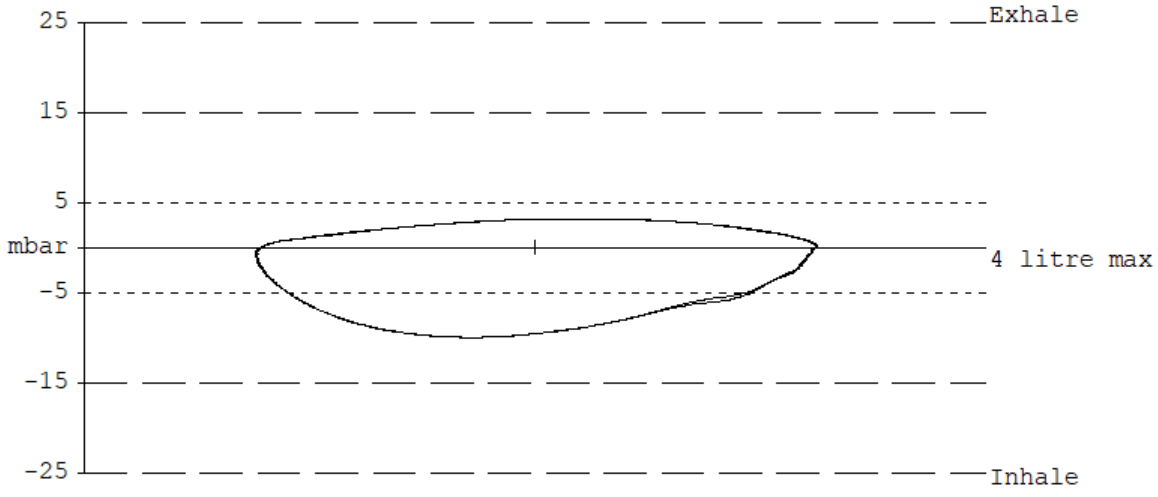


Figure 2-6: Test report graphic part

Results (2 Loops)	Mean	Min	Max
Inhale Pressure (mbar)	9.94	9.93	9.96
Inhale Pos Pressure (mbar)	0.25	0.24	0.26
Exhale Pressure (mbar)	3.21	3.21	3.21
Ext Work of Breathing (J/l)	0.95	0.95	0.96
Inhale Work (J/l)	0.72	0.72	0.73
Pos Inhale Work (J/l)	0.00	0.00	0.00
Exhale Work (J/l)	0.23	0.23	0.23

Figure 2-7: Test report values part

All FF masks are subjected to Sealing test: CO2 testing machine connected to a vertical liquid column pressure gauge is used to perform this test. The mask is assembled on a Sheffield head. The technician must press the masks against the face, creating a depression (10 cm of water column). When the depression is stable, he verifies how long the liquid fells in 8 seconds. The test is considered «Pass» if the liquid drops less than 7 cm.

2.3.1.3 Repurposing Scenario Requirements

All reconverted FF masks are subjected to the same testing procedures as the regular PPE products, but they have to be tested with the dust filter certified EN 143:2007 installed.

There is the need to perform the tests more efficiently, saving time, and have the results immediately available to SEAC's personnel and Eur3ka platform. To do that it is necessary to make the two testing machines working together, through a new software interface. SEAC plans to automatically perform both tests, getting as a result one test report from both machines. All data printed in one document available to SEAC and Eur3ka platform. The report will be automatically addressed the Quality Dept. and to the cloud. Having the test report available in the Eur3ka platform will allow the team to address the production depending on the needs. Also note that:

- All the technicians involved need to be trained.
- Training sessions need to be focused on very specific actions required to achieve Eur3ka goals.

2.3.2 Third Party Case Studies

This section provides a summary of the case studies conducted in the scope of the deliverable based on interactions with third-party manufacturers (i.e., outside the consortium). The case studies were selected to represent different nodes across the supply chain network, from suppliers, manufacturers to technological and solution providers. Respondents from the case studies are senior managers directly involved with repurposing activities. As evident from Table 2-1, the names of the manufacturers that were interviewed are not included in the table. This is purposeful and aimed at ensuring the confidentiality of the provided information. It was agreed with the participants to the relevant survey and interview processes.

CASE STUDIES	BUSINESS SECTOR	PRODUCT	TECHNOLOGY	REGION
A	Research and Technology	Visor holders for magnifying glass	Additive Manufacturing	Denmark
B	Sanitary systems and parts manufacturer	Face shields	Injection Moulding	Switzerland
C	Technical articles	Face masks and medical gowns	Digital Dataspace	Italy
D	Textile	Face masks and medical gowns	None	India
E	Technical textiles	Face masks and medical gowns	Digital marketing	Netherlands
F	Research and Technology	Face masks	Nanotechnology	Malaysia
G	Research and Technology	Nanotechnology air filtration system	Nanotechnology	Malaysia

Table 2-1: Overview of Case Studies and Their Main Characteristics

2.3.2.1 Case Study A: Visor holders for magnifying glass

The effect of the pandemic was described as a “Latency reaction” where there was an unnatural decrease in demand from the customer side. At the same time, there was still abundance of work in the pipeline when the first wave struck. The main motivation for Company A was from a “sense of assisting”. This was primarily triggered by the outbreak in Italy raising the question of “what can we do?”

The repurposed product was in the form of a visor holder for magnifying glasses, meeting the new demands of the dentist sector. This project took approximately less than a week due to the restructuring of manufacturing procedures, building faster and smaller batches and optimizing the manual procedures. A typical product would have taken about 5-10 weeks. When analysed, this optimization was possible due to the decreased iterations from the customer side. In the development of this product this iteration was optimised with 3 design loops only.

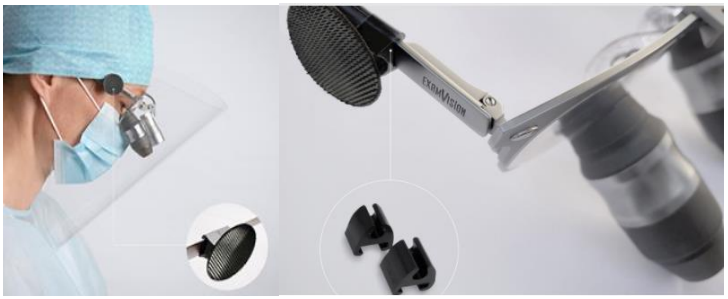


Figure 2-8: Visor holders for dentists [Photograph: DTI & ExamVision]

There was no additional capital investment as it was already aligned with current processes of additive manufacturing. Regulatory issues did not pose as the main challenge. However, instead, the challenge was the ability to ensure the continuous run of production with minimum supply chains disruption. The ordered products could have taken 3 days if they were printed continuously. However, there was a need to adapt to the current production schedule. Nevertheless, the entire production was delivered within a week, and the end-to-end process took no more than three weeks. As an increased complexity, Company A faced an incident case and had to re-task operational manpower to ensure continuity of the lines.

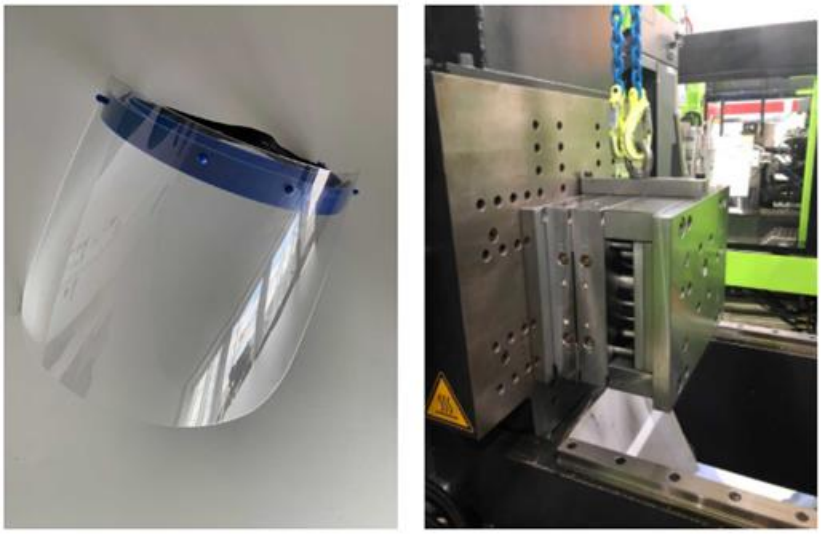
The role of digital technologies in this case study is primarily additive manufacturing. A digital platform was also utilised to serve as a marketplace. This however was not beneficial and did not yield significant results, according to the senior manager, “It did not provide many leads”. The alternative technology for this product, injection moulding was also taken into consideration during that time. However, injection moulding was not used due to the short time-to-market. but due to the time constraint this did was not used. In this circumstance, the building of the mould for injection moulding was seen to have taken far too long to meet the demands.

2.3.2.2 Case Study B: Face shields with injection moulding

Company B was adversely impacted by COVID19 where it experienced a decline in sales by 3.9%. During that time, there was a huge uncertainty on the ability to supply protective equipment to last beyond the week. Thus, Company B was motivated by a joint vision to save lives and to contribute to the community during the crisis. Company B was approached by a renowned Professor from a Swiss University and from there, this response started to materialise.

Being a large sanitary systems and parts manufacturer coupled, Company B responded through repurposing injection moulding machines to produce face shields. There were no product related regulatory challenges. The product is CE certified and complies with EU regulation of PPE. However, they faced a logistical regulatory challenge to export the products. This limited the potential capabilities to extend the market reach beyond the Swiss borders.

From the operations aspect, minor rescheduling was required, and production of the face shields were integrated during the 4-shift production. The development time frame for this was noticeably shorter.



S

Figure 2-9: Plastic face shield (left) and injection moulding tool for production (right) [Photograph:helfulETH and Geberit]

Instead of a 3D printer, an injection moulding method was used for the frame of the face shield. Company B provided their expertise and manufacturing facilities through ensuring the component was production ready. The injection mold frame was realized within 3 weeks. This was made possible due to the concerted effort including the initiative of the mold maker and some of the most experienced specialists.

The visor portion of the shield was provided by a Packing manufacturer. Through this, 5000 shields were manufactured and ready to be delivered within days to the Swiss-based hospital free of charge.

Currently, this product is no longer manufactured as there is a decreased demand due to the constraints of export boundaries of export enforced. However, the mould is readily available and can be ramped up at any point in time when required.

2.3.2.3 Case Study C: Textiles for face masks and medical garments

Company C experienced a decline in revenue of 20% compounded with uncertainties of demands. This was a result of the nature of the industry where their customers' products were dependent on seasonal items. Company C is a large technical products manufacturer producing products such as spunlace, needle punched fabrics, foam rubber, embossed products and with "special finishes". The response to the pandemic has been described as a business decision to "ride the wave" as it was identified as a potential opportunity for market penetration and sales.

Through their spunwoven product, Company C has explored the potential option of repurposing their spunwoven textile for face masks. However, it was found that the price differential was too large to retain its competitive edge and thus halted this business proposal.

Through Euratex (European textile and clothing industry), a digital dataspace was explored to facilitate connection to potential customers. This digital platform, however, did not result

in potential customers purchases despite the increased connection and exposure. The core reason for this unfavourable result was attributed to the price point of the repurposed textile that was not competitive to match the current Polypropylene (PP) masks. (Four times higher than the PP masks)

The regulations and policies experienced by Company C also placed it at a disadvantageous situation. Firstly, there was a maximum ceiling of price set for a face mask. This decreased the business case for Company C as their textile cost was initially four times higher than the commercial Polypropylene masks in the market. Moreover, the regulations for certifications were unstructured and thus this added to the barrier of entry for Company C.

However, Company C explored another innovative route of ensuring their material is sustainable for future usage and applications. This however would be 8 times more expensive than the commercial disposable masks.

It is interesting to note that Company C viewed the pandemic as challenges in business similar to the daily basis except for the fact that it was the level of emergency that differed it. The respondent emphasised the need for a fast and flexible response and to “keep your eyes always open”.

2.3.2.4 Case Study D: Textiles for face masks and medical garments

The pandemic had a significant impact on Company D where there was a decline of sales by 50% due to the stark drop in demand. Despite being a textile supplier to large retail fashion brands, the orders were halted once the onset of the pandemic due to the uncertainties arising in the market.

This motivated Company D to venture into the potential of PPE production, as this was seen as a “lucrative opportunity for the future” and as a “safeguard” for the lack of businesses.

An interesting observation was that the initial perception of “first mover advantage” did not exist in India. The “first mover advantage” view was shared across the different entities across the supply chain and there was a flood of market entry in the production of PPE. An evidence of this could be observed through the increased imports of melt-blown machines for masks production resulting in a significantly decreased cost of machine price. There was a rise of many “middle-man” which then disrupted the market as this increased the barrier between the manufacturer and the customers.

Regulatory approval was completed within 2 weeks and was not the barrier of entry for Company D. Instead, the main challenge was the cost of production. Due to the inability to obtain economies of scales, given the sheer size of Company D of 350 machines, they were unable to compete with the smaller businesses. Their inability to secure customers were attributed to the lack of “trust” due to the perception of “inexperienced manufacturer” in this area. Moreover, they did not have partnerships with the Government unlike the major industrial players and thus was unable to secure large enough orders for productions.

2.3.2.5 Case Study E: Structural support layer in face masks

The pandemic did not affect Company E as significantly due to its role upstream of the supply chain, coupled with its diversified portfolio. Company E is global leader in high performance materials in more than 60 countries worldwide and manufacturing in Europe, North America, the Middle East, and China. During the onset of the pandemic, the response was when the Business development manager recognized the potential role of their inhouse Colback material. This material has a specific stability functionality as a support for FFP face-mask. The repurposing initiative into a new market segment was primarily a business-driven decision coupled with the initiative to produce masks locally for the local people.

Figure 2-10: Face masks enhanced with structural layer [Photograph: Colback Solutions]

There was no significant change required from the manufacturing aspect in this repurposing initiative. Instead, the repurposing initiative transcended in the form of the final application of the product into a new market segment as a strengthening layer in the mask. This required an extensive effort from the R&D team. The R&D team faced a spike of demands from the new customer segment for support due to the many new entrants in the market. The customers were seen to have a large range of capabilities and know-how in the product ranging from completely inexperienced to fully experienced. This placed enormous pressure on the team to cope with the increasing demands and expectations of know-how to support the manufacturing efforts of the customers to deliver the final product.

The digital technologies used were mainly in the form of digital marketing to market the new application of the material. This however did not generate enough exposure and the respondent expressed that he would have fully exploited it if given a chance to again.

In this case study, the role of the government could have been more involved both from the financial aspect and the communication aspect. It was highlighted that there was a lack of structure to identify the key partners in the industry to strategize the response. This resulted in a delay and a shortage of PPE at the beginning of the pandemic.

2.3.2.6 Case Study F: Nanotechnology antimicrobial coating for face masks

The pandemic adversely impacted the sales for Company F by 20%. Company F was established in 2015 mainly focusing on medical textile, automotive and industrial textile. Due to the pandemic, there was a shift of focus to the anti-microbial and hygienic line. Being a technological enhancer provider to the final textile product, it was a challenge to raise the awareness of the people during the pandemic. This was due to the increased cost of this technological treatment and the public awareness of the efficacy of this technology.

To achieve a better market penetration, Company F restructured the organization through the combination of the business strategy team and corporate strategy team. This restructuring was primarily motivated to streamline the organization, as mentioned by the CEO, "…to operate in a lean and efficient manner." This move streamlined the communication channels and information flow within and beyond the organisation providing the platform required for Company F to venture from a B2B model to a B2C model.

Figure 2-11: Face masks coated with Nanotechnology layer [Photograph: Nanotextile]

It currently applies its technology for facemasks in collaboration with a leading automotive company. This initiative is in line with its 2021 yearly theme of sustainability theme where the production of masks was made in a sustainable manner. The production of masks in this repurposing initiative is mainly to support the single mother's income source during the pandemic. Although the starting volume is at a low quantity of about 20,000 pieces, Company F is optimistic for potential growth of the nanocoated material products.

Currently, Company F's focus is to penetrate the healthcare market as a supplier for hospital beddings and textile to provide an enhancement of antimicrobial properties to the fabrics used in healthcare facilities.

2.3.2.7 Case Study G: Nanotechnology solution provider for antimicrobial air systems

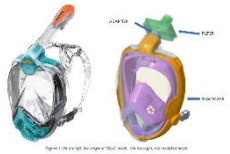
The pandemic did not impact Company G directly due to its role as a nanotechnology venture capitalist. However, innovation-based projects were halted, and funds were channelled to pandemic response projects instead. Company G repurposed its application of nanotechnology to respond to the pandemic. This is accelerated through its role in the COVID19 response committee representing the Science, Technology, and Innovation sector where the key stakeholders for nationwide implementation are directly involved in this platform.

A key emphasis by the CEO of Company G was on the power of knowledge to respond to the pandemic. He also highlighted the importance of decision making during the times of a crisis. The selection of strategy deployed during the times of utmost uncertainty should be data driven. Moreover, this should also be equipped with the necessary resources to achieve the desired outcome during times of crisis. He further added that it is vital to have clear communications and quick responses to deploy technologies in a timely manner.

Currently Company G is in the midst of rolling out a nationwide nano-filtration technology for public transportations and buildings.

2.3.2.8 Other (Additional) Case Studies

Following (landscape) pages (Table 2-2) summarize several additional case studies. They comprise of a mix of case studies based on interviews and online research. From these, various tags are assigned to each case study to understand the effects of location, product complexity, volume and scale, and the various challenges faced.

Company Name	Location	Product	Photo of Product	Volume Produced	Challenges	Source
Seacsub	Italy	PPE Masks		N/A	• Regulatory Challenges for PPE • Lack of skills and training Production challenges	Interview
DTI	Denmark	Equipment for Dentists		11000	• Lack of visibility in demand and to connect various parties • Lack of Knowledge and skills	Interview
Geberit	Switzerland	Face shield		11000	• Importance to rely on existing resources • Importance for product design optimisation	Interview
Midton Acrylics	Scotland	Visors		10000	• Importance of community funding support • Supply chain relationship with suppliers	Online resource
Display Mode	England	Visors		7000000	• Challenges for connectivity to customers • Raw material procurement challenges	Online resource

Company Name	Location	Product	Photo of Product	Volume Produced	Challenges	Source
LJA Miers	England	Visors		1800000	• Challenges to connect to customers	Online resource
Prime Group	England	Visors		300000	• Raw material supply challenges • Challenges to obtain funding • Challenges to reach customer orders	Online research
Issinova	Italy	Ventilators (Adjusting snorkeling mask)		N/A	Challenges of certification	Online research
Berry-BPI	Scotland	Long-sleeved Aprons		200000	• Response from raw materials • Resources and speed of response	Online research

Table 2-2: Summary of Known Case Studies of Production Response during the COVID19 Pandemic

2.3.2.9 Key Challenges for Production Repurposing and Manufacturing Response

The key barriers to entry for repurposing identified from the above-listed case studies are:

- Government Policies, Regulations and Standards.
- Market Uncertainty.
- Business Case.
- Contextual Factors.
- Trust of Customers.

One of the key challenges faced was the lack of structure and support from the governmental and regulatory bodies. Among the issues highlighted was the lack of financial support and information on regulatory requirements for the manufacturing of PPE. This resulted in a delay of response and also losses due to uncertified PPEs.

Market uncertainty was also another key challenge highlighted due to the lack of visibility across the supply chains. This hindered manufacturers to connect with the necessary suppliers and customers involved. The lack of visibility of the market resulted in new entrants struggling to understand the dynamics of the new market ventured.

Moreover, the business case for repurposing was often not justifiable due to the high cost of products. This was made worse when the economies of scales were not achieved due to the lack of trust from the customer. This lack of trust primarily stemmed from the fact that the manufacturers did not have prior experience in this field. Furthermore, they also faced significant challenge to close deals without in person meeting. This working condition placed a larger gap between new entrants and potential customers.

Contextual factors also posed as a challenge for manufacturers as the flood of competition in some regions were more intense than others. For example, in India, there was a huge flood of melt-blown machines purchased to tap into the repurposing market segment while in other European countries, this was not the case.

2.3.2.10 Best Practices and Lessons Learned

The best practices experienced and suggested by the companies are listed below:

- Agile Response.
- Knowledge Management.
- Demand and Supply Visibility.
- Inventory Management.
- Manufacturers and Capabilities Visibility.

There was a strong emphasis on the need for an agile response and quick action to the fluctuations in the market. It was important to identify new market segments for existing products to ensure business continuity during the times of crisis.

There was also a clear need for knowledge management due to the repurposing of products or market segments. Companies which repurposed successfully relied on a systematic knowledge dissemination as well as skilled R&D entities within the organisation.

Furthermore, many companies stressed the importance of demand and supply visibility in order to connect to potential customers. During the onset of the pandemic, there was no visibility of the key players in the market and thus this delayed the repurposing response as time was spent identifying the required players for partnerships and sales. This role is suggested to be undertaken by policy makers where key industrial players and capabilities are identified in the supply chain network for efficient and effective response in crisis management.

Lastly, inventory management is also identified as critical. This was highlighted as the role for governmental bodies to provide a standardisation and healthy inventory levels utilising historical pandemics as a baseline. Reshoring was also mentioned as a potential choice.

2.3.3 Third Party Case Studies on Medical Products

In the sequel two product specific cases studies are presented. They consolidate experiences from the manufacturing of relevant medical products that fall in the scope of the Eur3ka project and the Eur3ka pilots.

2.3.3.1 FFP2 Mouth Masks[4]

Overview: At the start of the pandemic, it became clear that FPP2 Mouth Masks would offer the needed protection for the COVID19 virus. Which in turn meant there was a high increase of demand for these mouth masks. However, during the COVID19 pandemic they experienced several disruptions within the supply chain, which in turn caused several delays in the availability of these masks. These delays were mainly caused by the unavailability of the necessary raw materials but also by the current dependency on Asia (China) and the USA, which are important chains in the current supply chain. Due to the imposed restrictions on trade, travel and the necessity of these masks in other countries/continents the supply was running low. A lot of the masks were being produced in either China or the USA and because of the trade and travel restrictions during the COVID19 pandemic, and the situation in those countries, it made it extra hard to meet the current demand. This was noticeable in all of Europe and the main reason why wearing FPP2 mouth masks was banned for the general public in a lot of European countries.

To meet the current demand and to come up with a possible solution without Asia or the USA, production of these masks had to be started within the Netherlands (or Europe). That did not seem like too big of a task, as these mouth masks are not complex by nature. The biggest issue however during this process was the certification of the FPP2 Mouth Masks seeing as they are considered as medical equipment. Certification required the right kind of information and guidelines, and therefore a general governing body to oversee this. As there

[4] https://www.trouw.nl/nieuws/made-in-holland-de-moeizame-weg-van-het-zelf-produceren-van-mondkapjes~b435f622/

was no governing body available within the current network it took a lot of time to get in touch with one, in order to get the masks certified.

The second issue, like mentioned earlier, was the lack of raw materials to meet the current demand. Not only material to produce the masks but mainly raw materials to produce the necessary equipment in order to produce the masks within the Netherlands. To produce the proper FPP2 mouth masks matching current regulations, ultrasonic equipment was necessary. These machines were not right available within Europe and seeing how Europe was dependent on Asia for the supply of raw materials a bigger problem arose. Polypropylene, which was the necessary raw material, was not currently being produced in the Netherlands/Europe anymore and therefore scarce. This meant the first step in order to deal with the current problem was to either find new suppliers for Polypropene or start the production of the material within Europe/The Netherlands.

VDL & DSM (which are the involved companies) set up a collaborative effort in order to set up a new supply chain within the Netherlands. They are currently working with and on a flexible supply chain in order to meet the demand of the FPP2 Mouth Masks.

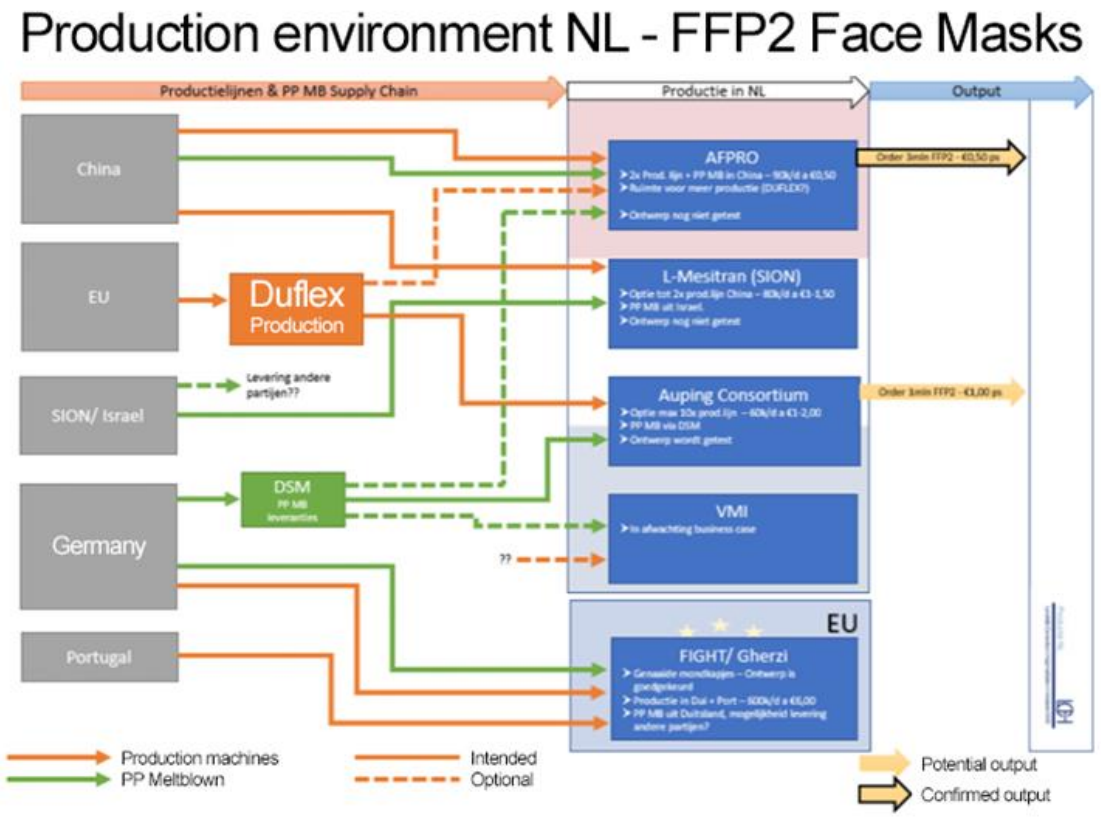


Figure 2-12: FFP2 Mouth Masks Production - Supply Chain Processes

Barriers and Challenges: The main barriers and challenges that are associated with the above-listed case studies were:

- The dependency on Asia / USA (or other links outside of Europe).
- A Huge increase in demand and a drop in supply due to travel and trade restrictions.
- The need for upscaling and downscaling of the production (e.g., finding the right suppliers).

- Lack of flexibility within the supply chain.
- Lack of contact with the necessary governing body to get certification.

These challenges are incorporated in the main scenarios studied within Eur3ka, which are outlined in the next section.

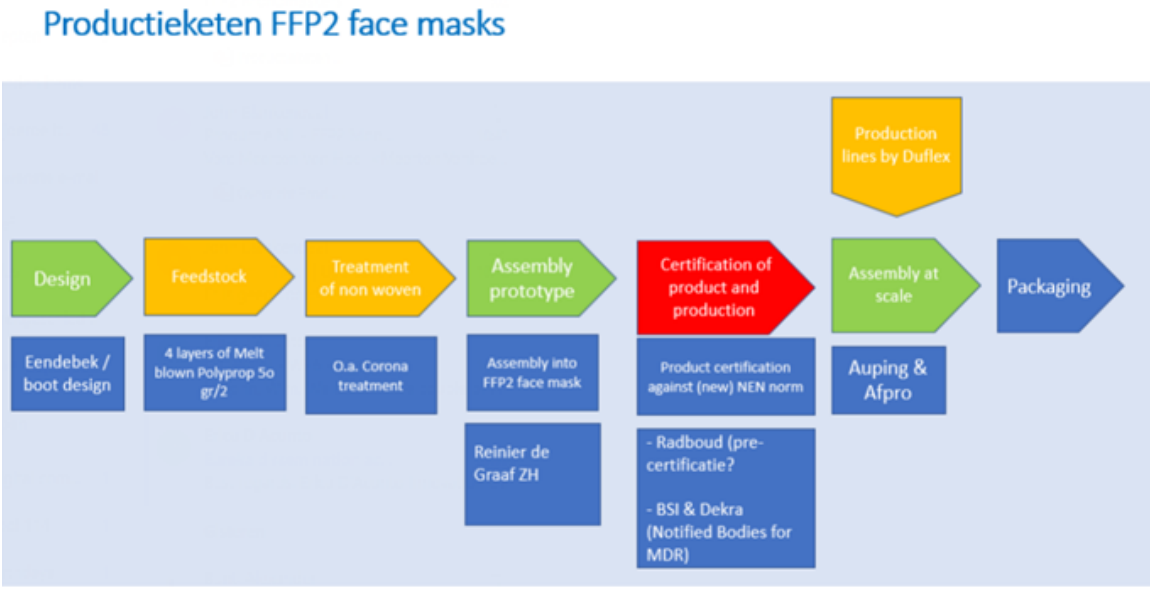


Figure 2-13: FFP2 Mouth Masks – Production Workflow

2.3.3.2 Respiratory Equipment Production[5]

Overview: During the COVID19 pandemic it became clear that there was a lack of necessary respiratory equipment within the Netherlands. Demcon[6], one of the leading organizations within this supply chain, noticed that early on. Demcon is a supplier that is used to producing a lot of modules and parts for medical equipment, however an entire respiratory equipment unit was new to them. To meet the current demand for respiratory equipment they decided to start the process and production of respiratory equipment, they have the necessary technical know-how and had the specific designs available to produce the equipment.

The first issue that arose was the lack of a certain part to produce the equipment. Due to large increase in demand this necessary sensor became quite scarce. Finding another supplier was quite difficult, either the production capacity was too low, or the prices were too high. In order to find another supplier, they made a deal with the Dutch government which covered a lot of the costs.

The second issue was the certification of the equipment and the time it took to get the equipment certified. Before COVID19 certification was done after the equipment became an actual finished product. That meant that it could take a lot of time to get the equipment the necessary certification. To deal with this issue Demcon involved the governing body early in

[5] https://www.icthealth.nl/nieuws/dreigend-tekort-aan-beademingsapparatuur/
[6] https://www.demcon.nl/tag/beademingsapparatuur/

the design, decision and production process. That meant that they worked on the product and simultaneously communicated every change and every specification directly to the governing body. This significantly sped up the certification process.

By focusing on the necessary steps to take in order to get a working product ready for shipping they managed to save a lot of time. By first involving the governing body in order to speed up the certification process and to focus on the bare bones of a working product, they managed to cut down the necessary design and production time to 1 month instead of up to a year. However, the first order of the Dutch government, which was 500 units in advance, did help in other to cut a lot of necessary costs.

A point of attention however was the need of documentation and designs. Demcon feels like in order to battle a crisis or pandemic copyright becomes a very difficult subject. If you want to respond in a quick manner in order to answer the current demand to battle the COVID19 pandemic you can't get stuck on copyright issues. The need of information and data sharing is high but the need of anonymity was therefore a big struggle point. In order to quickly respond in changes in the demand within a supply chain it's necessary to know everything about your partners within the supply chain.

According to the head of R&D at Demcon there where several main focus points:

- Clear and direct communication within the network.
- Avoiding discussions on semantics or other trivial stuff.
- Creating the right environment with the appropriate necessary 'mind shift' (and mindset).

Most important key drivers in order for success included costs, time, availability, reliability (and certification).

Barriers and Challenges: The main challenges for this production case study concerned:

- Dependency on Asia / USA (or other links outside of Europe).
- Huge increase in demand for several unique parts (increase in costs).
- Upscaling and downscaling of the production (finding the right suppliers).
- Lack of flexibility within the supply chain (fear of upscaling and a drop in demand afterwards).
- Data and information sharing (copyright issues).

The Eur3ka scenarios in the following section incorporate these challenges.

Lessons Learnt: The main lessons learnt from the case study can be summarized as follows:

- To speed up the process the inclusion of a governing body for certification was necessary.
- The 'mind shift' needed in order to quickly address the current demand during a crisis.
- Short lines of contact between the actors within the network are important.
- Open, clear, and direct communication was necessary in order to quickly pinpoint issues.

- The willingness to share documents and designs depends on the anonymity within the network (fear of sharing information with competition which would give them an edge).

Demcon would be interested in how Eur3ka could help actors within a supply chain with information and data sharing. Certain specifications could become issues according to the head of R&D, who is curious how we would create a common understanding within such a big network of suppliers. Eur3ka will strengthen the collaboration links with Demcon as part of its community building, exploitation, and commercialization planning processes.

3 Motivating Scenarios and High-Level Overview of Eur3ka Services

3.1 Eur3Ka Motivational Scenarios: Four Grand Manufacturing Repurposing Process Scenarios

3.1.1 Overview

Eur3ka Resilient and Reliable Repurposing Manufacturing network address the modernisation and digitalisation of factories with the aim to support sudden demand peaks of Vital Medical Supplies and Equipment (PPE/CCE).

The Eur3ka manufacturing repurposing process grand scenarios need to be considered in terms of products of increased manufacturing complexity according with the WHO (World Health Organization) classification (Protective Personal Equipment or PPE, Diagnostic Equipment, Clinical Care Equipment or CCE).

Category	Critical items identified by WHO	Example of facilities that might be repurposed
Protective personal equipment (PPE)	• Gloves, examination • Gloves, surgical • Goggles, protective • Gown, protective • Face shield • Mask, particulate respirator • Mask, surgical	• Textile factories • Garment plants • Yarn spinning mills • Electronics assembly plants • Injection moulding facilities • Prototyping shops (including 3D printing)
Diagnostic equipment	• Lab screening test kit • Lab confirmation test kit • RT-PCR kit • Extraction kit • Cartridges for RT-PCR automatic systems • Swab and viral transport medium	• Pharmaceutical preparations • Biopharmaceutical preparations • Pilot biotech plants • Clinical research laboratories
Clinical care equipment	• Pulse oximeter • Concentrator O2, 10L, 230V, 50 Hz + acc. • Nasal oxygen cannula, with prongs, • Ventilator patient, for adult, pediatric. • CPAP with tubing and patient interfaces for adult and pediatric. • Suction pump, mechanical • High-flow nasal cannula (HFNC)	• Automotive production lines • Aerospace manufacturing plants • Specialized engineering service and testing facilities • Manufacturing technology and innovation centres • Vacuum cleaner assembly plants • Machining shops •

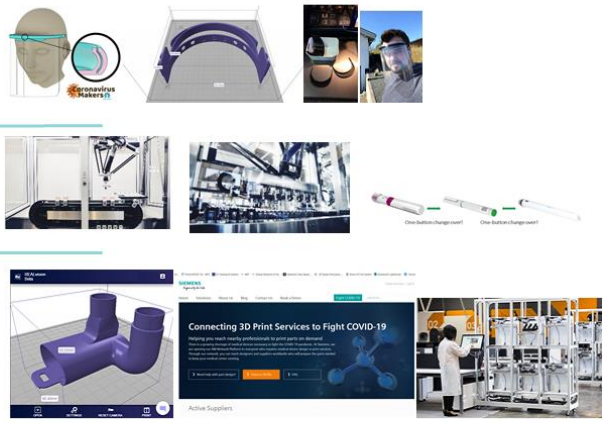


Figure 3-1: WHO medical supplies and equipment classification

To repurpose their manufacturing activities and to meet the specific demands of production of specific CCE/PPE products, Eur3ka digital factories would need to adopt several transformations.

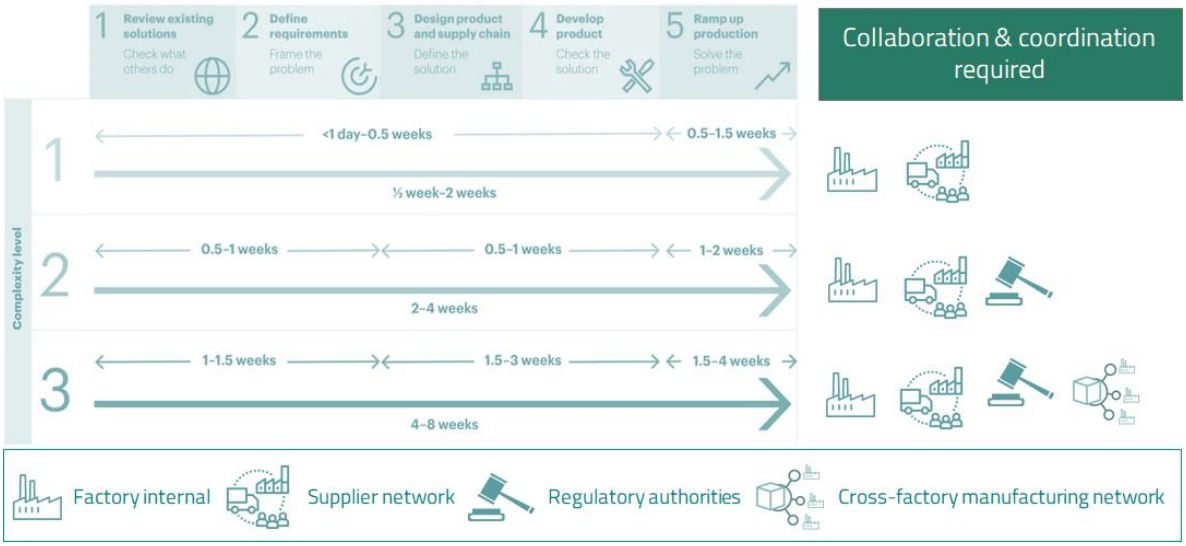


Figure 3-2: Transformations behind digital factories repurposing life cycle

Such Manufacturing Repurposing Transformation (MRT) would imply also increased levels of modernisation, collaboration and coordination among:

1. Factory internal processes.
2. Supply network processes.
3. Regulatory processes.
4. Cross-factory manufacturing network processes.

While PPE production demands mainly a revision of factory internal processes and supply network capacities. The development of diagnostic equipment and/or clinical care equipment would also imply a transformation and revision of regulatory and collaborative manufacturing networks.

In following paragraphs, we outline four motivation scenarios involving MRT, as well as how they can be addressed by Eur3ka. While they do not provide a detailed specification of Eur3ka pilots and use cases, they can be used to motivate the specification of Eur3ka components in the following paragraphs.

3.1.2 Scenario 1: Rapid reconfiguration and continuity of production line operation

The description of the scenario is provided in the following table.

Overview of Need: Manufacturing companies need to re-configure their production lines for two main reasons: reduction of orders / personnel, need for social distancing.
Required modernisation and digitalisation**: Modelling and simulating production lines with reduced production capacity and reduced (or null) workforce presence.**

The Eur3ka Solution: Common methods and tools for virtual commissioning of safe and secure reconfigured Production Lines Digital Twins and Digital Personas[7] and how they interact (RAMI 4.0 AAS (Asset Administration Shell) and Industry 5.0[8]) in flexible/modular highly automated production lines.
Eur3ka Pilots Requirements**: Usually this already happened (e.g., as part of the cases listed in Section 2), but with proprietary ad-hoc no standard and structured methods-tools-platforms. In the scope of the project, Eur3ka technologies and tools will be used, while relevant KPIs (e.g., time, cost, and quality related) will be measured. The use of Eur3Ka tools can be simulated and relevant KPIs will be measured and compared with known performance KPIs. This will highlight and quantify the potential benefits of the Eur3ka approach.**

Table 3-1: Description of Scenario 1: Rapid reconfiguration and continuity of production line operation

3.1.3 Scenario 2: Reliable repurposing of production processes

This scenario is described in the following table.

Overview of Need**. Manufacturing companies need to repurpose their factories to produce different products and consequently their production lines for two main reasons: high demand of PPE and CCE, low demand of their original products.**
Required Modernisation & Digitalisation**: New Product Design, Engineering, Simulation as well as increased Manufacturing Automation, Quality Management and Certification with Medical standards and normative rules.**
The Eur3ka Solution**. Common methods and tools for representing Product Digital Twins (e.g., Digital Production Models covering the entire product lifecycle) assessing Quality and Certification needs in flexible/modular highly automated production lines. Usually this has already happened but without standard and agreed methods and tools for quality inspection, management, and certification. Eur3ka methods and tools will improve quality and certification KPIs (time cost quality) of existing products samples (as-is real; to-be real).**
Eur3ka Pilots Requirements**: In the scope of the pilots of the project, the repurposing of production lines to produce new products will be showcases. Using Eur3ka's certified manufacturing assets, manufacturer should improve the quality of the new product, while shortening and easing process of medical certification.**

Table 3-2: Description of Scenario 2: Reliable repurposing of production processes

[7] H2020 Connected Factories Project, Deliverable 4.2 Organisation of first European Scenario building workshop, available at: https://www.connectedfactories.eu/

[8] European Commission, What is Industry 5.0: https://ec.europa.eu/info/research-and-innovation/research-area/industrial-research-and-innovation/industry-50_en

3.1.4 Scenario 3: Resilient smart supply networks

This scenario is presented in the following table.

Overview of Need: **Manufacturing supply chains can be broken by the pandemics and/or need to be reconfigured (re-shoring) for political (sovereignty) or market reasons.**
Modernisation & Digitalisation Requirements**: Trusted digital Supply Chain Networks need to share Production Capacities (represented in terms of yield and production throughput) to match demand with supply/offer. The common business model is Manufacturing as a Service in a network of trusted companies which share data in a common/shared Data Space (datasets, metadata, transformation apps, connectors, governance models).**
The Eur3ka Solution**: IDSA (International Data Spaces Association) Data Sovereignty principle is implemented by some Data Sharing Platforms developed under the same Reference Architecture, Industrial Agreement and a trusted pan-European federated networking and computing infrastructure.**
Eur3ka Pilot Requirements**: In the scope of the Eur3ka pilots several cases where customers' existing orders can be matched by a better Supply Chain (as-is, to-be real KPIs) can be studied. Likewise, scenarios where customers' brand-new orders are placed in the marketplace will be explored. Consider for example a case where a manufacturer needs to produce a component in 1000 pieces within 3 weeks' time and with a cost of less than 12.000 EUR. The Eur3ka supply chain matching solution must be able to indicate the regional supply chain that is able to fulfil this production request with the given constraints.**

Table 3-3: Description of Scenario 3: Resilient smart supply networks

3.1.5 Scenario 4: Robust on-demand remanufacturing networks

The scenario is illustrated in the following table.

Overview of Need: **This is a scenario subsequent to scenario 3, which focusses on the execution of the order (usually a "one-of-a-kind" product) through an Additive Manufacturing production line (on-demand).**
Modernisation & Digitalisation requirements**: On-demand production networks should share transparent description of Production Capabilities (represented in terms of Manufacturing Autonomy Level (MAL)), Certification Levels for medical product manufacturing as well as trusted means for basic digital asset information to be shared in a very confidential manner - CAD specification (or part of it) of the new product as well as minimum tolerance values, with some important constraints for the Additive Manufacturer about "no duplication", "just three exemplars", "dissolve after the printings or in two days".**

The Eur3ka Solution: **For a fair quotation of production costs IDSA Data Sovereignty principle is implemented by some Data Sharing Platforms developed under the same Reference Architecture. Additional constraints about access and usage rights must be added and implemented, maybe also in a selective way on the different sections of the CAD file exchanged.**
Eur3ka Pilot Requirements: **The pilots will study several cases where customers' brand-new orders are placed in the marketplace and constraints are technologically enforced. For instance, cases where some exemplars of a piece must be 3D printed should be explored, subject to constraints such a tolerance level and the assurance of maximum confidentiality.**

Table 3-4: Description of Scenario 4: Robust on-demand remanufacturing networks

3.1.6 Mapping of Scenarios to Transformations

The above listed 4R Grand Scenarios for manufacturing repurposing can be mapped to four main transformations that must be addressed by Eur3ka as shown in the Table below. The mapping considers the above-listed outlined of Eur3ka solutions, while addressing most of the requirements/challenges outlined in the previous section.

The first two Rs mainly address improvements in the Factory Internal Processes and would therefore be suitable to manufacturing repurposing for products complexity 1 (CCE), implementations of the additional 2Rs would allow factories to deal with products of higher complexities (level 2 and level 3).

		Manufacturing Repurposing Transformations			
		Factory Internal	Supply Network	Regulatory Process	Manufacturing Network
4R Grand Scenario	**R**apid reconfiguration and continuity of production line operation.	x			
	Reliable repurposing of production processes.	x		x	
	Resilient smart supply networks.		x		x
	Robust on-demand remanufacturing networks.	x	x	x	x

Table 3-5: Manufacturing Repurposing Transformations

3.2 Overview of Main Components and Services

3.2.1 Overview and Classification

To support the above listed repurposing transformation, Eur3Ka will develop and offer a set of standards-based components and services. In most cases, these components and services will be built on top of existing digital manufacturing technologies of the partners. The Eur3ka components and services are destined to be general, reusable, and applicable to a wide range of manufacturing repurposing and resilience scenarios. They are also fully aligned to and motivated by the four scenarios that are presented in the previous sub-section. However, they could be potentially used in more than one scenario, depending on its requirements and scope.

In the scope of the present deliverable, the Eur3ka components and services are clustered in the following broad categories:

- **Services for production flexibility and reconfiguration**, which are key to support internal repurposing and reconfiguration of production processes. Furthermore, they include new manufacturing capabilities (e.g., 3D printing) that are suitable for on-demand manufacturing scenarios.
- **Services for trusted and flexible supply chains,** which are key to addressing (COVID19 related) disruptions in the supply chain, while at the same time facilitate the seamless and trusted flow of information across relevant manufacturing actors.
- **Services for Digital Quality Management and Zero Defect Manufacturing,** which are important for overcoming quality problems during new product design.
- **Services for supporting manufacturers in certification and regulatory processes,** which are an integral elements of production processes for medical products like PPE and CCE.
- **Services for the business continuity of production plants,** which enable manufacturers to operate under restrictions, including for example restrictions in the number and skills of workers.

Following paragraphs provide an overview of the above listed Eur3ka services and capabilities, along with their mapping to the presented scenarios. A detailed presentation of the services is provided in following sections (namely Section 4 through Section 7).

3.2.2 Production Flexibility and Reconfiguration

To support the rapid transformation of the factory internal production processes, manufacturers must establish flexible production lines that can rapidly adapt to changing the changing conditions of extremely disruptive events such as a healthcare crisis. Flexible Production Lines include both technological and organizational elements. The technological elements include digital technologies (e.g., digital automation platforms) that boost flexibility in the configuration of the line towards adapting in changing needs. Likewise, the organizational elements include flexible processes that enable the factory to operate under dynamic changes in the production capacity and workforce presence. To support the flexible production line Eur3ka will adapt and integrate the following enabling elements:

- **Digital Simulations and Digital Twins**, as core technology for implementing dynamically changing scenarios. The technologies outlined in Section 4 enable the implementation of Digital Twins for supporting production flexibility and repurposing as required by Scenario 1. Likewise, Section 5 presents digital quality management and digital lean manufacturing technologies, which can support the realization of Digital Twins for new product design, as required by Scenario 2.
- **3D Printing and Additive Manufacturing solutions**, which can boost the flexibility of a production line in the absence of specific materials or parts. This can be useful for several of the presented manufacturing repurposing scenarios, including Scenarios 1 and 2. It can also enable the provision of on-demand manufacturing capabilities (i.e., manufacturing as a service), as required by Scenario 4. The Eur3ka AM solution is illustrated in Section 4.

The organizational aspects of internal production transformations are primarily addressed by the Eur3ka business continuity framework, which is outlined in a following paragraph.

3.2.3 Flexible and Trusted Supply Chains

Beyond flexibility in production lines and production operations, Eur3ka will also provide technologies for flexible supply chain management. In this direction, two main technologies and related services are provided:

- **Services for trusted exchange of information in the supply chain**, which boosts the flexibility of supply chain decisions.
- **Services for smart matching making of supply and demand**, which enable manufacturers to take optimal supply chain decisions under constraints and limitations such as location, time, and cost related limitations.

Both technologies are described in Section 4 of the deliverable. They are used to support the third of the reference scenarios (i.e., Section 3), yet they can be exploited in variations of the other scenarios as well.

3.2.4 Digital Quality Management and Zero Defect Manufacturing for Effective New Product Design

Eur3ka will offer Digital Quality Management and Zero-Defect Manufacturing services, which facilitate the rapid discovery of quality issues in the production (e.g., defective products), along with relevant remedial actions. The Eur3ka components for Digital Quality Management are outlined in Section 5 and are vital for simulating ramp-up times and identifying quality issues in cases of new products design (i.e., Eur3ka Scenario 2).

3.2.5 Support for Regulatory and Certification Processes

To support regulatory processes there is a need to follow rules, best practices, and regulatory mandates, as part of a multi-level Certification Framework. The latter shall ensure

the compliance of sites, processes, and equipment. The Eur3ka multi-layer certification framework is presented in Section 6.

3.2.6 Business Continuity Framework – Ensuring Continuity of Production Operations

Eureka will provide various business continuity services as part of a Business Continuity Framework. The latter will ensure that factories can continue to operate effectively, yet with reduced production capacity, when restrictions (e.g., COVID19 constraints and related work policies) are in place. The Eur3ka business continuity framework comprises a wide range of sub-systems and components, such as component for risk assessment, training and reskilling resources, technologies for supporting remote process instead of physical processes, as well as components for financial impact assessment. The Eur3ka approach to business continuity is presented in Section 7 and is among the key prerequisites for supporting Eur3ka Scenario 1, yet it can be useful for the rest scenarios assuming that factories need to operate under COVID19 restrictions (e.g., site lockdowns, teleworking policies). Moreover, elements of the Business Continuity Framework (e.g., the ROI analysis service) could be useful for a wide range of manufacturing repurposing transformation scenarios, including all the four scenarios listed above.

3.2.7 Mapping of Components to Scenarios

In-line with the information presented in previous paragraphs, the following table provides a mapping between the four reference scenarios and the various Eur3ka services that are presented in following Sections of the deliverable.

Eur3ka Transformation Scenarios	Production Line Reconfiguration	Quality Digital Management	3D Printing / Additive Manufacturing	Digital Simulations and Digital Twins	Smart Match Making in Supply Chain	Regulatory Compliance and Certification	Trusted Information Sharing Industrial Data Space	Business Continuity Framework
S1: Rapid reconfiguration and continuity of production line operation.	M		M	M				M
S2: Reliable repurposing of	O	M		M		M	M	O

production processes								
S3: Resilient smart supply networks				M	M		M	O
S4: Robust on-demand remanufacturing networks			M			O	O	O

Table 3-6: Mapping of Eur3Ka Components and Technologies to the Eur3ka Reference Scenarios

The table marks with an “M” the Eur3ka services that are mandatory for supporting each one of the listed scenarios, yet it also indicates with an “O” i.e., optional other opportunities for using the services in variations of the listed scenarios.

3.3 Eur3ka Platform Integration Concept

Figure 3-3 illustrates the Eur3ka services that will be defined and specified in following sections. Furthermore, it clusters them in different categories, including:

- The Eur3ka plant and supply chain flexibility services, including the project’s Additive Manufacturing Network and Smart Matching services, which are presented in Section 4.
- The Eur3ka Digital Quality Management and ZDM framework, which is foundational for new product design and is detailed in Section 5.
- The Eur3ka Certification Framework (presented in Section 6), which includes requirements for site, equipment, process, and product certification. These requirements and relevant guidelines for their fulfilment can be clustered per different medical products.
- The Eur3ka Business Continuity Services, which include services for plant risk assessment, shifts allocation, context awareness, remote support, training, and reskilling, as well as financial impact assessment services. These services are defined and detailed in Section 7.

Key to the integration of the various services is the Eur3ka industrial data space, which will enable the secure and trusted exchange of information across the various stakeholders. It will be designed and implemented based on the IDSA background and principles, as described in Section 4. Moreover, the project’s ontologies and semantic interoperability framework will play a key role for ensuring semantic data integration and avoiding data silos. The Semantic Interoperability Framework of the project is defined in Section 5, which outlines the principles of its design and implementation as well. Note that semantic interoperability has a broader scope than supporting the digital quality framework of the project, as outlined in the figure. Hence, the fact that it is presented in Section 5 does not

mean that it is relevant only for the quality management for new product design functionalities of the project.

The integration concept is very high level. This is purposeful, as it is expected to be refined and detailed as part of WP2 of the project and more specifically as part of the Eur3ka reference architecture specification. Moreover, the implementation of the integration concept (i.e., the actual integration of the platform) will take place in WP4 of the project. As already outlined, the present deliverable will serve as input to these activities.

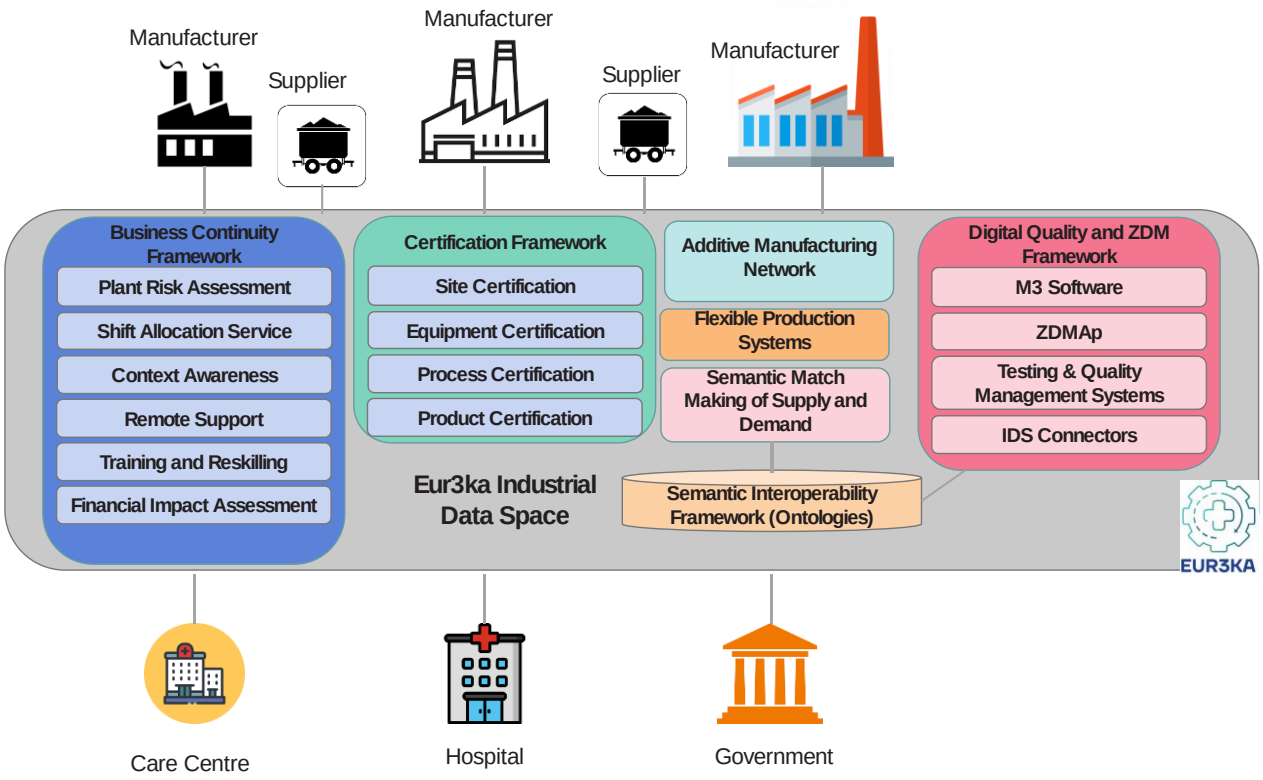


Figure 3-3: Overview of Eur3ka Platform and Services – Integration Concept

4 Technologies and Specifications for Flexible Production Reconfiguration and Flexible Supply Chains

4.1 Background Technologies Overview

4.1.1 Flexible Production Lines

4.1.1.1 Flexible Production Systems

Flexible production lines have been widely exploited in manufacturing systems to meet increasingly competitive markets moving towards mass customization and seeking to find the perfect balance between high quality and low cost [Keller14]. The design and deployment of flexible lines are more expensive than standard equipment. However, the improved efficiency, the capability to adapt to different customer needs or product innovations, accommodate fluctuations in demand and respond to unexpected events (e.g., failure of one component) compensate for the increased up-front costs. For this purpose, modularity plays a key role. The core concept is that subdividing a complex process into interacting, but mostly independent units can enhance flexibility and system reconfigurability. Indeed, the addition, removal or replacement of individual modules can address specific needs [Shaik14]. Concerning reconfiguration, the evaluation criteria for a modular architecture, as proposed by Mesa et al. [Mesa15], are:

- **Mobility**: quantity of modules, required transport and storage availability.
- **Functional variety**: available functionalities that can be executed simultaneously or not.
- **Adaptability**: possibility to adjust to market requirements.
- **Ease to reconfiguration**: ease of system rearrangement.
- **Modular independence**: the ability to work without the interconnected modules.
- **Useful life**: the estimated period of use.
- **Reusability**: effective use of modules that are preferred to work as long periods as possible.

Flexible lines are usually largely automated and involve dedicated machine tools and automatic logistic devices. In this context, Computer Numerical Control (CNC) machining centers and robotics cells are the most significant components, featuring high reliability and adaptability to different products. Besides material flow, the information flow is of crucial importance to coordinate and interconnect the system elements. Indeed, the availability of real-time data is a necessary condition for global process optimization throughout large networks. In this view, industry 4.0 has seen the spreading of key technologies, such as the Internet of Things (IoT) and Cyber Physical Systems (CPS), which enable the communication between machines, humans, and products, as well as relevant progress in Artificial Intelligence (AI) algorithms, giving rise to the intelligent manufacturing concept [Zhong17].

4.1.1.2 Robotics Cells – Virtual Manufacturing – AR/VR

Robots have continuously increased its presence in the manufacturing domain [IFR2020], price reduction and flexibility to be used in different manufacturing tasks are the base of its success. Commissioned in fully automatic cells or in collaborative environments have become part of the factories' landscaped, combined with virtual manufacturing tools such as 3D simulation and virtual commissioning technologies which have facilitated its deployment and utilization, as have improved its programming and commissioning in flexible production lines.

Virtual manufacturing tools have simplified the development of flexible production lines. Combined with levels of automation as a design parameter has enabled the design, development, and commissioning of flexible manufacturing systems more efficiently. 3D simulation, virtual commissioning and digital twins have improved the overall processes reducing the times from concept to commissioning and enabling the reconfiguration to optimize productivity, increasing the number of products and variants to be manufactured and reducing errors. [Johansson et al. 09]

Furthermore, the virtual 3D environment provides the data sets which combined with VR and AR technologies have demonstrated to be decisive on supporting the operators to analyse and predict outcomes of changes in the production system before taking any action in the real manufacturing system. The virtual environment provides the data sets to train the operators on the use of the equipment, and help them to reconfigure production, reducing ramp up times and avoiding costly errors [Factory2Fit18]. The Digital Twin that connects the virtual environment with the real factory, has enhanced the training of the employees with flexible manufacturing systems in runtime operations [David18], particularly robotic systems.

4.1.2 3D Printing - Additive Manufacturing (AM)

AM is one of the main components of Industry 4.0. It enables access to manufacturing capabilities as a service (i.e., Manufacturing-as-a-Service), which can revolutionize manufacturing processes and enable new business model.

3D printing emerged during last years as a promising set of tools able to produce customized artifacts out of various types of materials and serving a wide range of applications, from life support devices components up to optimized gas turbine burners. Due to their features, geometries impossible to obtain by classical mechanical processing are now available at a controllable cost and expected quality of execution.

In addition to the extended range of materials, companies using 3D printing devices can be deployed, offering a mesh of services towards the delivery of customized products.

The process linking demand of customized parts with the potential providers of printing services contains a set of generic steps capable of linking both ends, namely buyers/designers and suppliers.

Manufacturing-as-a-Service based on AM enables the design and manufacturing of new products with much better performance in terms of customized design and execution,

including improvements in quality and cost, since a specialized Additive Manufacturing Network includes a Request for Quotes (RFQs) step where various control variables can be considered. In Eur3ka, the consortium has access to the SIEMENS AMN manufacturing network, which supports:

- **Part Requestors** to accelerate the adoption of AM technologies in their products and operations.
- **Part Suppliers** to streamline their processes, set their operations to scale effectively and grow their business.

Figure 4-1: Workflow Orchestration Concept

The manufacturing network facilitates and orchestrates industrial AM processes end-to-end, including part qualification, collaboration, quoting, order management, planning and scheduling, build preparation, production execution, as well as reporting & shipping steps (Figure 4-1). Specifically:

- **Part Qualification**: This step enables manufacturers to easily verify and validate their customers AM designs. Additionally, using the SIEMENS manufacturing network, it is possible to guide customers to easily define AM specifications in terms of part design, selection of material use and validation of implementation (for our case associated exploitation risks), while including printability checks and 3D file integrity pre-purchases. Furthermore, the platform provides a single system to organize technical and commercial information and documentation (see Figure 4-2).
- **Collaboration**: As part of this step, the network facilitates the design of valid and potentially better AM parts in a collaborative way. It enables participants to the AM network to: (i) Collaborate effectively with experts or teammates on orders, when they can benefit from domain specific experiences over types of technologies and materials to be employed; (ii) Easily assign tasks to team members; and (iii) Archive communication and notes for future use (see Figure 4-3), allowing continuous evolution of experience base. This feature might be of high relevance for the new Smart Matching

of capabilities based not only on available descriptive knowledge but on acquired experiences.

- **Quoting**: This enables participants to locate the best fitted supplier for their production task. Specifically, it provides support for: (i) Finding industrial AM suppliers in terms of accepted design and material; (ii) Reviewing and managing proposals from multiple suppliers in one system; (iii) Save time on preparing proposals and cost calculation; (iv) Enhancing the customer service and win more jobs (see Figure 4-4).
- **Order Management**: This is about aligning sales and operations through seamlessly transferring order information to production. It allows participants to achieve greater transparency on the status of their orders. This step allow non-functional requirements like time of delivery, material and process related risks to be known, aligned and agreed on both ends of the process
- **Planning and Scheduling**: This step simplifies planning and scheduling processes enabling increased productivity. Specifically, job routing is planned to improve production flow and quality control. Moreover, build jobs are scheduled for all orders and machines towards better utilization of resources. Furthermore, there are functionalities that enable shift response to production changes (see Figure 4-5). Relying on previous step, this step monitors the effective capability on supply end to provide certification data, process data and any other feedback needed on both AM Network side and buyers to evaluate their own processes and risks.
- **Build Preparation**: This is a set of functionalities that aims at preparing and optimizing build jobs. They facilitate seamless transform of production schedule information to build preparation. Moreover, job productivity optimizations are supported using 2D/3D nesting and build preparation tools. This capability is by utilizing a connection to NX software from AMN. NX has nesting and build preparation capabilities built-in to their additive module. This means that a prerequisite of having NX licensed and installed is required to implement such a capability with AMN.
- **Production Execution**: This provides full shop-floor visibility towards tracking and monitoring production progress. It provides customers with a fast and simple way to track order status (see Figure 4-6). Is important to mention that for this step AM Network do not automatically collect data from shop-floor instrumentation but is the option of supplier to report in the platform the current status.
- **Reporting and Shipping**: This step deals with analysis and continuous improvement of the performance of AM processes. It supports archival of order information for future reference, along with generation of reports for billing and shop performance monitoring.

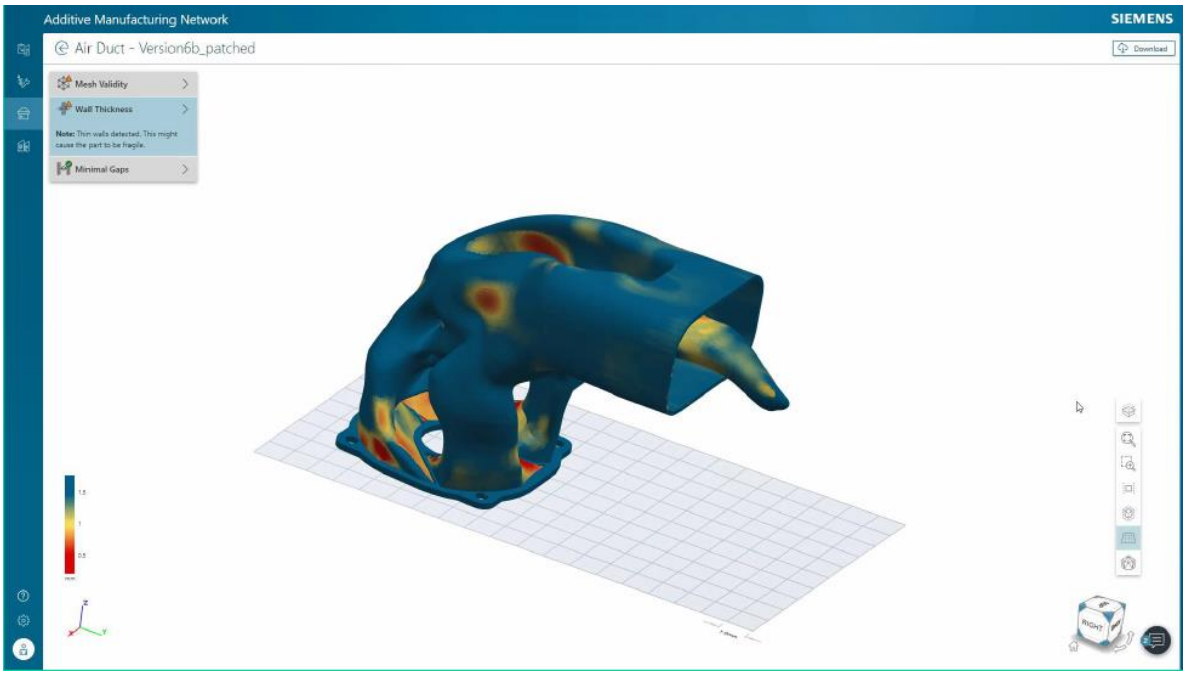


Figure 4-2: Part Qualification Process

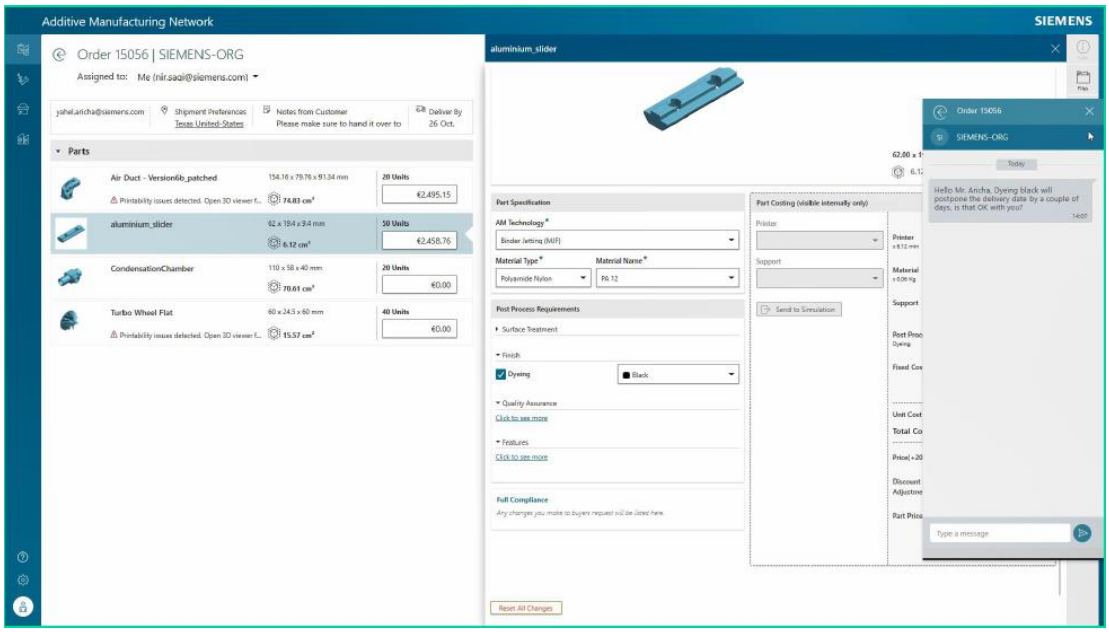


Figure 4-3: AM Collaboration Process

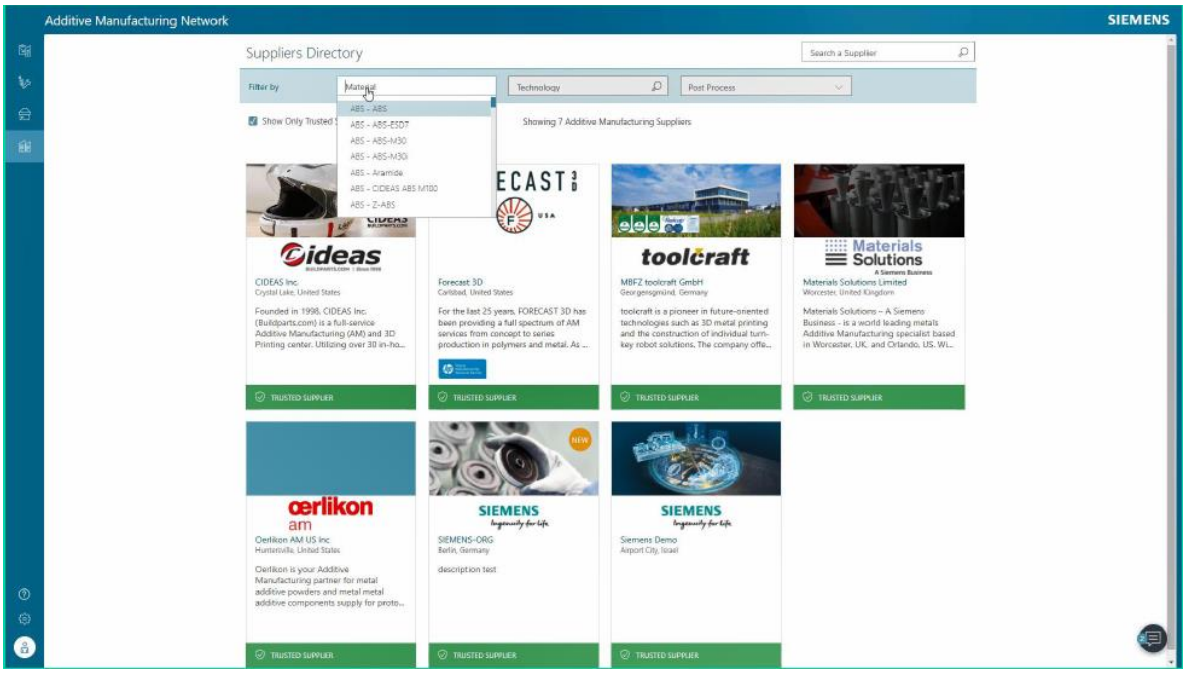


Figure 4-4: Quoting Interface

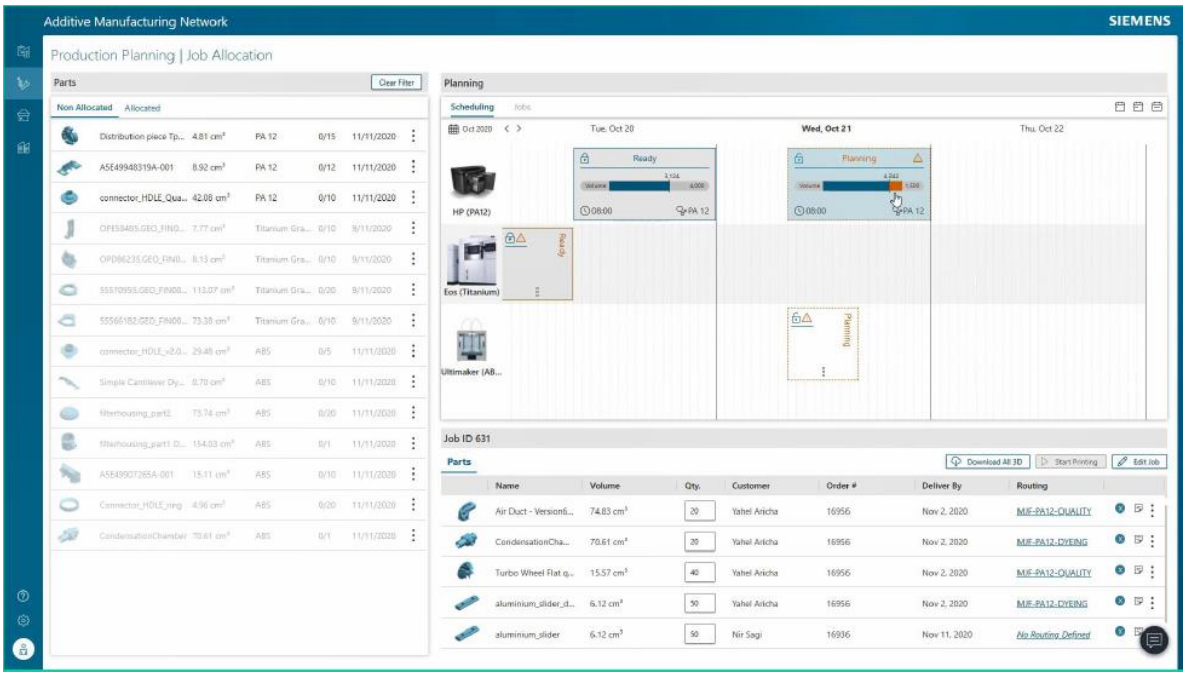


Figure 4-5: Planning and Scheduling Interface

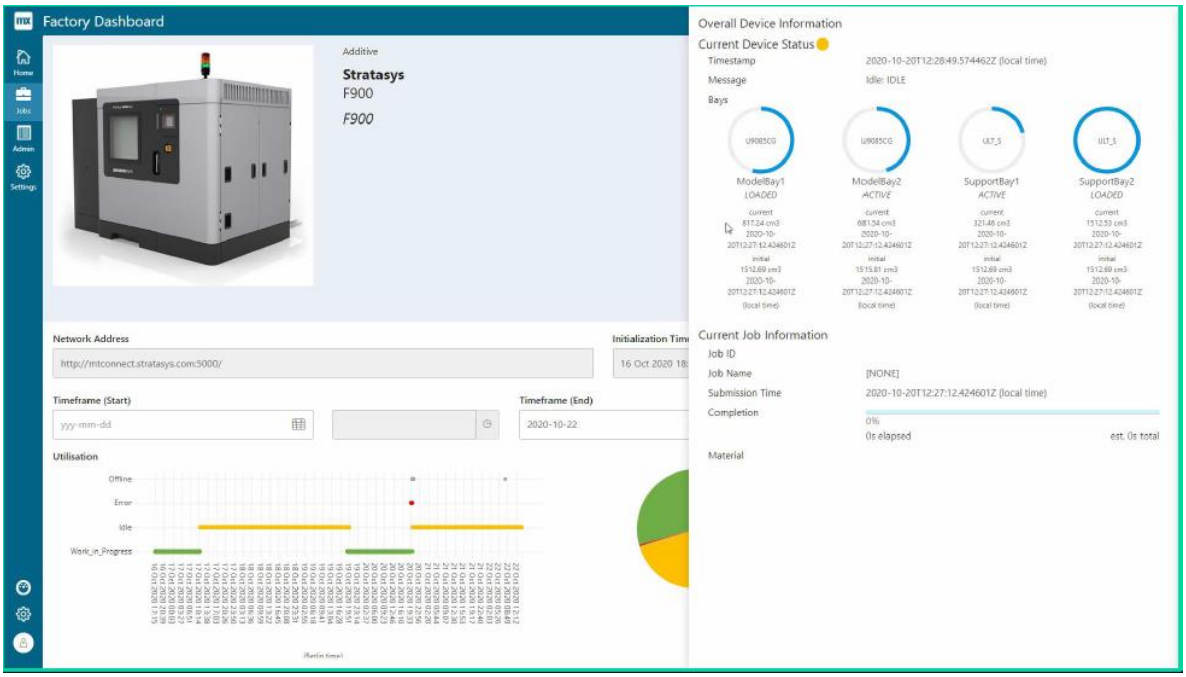


Figure 4-6: Production Execution Interface

4.1.3 Supply Chain Management Platforms

Supply Chain Management Platforms (SCMP) aim to connect partners across the supply chain by facilitating data sharing. SCMPs often centre around supporting the purchase-to-pay process, i.e., the process of acquiring goods of a third party. This includes exchanging information such as: quotations, orders, logistical information, technical specifications, forecasts, and invoices. There has been a large history of supply chain management solutions, below a brief overview is shown and how this relates to the DIH Smart Connected Supplier Network (SCSN).

Two-corner model

The Two-corner model describes a traditional approach for setting up a communication network between several organizations. This model is rather straight-forward and easy to implement. Whenever two organizations want to exchange information, a new connection is made between these organizations. The organizations are together responsible for the definition of the communication, the maintenance and improvement. Traditionally, the FTP (File Transfer Protocol) or even e-mail is used as transportation protocols for the communication, but nowadays custom-made REST APIs are more common.

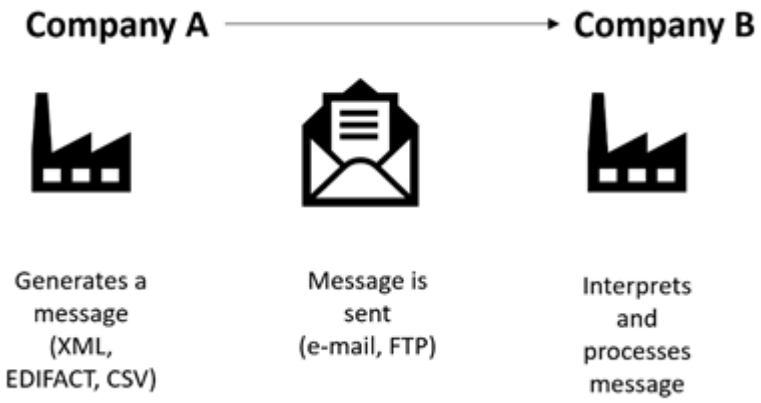


Figure 4-7: The Two Corner Model

The advantage of this model is that it is very flexible. The disadvantage is that the organizations itself are responsible for setting up and maintaining the connection, which is often not their main focus. Furthermore, whenever a new company C enters the network, both company A and company B have to setup a new connection to this new organization. Such a network results in extremely high numbers of connections between companies, which are often not even standardized, and is therefore not scalable.

Three corner model

The three-corner model acknowledges the major limitation of the two-corner model, namely its lack of scalability by introducing a mediator between all companies. This mediator, named Service Provider and is often an IT integrator, sets up a connection with all companies. This connection between the service provider and the company can be customized, e.g., Company A might send messages via e-mail while Company B sends messages via FTP. The Service Provider is responsible for converting the different messages and transportation protocols such that Company A can read messages from Company B in its preferred format. This solves the major limitation of the Two-corner model, i.e., scalability, because each company only needs a single connection to the central service provider in order to communicate to all connected companies.

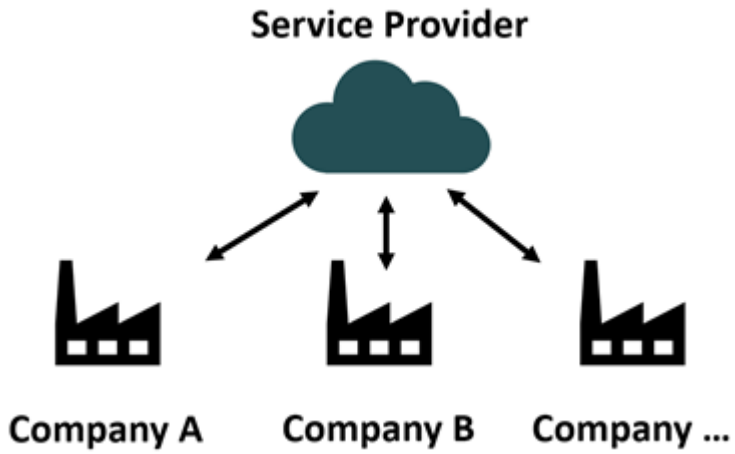


Figure 4-8: Three Corner Model

However, the Three-corner model also has disadvantages. In this model, the service provider becomes an essential party for all companies and might thus become very powerful. Moreover, this model only works when there is only a single service provide which every company agrees on. In practise this rarely happens as multiple companies might start offering service provider functionalities. When there are multiple service providers, with each their own set of connected companies, it is still not possible to connect to all companies at once via a service provider. In order to connect to all companies, each company should connect to all service providers which limits the model's scalability.

Four Corner model

The Four-corner model aims to finally solve the scalability issues of the former two models by uniting the service providers in a network. Each company, again depicted in blue in the figure below, is free to choose the service provider which best meets its requirements. Each company can, similarly to the Three-corner model, setup a connection to its service provider with a communication method of choice (e.g., FTP, e-mail). The service providers are all connected to each other via the model's inner-network, meaning that each service provider can communicate with all other service providers. The service providers are responsible for translating all incoming messages in a common format, in our case the SCSN communication standard. The translated SCSN message is then sent to the service provider of the message receiver, who translates the message and finally sends the message to the receiver.

Figure 4-9: Four Corner Model

The four-corner model is very scalable because each company only has to setup a single connection to a single service provider. The service providers are responsible for translating and sending the message to the receiver. This model is comparable to the telecom sector, where each customer is connected to only a single service provider. The service provider is responsible for sending messages to the receiver, regardless which service provider the receiver has chosen.

Additionally, it should be noted that besides the service providers another central component is required, namely the address book. This address book contains all members of the network and their corresponding service provider. The service providers need to access this address book in order to route the message to the right service provider.

4.1.4 Smart Matching and Mediation Services for Automotive and Medical supply chain

The Smart Factory Web, an approved testbed of the Industrial Internet Consortium (IIC) (cf. http://www.iiconsortium.org/smart-factory-web.htm and http://www.smartfactoryweb.com) that started in 2016. Smart Factory Web (SFW) shall network a web of smart factories to improve order fulfillment by aligning capacity across production sites.

The SFW is a platform that connects smart factories over a network to enable flexible sharing and management of resources, assets and inventory to maximize production and efficiency. To become part of the SFW, network participants describe their products and factory capabilities so as to improve factory-to-factory collaboration. A Smart Factory Web Portal (SFWP) enables secure data and service integration in cross-site application scenarios as well as 'plug & work' functions for devices, machines, and data analytics software by applying industrial standards.

The transparency and management of supply chains and entire supply networks is of great importance for companies. The COVID19 pandemic has shown how vulnerable supply chains can be and how quickly supply bottlenecks can occur. In addition to the avoidance of supply failures, so-called supply chain laws are another reason for the transparent description of supply chains. For the prevention of supply chain disruption, the resilient development of supply networks, and the verification of safety, environmental, and human rights standards, the entire supply chain must be described and monitored transparently. Flexible, standardized information management systems are needed to transparently describe and monitor supply chains. The SFW platform is one of these information management systems that enables the modeling and visualization of supply chains.

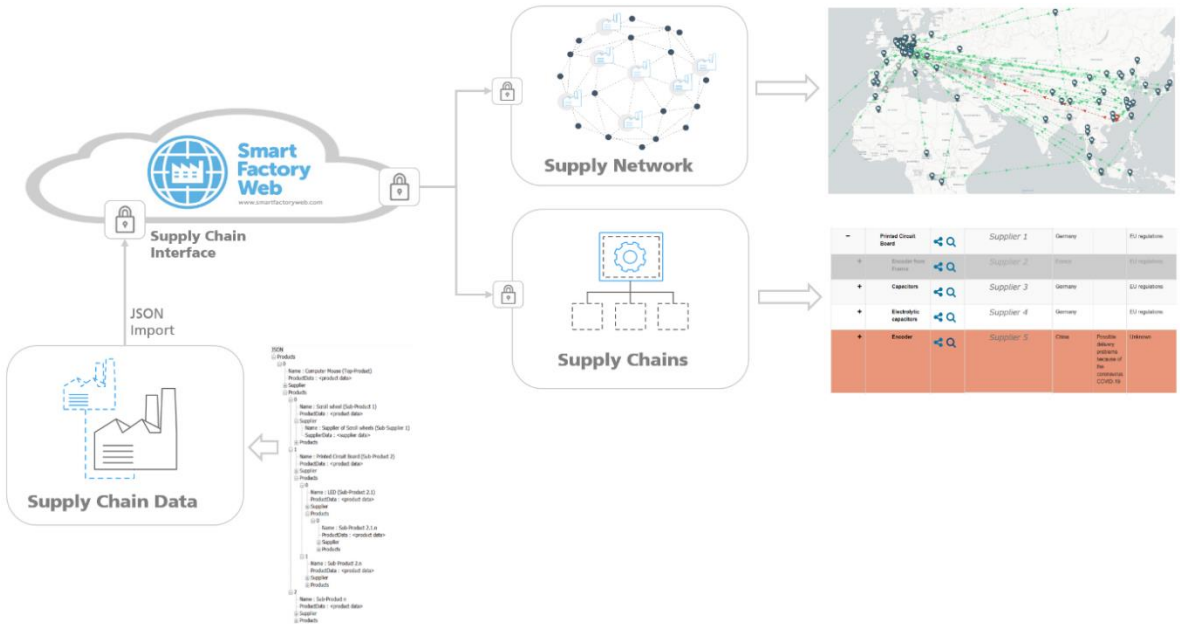


Figure 4-10: Supply chain interface of the Smart Factory Web platform

To model the capability of a factory as well as to model the supply chains the SFW ontology shown in Figure 4-11 is used. The individual ontology concepts are defined in more detail in Figure 4-12. The relations between the concepts show how the individual ontology concepts are related to each other.

We note here that the supply chains in the SFW platform are modeled according to the product structure. Starting from the top product in the supply chain, the product and supplier structure is broken down to the individual raw materials and raw material suppliers. From the Original Equipment Manufacturer (OEM) to the individual raw material suppliers (tier-n), the entire product and supplier structure can thus be mapped.

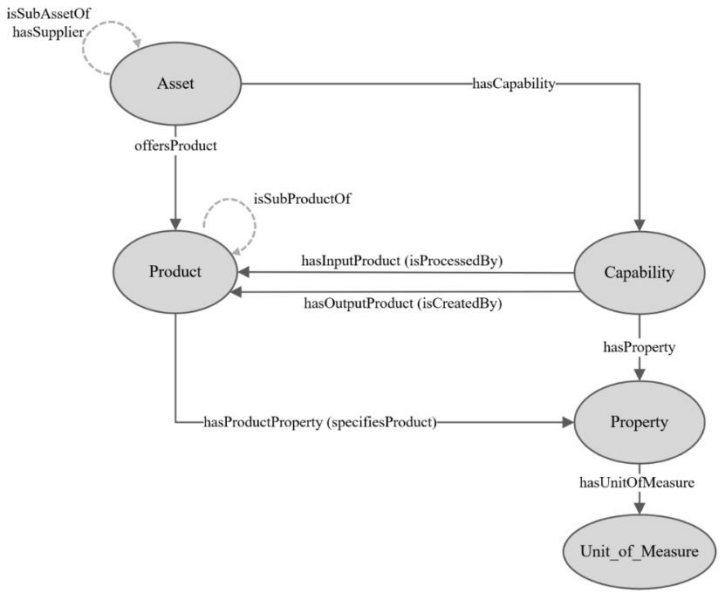


Figure 4-11: Excerpt of the SFW-Ontology

Ontology Concept	Definition
Asset	Asset is a factory or part of the factory equipment hierarchy as defined in [IEC 2013] = manufacturing resource
Capability	Capability (of an asset) is described in terms of what (product) the asset can produce, or in terms of how the product can be produced.
Product	Input (materials, part products) or output (result) of a production process
Process (step)	Execution of a capability by an asset with defined input and output products and BOP
Property	The property concept is used to describe the capabilities of assets in more detail and for the specification of products.

Figure 4-12: Ontology concepts for the modeling of production and process steps

The search for production and process steps is becoming increasingly important for industrial production marketplaces. Complex, mostly in-house production processes could thus be planned and coordinated across factory boundaries. In addition, collaboration along the entire value chain can be improved and optimized. The Smart Factory Web Platform provides a GUI as well as a web service interface for searching for production and process steps (Figure 4-13).

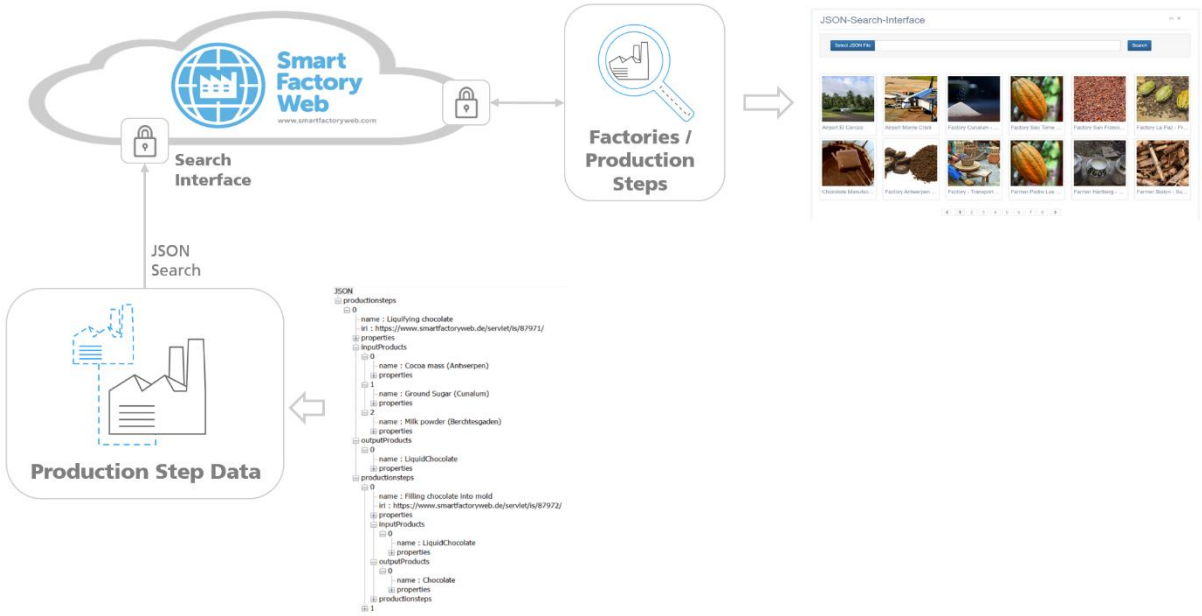


Figure 4-13: Web service interface – Search for production steps

Via the search interface of the SFW portal, a JSON file can be selected for the search for production and process steps. In addition to the production steps and the dependencies to other production steps, the JSON file also contains information about input and output products. The products and production steps are specified in more detail using their properties.

After selecting a JSON file, the search is started. The search will look for all released factories that have the production steps defined in the selected JSON file. The SFW portal shows as search result all factories that own and can apply these production steps.

4.1.5 Industrial Data Space for Trusted Data Sharing

The Industrial Data Space fosters secure data exchange among its participants, while at the same time ensures data sovereignty for the participating data owners. It is based on the IDS Reference Architecture Model (RAM) developed by the International Data Spaces Association (IDSA), a non-profit association with more than 120 members from all over the world. The IDSA aims to guarantee data sovereignty by an open, domain agnostic and vendor-independent architecture for a peer-to-peer network which provides usage control of data, to the data owner, which decides the terms and conditions of usage, ensuring the secure and trust data exchange across the entire data supply chain. It is important for all participants in the Industrial Data Space to trust the identity of each Data Provider and Data User. Therefore all “end points” may connect to the Industrial Data Space via a certified software (Connector) only. The Connector also incorporates authentication and authorization functionality.

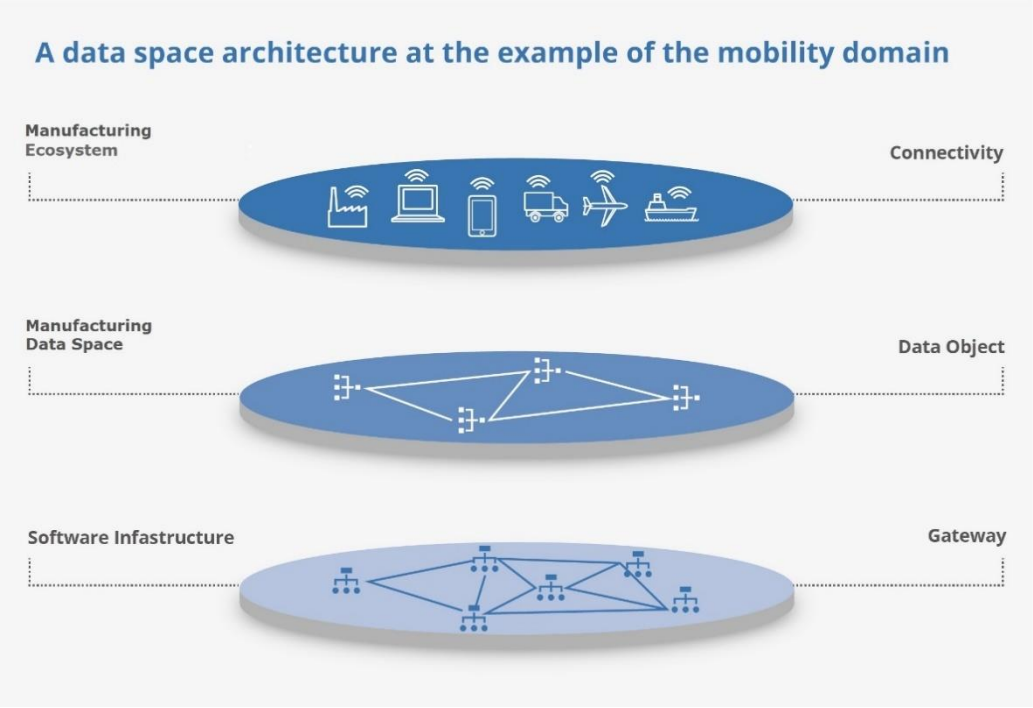


Figure 4-14: Industrial Data Space Overview [IDSA-RAM19]

Coming back to the description of the Industrial Data Space, it is key to reinforce that the aim is to facilitate the exchange of data between Data Providers and Data Users, that in order to be secure and the linking of data to be based on a simple concept, it is necessary also to introduce some other roles as the Broker, the AppStore Operator and the Certification Authority.

- The Data Provider possesses data sources and offers data from these sources to be used by other participants in the Industrial Data Space considering:
  - Describes the data source (metadata) to be registered by the broker for the data users.
  - Preselects the data to be shared through the Industrial Data Space Then process, integrate and transform into the target data model.
  - Makes data available to be requested by certain contractors.
  - Receives data service apps, vocabularies, schemes, and the Industrial Data Space Connectors over the IDS AppStore.
- The Data User receives data from the Data Providers and performs the following activities:
  - Retrieves data from certain contractors.
  - Receives data service apps, vocabularies, schemes, and the IDS Connectors over the IDS AppStore.
  - Preselects data from various sources, processes, integrates data and transforms it into a target data model.
- The Broker is the mediator between the Data Providers offering data and Data Users requesting data, supervising the exchanges of data. In more detail, the Broker:
  - Provides Data providers with functions to publish their data sources.
  - Provides Data Users with functions to search through the data sources of Data Providers.
  - Provides Data Providers and Data Users with functions to make agreements on the provision and use of certain data.
  - Supervises and records data exchange transactions, but also supports the rollback in case of faulty or incomplete data exchange.
  - Furnishes reports on the search for data sources and on data exchange transactions.
- The AppStore Operator provides:
  - Functions by which software developers may describe data services and make these services available to other participants.
  - Functions by which participants may retrieve and download data services.
  - Functions for payment and rating of data services.
- The Certification Authority makes sure that the software components of the Industrial Data Space meet the requirements jointly defined by the participants and rules and standards are observed. It supervises each certification procedure from the beginning until the end (approval/refusal).

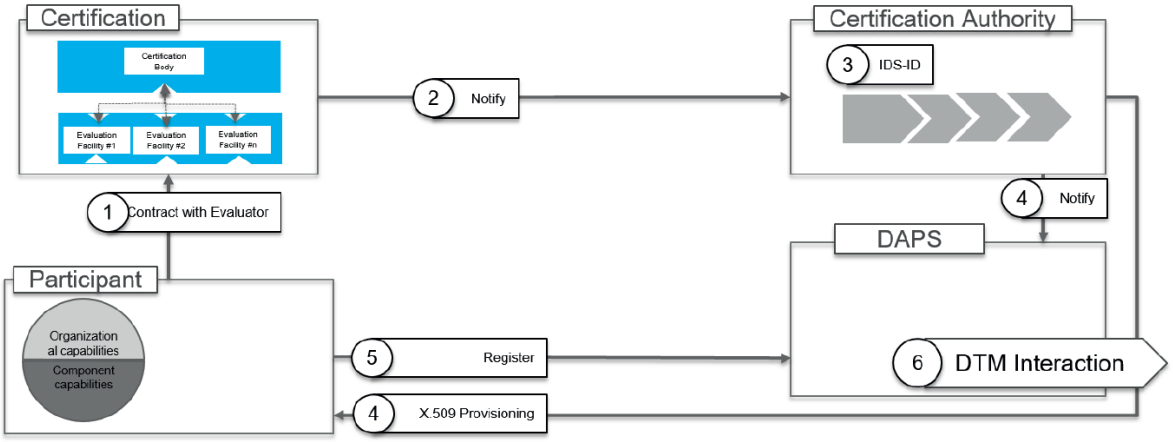


Figure 4-15: Interactions required for issuing a digital identity in the IDS

Referring to the IDS RAM, it is based on a decentralized approach. The Industrial Data Space is constituted by the total of all end points connected to the Space via the Industrial Data Space Connector. This means that there is no central authority in charge of data management or supervision of adherence to data governance principles, based on the rules derived from the requirements of the users, which will determine the rights and duties required for the data management.

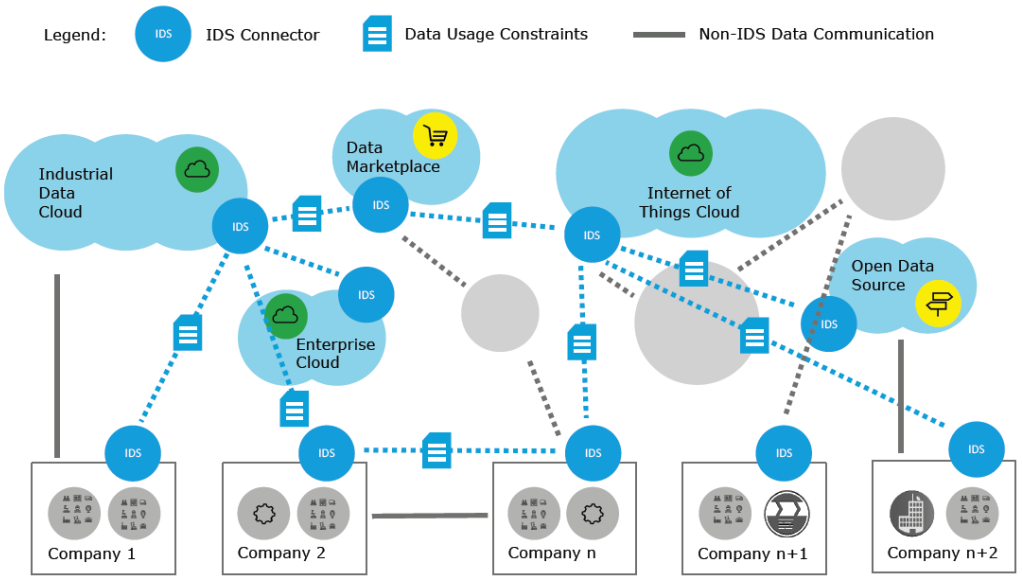


Figure 4-16: Industrial Data Spaces Connecting Different Cloud Platforms [IDSA-RAM19]

This IDS RAM is based on behalf of three cross-sectorial perspectives: The Security, the Certification, and the Governance perspectives.

The IDS Security architecture (as described in section 4.1 of IDS Reference Architecture Model[9]) provides means to identify Participants, protect communication and data exchange transactions, and control the use of data after it has been exchanged. For these purposes,

[9] https://www.internationaldataspaces.org/wp-content/uploads/2019/03/IDS-Reference-Architecture-Model-3.0.pdf

the IDS Connector ensures that the specifications and requirements of the Security Architecture materialize in everyday interactions and operations in the International Data Spaces, considering different levels of protection.

	Base Free	Base	Trust	Trust+
Development	Developed as Open Source	Developed in the IDSA Community	Developed in the IDSA Community	Developed in the IDSA Community and bound to strong SLA regarding security updates.
IDS Roles supported	Not certified, therefore the public IDS infrastructure is not available	All IDS Roles (section 3.1.1) supported, but support for Clearing House is optional	All IDS Roles (section 3.1.1) supported,	All IDS Roles (section 3.1.1) supported,
Communication abilities supported	Cannot connect to public IDS services or connectors.	Can connect to other connectors and exchange data.	Can connect to other connectors and exchange data. Can refuse a connection with a Connector with Base Profile.	Can connect to other connectors and exchange data. Can refuse a connection with a Connector with Base Profile.
Higher security features	Security level not defined	Standard security level	Extended security level	High security level

Figure 4-17: Overview of IDS Security Profiles and related dimensions

Considering that data security and data sovereignty are the fundamental value propositions of the International Data Spaces, therefore it is required the entity and component (IDS connector) certification to access the IDS. While the certification of organizations and individuals focuses on security and trust, the certification of components also refers to compliance with technical requirements ensuring interoperability.

The IDS Data Governance Model defines a framework of decision- making rights and processes regarding the definition, creation, processing, and use of data. While governance activities set the overall directive of the decision-making system, data management comprises three groups of activities regarding the creation, processing, and use of data. In the IDS context, data governance comprises also usage rights of data shared and exchanged within the IDS ecosystem. The management of metadata specifies data about data and comprises both syntactical, semantic, and pragmatic information. This is of particular importance in distributed system environments that do not rely on a central instance for data storage, but instead allow self-organization of different heterogeneous databases. Additionally, data lifecycle management is concerned with the creation and capturing of data, including data processing, enrichment, storage, distribution, and use. The following responsibility assignment matrix (RACI matrix) supports the allocation of these activities to enable a governance mechanism in the IDS ecosystem. RACI stands for “responsible”, “accountable”, “consulted” and “informed”. The focus lies on the „R“ and „A“ of the RACI matrix, supported by the notation „S“, which stands for „supported“.

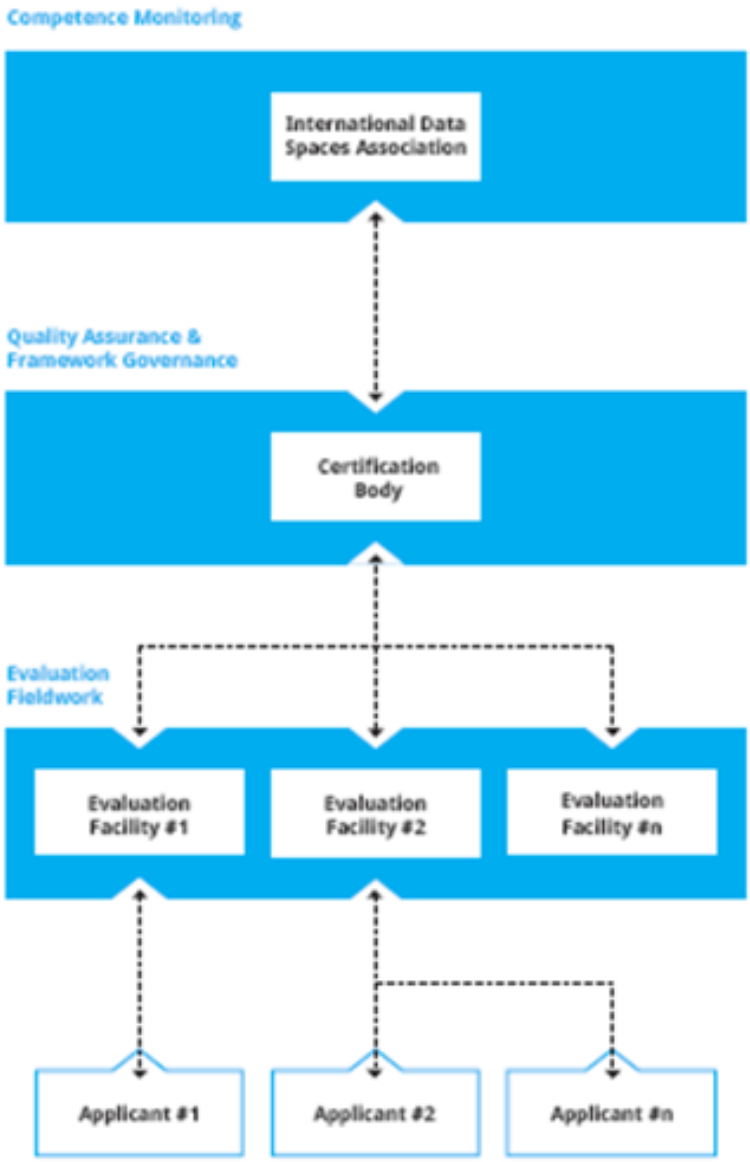


Figure 4-18: IDS Certification process

With all these capabilities, there are then multiple application scenarios where the IDS technology can be applied, providing the following features:

- Linking of data from several data sources.
- Integration of data of different classes.
- Combination of different categories of data.
- Integration of more than two enterprise architecture levels.
- Provision of smart services.

Activity	Data Owner / Data Provider	Data User / Data Consumer	Broker	Clearing House
Management				
Determine data usage restrictions (execute data ownership rights)	R, A	-	S	-
Enforce data usage restrictions	-	R, A	-	-
Ensure data quality	R, A	-	S	-
Monitor and log data transactions	S	S	-	R, A
Enable data provenance	S	S	-	R, A
Provide clearing services	S	S	-	R, A
Metadata				
Describe and publish metadata	R, A	-	S	-
Look up and retrieve metadata	-	R, A	S	-
Data Lifecycle				
Capture and create data	R, A	-	-	-
Store data	R, A	S	-	-
Enrich and aggregate data	S	R, A	S	-
Distribute and provide data	R, A	-	S	-
Link data	S	S	R, A	-

Figure 4-19: Roles responsible, accountable and supporting in data governance

(Legend: R – Responsible; A – Accountable; S – Supporting)

4.2 Customization and Use in Eur3ka – Eur3ka Services Specifications

4.2.1 Eur3ka Flexible Production Lines

The COVID19 pandemic has highlighted the weakness of current production systems and the need for improved flexibility. On one end, manufacturers are faced with large-scale disruption, concurrently affecting the supply-chains, the demand, and the production lines (e.g., reduction of human-human interactions), that required the reconfiguration of the manufacturing system. On the other end, the demand by medical institutions and the public for critical equipment supply, including Protective Personal Equipment (PPE), such as surgical masks and face shields, and Clinical Care Equipment (CCE), such as ventilators, is forcing the repurposing of existing production facilities. According to [Czifra20] and [Okorie20], the main enablers of these conversions are:

- **Flexibility**: Flexibility is needed both in terms of technology and organization. Indeed, if flexible production lines must allow fast adaptation to unstable scenarios, this constant changing cannot be performed without an adequate dynamicity in the decisional process. Thus, information systems, analytical capabilities, and well-defined protocols may improve the responsiveness of the firms.
- **Skills**: Specialized personnel, including qualified operators, engineers, and analysts are an essential prerequisite to production adaptation.
- **Digitalization**: Management and production optimization significantly benefit from extensive and transparent data availability in real-time.
- **Consumption models**: During the COVID19 crisis, the advantages in adopting a service-based approach instead of a machine-owning approach have been observed.
- **Adaptability to the market**: Careful attention in understanding and forecasting the market needs is essential.
- **Collaboration**: Collaboration among different industries is crucial, especially concerning the production of complex devices such as ventilators.

Given this, investing in industry 4.0 technologies, such as IoT, CPS, digital twins, and intelligent systems, may be crucial to get a faster and more effective response. In this context, remote interactions become essential, highlighting the potential of 5G technology as well as the possible benefits derived from virtual reality systems (e.g., staff training) and the flexibility related to collaborative robot exploitation [Malik20].

Although many of the listed enablers depend on the individual company strategies, the Eur3ka project will facilitate the reconfiguration and repurposing processes through three main approaches:

- **Guidelines and Protocols**: Provide guidelines and protocols to assist the industries in the adaptation procedures.

- **Distributed Production Networks**: Improve the adaptability of the overall European manufacturing system by connecting facilities with different competences to create a distributed flexible production network.
- **Knowledge Sharing**: Establish a trusted network of facilities to share expertise and exchange know-how.

The Eur3ka protocols and knowledge sharing network will be used to accelerate the company and product specific implementations of Eur3ka digital twins.

4.2.2 Eur3ka Additive Manufacturing Services and AM Network

Eur3ka will use the SIEMENS AM network to support manufacturing on demand functionalities for medical products. In a typical scenario, healthcare organisations and factories in immediate need for spare parts will be able to browse a catalogue of certified parts and accordingly to order them from proper suppliers. Of course, this do not forbid the processing and implementation of customized designs, if needed. The AM network will ensure that only certified suppliers that can provide this part will be available in the demand network. These suppliers will be accordingly able to provide a Quote for the demanded/requested products, based on the quotation process described in the previous sub-section. The initial specifications of the Eur3ka AM services based on the SIEMENS AMN are provided in Table 4-1.

Functional Overview**: The Siemens AM Network will allow healthcare employees (i.e., representatives of healthcare organizations) who have an immediate need for spare parts to browse a catalogue of certified parts and order it from Suppliers. The AMN will ensure only certified suppliers who can manufacture the parts, will be exposed to the demand and will reply with a Quote.**
Main Implementation Technologies**: Java, Javascript, Angular.**
Main Inputs**: 3D files, RFQs (Request for Quotes) /Orders, Suppliers, Materials, AM Technologies, PDFs**
Sample Inputs**: (i) Spare Part Catalog Administrator: Insert parts, 3D file, material, technology, Drawing PDF, Certificates requirements; (ii) End user: Select a part from the Catalog, customer details; (iii) Supplier: Supplier information, materials, technologies, certificates**
Produced Outputs**: The platform connects the end user RFQ / Order to the relevant suppliers. Data can be downloaded from the platform as 3D files, PDFs, CSV report.**
APIs Information**: The platform support REST API with Json messages format over HTTPs. The list of APIs is currently limited and will be extended over time.**
Deployment Architecture**: The Siemens AMN is deployed and managed by Siemens in a multi-tenancy mode, including for Eur3ka. it is installed on AWS and using different technologies from AWS and others.**
Security Mechanisms**: The data is encrypted both in Transit SSL and in Rest, including encryption.**
Components Licensing**: The various components of the AMN have many kinds of licenses, including third party components and open source. The full list of components can be found in the documentation of the AMN.**

Table 4-1: Specifications of the Customized Version of the Eur3ka AM Network

The specification and implementation of the Eur3ka AM network will also put emphasis on the secure and trusted exchange of digital information, which is a prerequisite for IP protection and a key for motivating part requestors and part suppliers to engage in the network.

4.2.3 Supply Chain Management Platforms

The Smart Connected Supplier Network (SCSN) is a Supply Chain Management Platform modelled according to the four-corner model. The infrastructure of SCSN is based on the International Data Spaces Reference Architecture Model 3 (IDS-RAM3) and is an isolated data space.

For Eur3ka, two major enhancements should be made to this data space. Firstly, it is essential that inter-data-space communication is setup. Since Eur3ka is targeting the complete European Industry, it is hard to imagine that a single data space such as SCSN will be the de facto data space of the complete of Europe. Therefore, it is important to interconnect the already existing data spaces such as the Smart Factory Web into the SCSN data-space. This can be done by considering the Federated Catalogue concept of GAIA-X, which describes a federated approach to interconnect various data spaces.

The second enhancement is to expand the purchase-to-pay models of SCSN with the ability to describe and publish company's production capabilities. To ensure supply chain resilience, it is essential to quickly find suitable suppliers when a disruption has occurred. For this, it is essential to have a standardized overview of what companies in the supply chains might contribute to the overall production. Moreover, after identifying which suppliers might be relevant, a private and secure exchange of order and capacity information can be started. The latter is already supported by the SCSN models.

This solution should also be modelled according to the four-corner model, as previously described, to ensure the high scalability of the solution. This can be ensured to use the IDS self-description models to also describe production capabilities in a standardized way. The IDS Broker and ParIS components can be used for the federated querying of suppliers.

4.2.4 Eur3ka Smart Matching and Mediation Services for Automotive and Medical Supply Chain

The Smart Factory Web (SFW) is a platform, where factory owners offer their production capabilities to customers world-wide. For example, the factory owner can share information about their product and production capabilities with verified SFW customers. The customers in turn can look for factories to handle the specified order request in the SFW search. Additional information like price limits, time requirements and supply-chain based risks can be included in the search. Since capacity and workload are sensitive data, the factory owners only allow this data to be used to enhance search requests. To technically enforce

this usage restrictions, the International Data Spaces (IDS) is a viable option. Details on the IDS can be found in the IDS Reference Architecture[10].

Figure 4-20 shows the proposed extensions of the SFW to be done in the scope of the Eur3ka project.

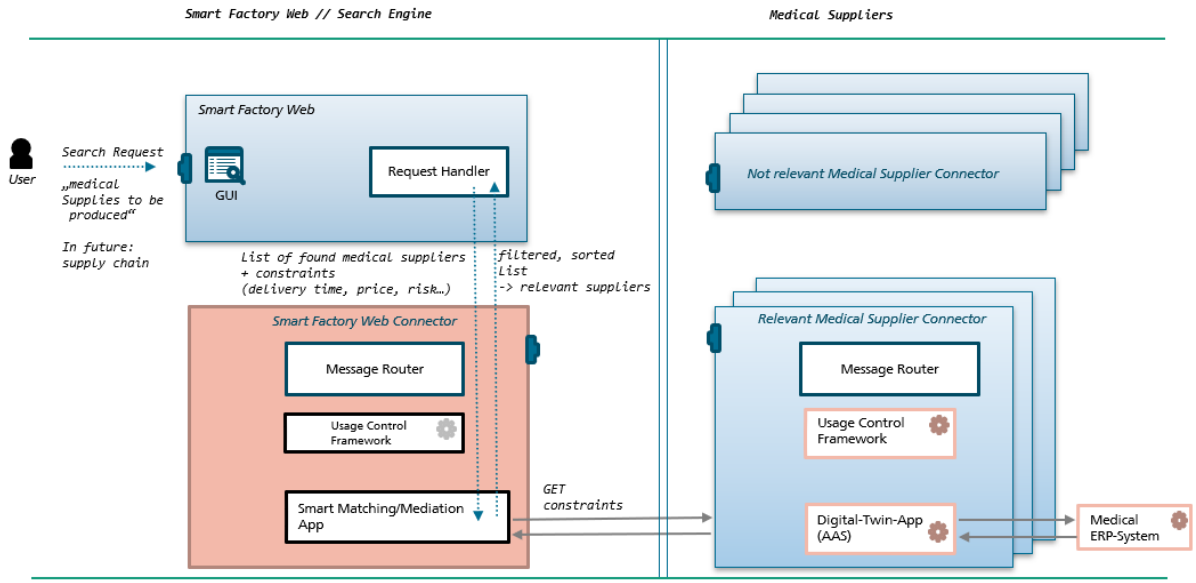


Figure 4-20: Architecture of SFW extended by medical suppliers

The SFW platform can be found on the web portal https://www.smartfactoryweb.de/ and includes an ontology-based smart search enhanced by a Smart Factory Web Connector (SFWC).

SFWC extends the SFW with an IDS connector (implemented based on AISEC Trusted Connector[11]) to enable data sovereignty for the connected suppliers. For the Eur3ka project, the focus will be on the medical suppliers. For this, the usage policies will be defined in usage control framework e.g., MYDATA[12] or FIWARE UC[13]. Our example policy restricts the usage of critical data like production plans and factory capacity to the Smart Matching/Mediation App (SMMA) in the IDS Connector. This app will provide the capability to filter the suitable suppliers based on given constraints like delivery time or price. Of course, the medical supplier needs to return the required data for effective matching. Therefore, we plan to introduce a digital twin to the factory that contains all required values for the matching. The digital twin will be based on the Platform Industry 4.0 Asset Administration Shell[14]. In order to provide valid information, a connection to an external medical ERP-System could be required.

[10] https://www.internationaldataspaces.org/wp-content/uploads/2019/03/IDS-Reference-Architecture-Model-3.0.pdf
[11] https://industrial-data-space.github.io/trusted-connector-documentation/docs/overview/
[12] https://www.mydata-control.de/
[13] https://github.com/ging/fiware-usage-control
[14] https://www.plattform-i40.de/PI40/Redaktion/DE/Downloads/Publikation/Details_of_the_Asset_Administration_Shell_Part1_V3.html

Since the SFW contains primarily manufacturing industry, its underlying ontology (see: Figure 4-20) will be extended with concepts of the medical domain (e.g., medical equipment).

An envisaged **usage scenario** is as follows:

- A user needs a medical product that needs to be produced;
- In the SFW portal, the user retrieves all factories which are able to produce this product;
- Additional constraints can be added like latest delivery time or maximum costs;
- Smart Matching/Mediation App (SMMA) requests the required information from the factories via IDS;
- This request might be handled by an ERP-system and is sent to the digital twin of the factory;
- SMMA applies intelligent search to further filter the factories based on the returned values to find matching factories and sorts the results based on the preferences. The information will be deleted after usage in SMMA. The SFW user has no access to it.
- SMMA returns the filtered and sorted factory list to the SFW.

Below we list the interfaces that should be implemented and/or extended:

- GUI search interface in SFW for users (needs to be extended).
- Search also possible over SFW API with JSON REST Request (in development, swaggerhub description will be available).
- Interface between SFW and SFWC → JSON Message over REST (in development).
- Interface between IDS Connectors → REST API (IDSA is improving IDS API, currently multipart IDS messages).
- Interface between Supplier IDS Connector and Digital Twin App → AAS REST API (Platform Industry 4.0 specified this API, but this API is still in active development).
- Interface between Digital Twin App and ERP-System → proprietary (for example SAP connection).

Table 4-2 illustrates the specifications of the Eur3ka version of the SFW platform.

Functional Overview**: The Smart Factory Web (SFW) platform enables factory owners to offer their production capabilities to customers world-wide. To enhance the search results for capabilities and products we expand the SFW with a Smart Matching/Mediation App (SMMA). SMMA provides a smart search algorithm with constraints like delivery time. The data sovereignty of the data owner is always considered.**
Main Implementation Technologies**: The SMMA uses Java and will be provided as Docker container.**
Main Inputs**: The main inputs for the factory and supply chain search are products or product groups, capabilities selected by the user and constraints like delivery time, price or number of pieces. The services provide a REST API which produces and consumes data in JSON format.**
Produced Outputs**: The main output is a sorted and filtered list of factories which are matched to the search request. The REST API produces data in JSON format. Additionally, the results are also accessible via the GUI.**
APIs Information**: The SFW and the SMMA provide a REST API over HTTPS. An API documentation will be provided. For the user only the SFW is accessible. Additionally, the SFW provides IDS Connector for external connections.**
Deployment Architecture**: See Figure 4-20.**

Security Mechanisms**: The SFW provides a user management with role-based access control. Connection from the user to the SFW are SSL encrypted. The IDS Trusted Connector applies usage policies for data from factories to SMMA[15].**
Use of Containers: **SFW and SMMA run both in separate Docker containers.**
Components Licensing**: SFW is closed source. SMMA and IDS Connector are open source.**

Table 4-2: Specifications of the Customized Eur3ka Smart Matching and Mediation Services

4.2.5 Eur3ka Industrial Data Space for Trusted Data Sharing

One of the main challenges to be tackled in Eur3ka for the rapid manufacturing repurposing response achievement is the need to break down data silos, making available the data that must be exploited to be capable to improve the manufacturing process or the joint collaboration with other companies. Through the application of the industrial data space framework, it is possible to ensure cross-company data exchange that guarantees data sovereignty for the data provider.

The IDS framework, however, is not about technical requirements only. To create trust between the different participants in a data space, both the technical components (connectors, applications, etc.) and the participants (especially the operational environments) are certified according to the IDS standard. This certification process demonstrates to all participants of the ecosystem, that the operational environment offers a certain level of security regarding availability, confidentiality, and integrity that all users can trust. The certification approach is displayed in two dimensions:

1) The horizontal dimension is evaluation depth, describing the level of detail at which an evaluation is performed.
2) The vertical dimension is the increasing extent of the security requirements that need to be fulfilled.

This way, it can be ensured that no "backdoors" are built into the software. Moreover, the security mechanisms are checked as well, and they are made visible to other participants as a "trust level". Based on this information, everyone can decide whether the specified trust level of a potential partner is sufficient for their own use case or whether other partners need to be searched for.

During 2020 by the time that the COVID19 pandemic was starting to spread worldwide, this IDS framework become standard (DIN SPEC 27070[16]), which is the first in a row of upcoming standards that will define the design principles for data spaces also on an international level.

Under the umbrella of these new standard requirements, and due that in Eur3ka the intention is to build the Eur3ka trusted global manufacturing response network, in order to provide a trusted and unique capability to plug and collectively respond to a sudden demand increase, in a coordinated and effective manner, it is then clear IDS connectors are going to be the

[15] https://industrial-data-space.github.io/trusted-connector-documentation/docs/overview/
[16] https://www.internationaldataspaces.org/ids-officially-a-standard-din-spec-27070-is-published/https://www.internationaldataspaces.org/ids-officially-a-standard-din-spec-27070-is-published/

main technology connecting all stakeholders between each other in order to pool their resources and expertise, to make sure that manufacturing companies get what they need to repurpose their manufacturing lines and equipment to comply with production requirements and regulatory compliance. Based on the work that will be performed through Eur3ka project, both the functionalities and components of these IDS connectors will be updated to comply with the new DIN Spec27070 requirements; this allows therefore to integrate an interoperable and secure data exchange system.

5 Quality Management and ZDM Technologies and Specifications

5.1 Background Technologies Overview

5.1.1 Digital Lean Quality Management Framework

As the manufacturing landscape evolves, the need for automated quality processes tops the list as the most sought-after capability of today´s product lifecycle management (PLM) technology platforms. At a time when companies are looking to enhance and extend governance and traceability, they are also looking for tangible business results in terms of Best-in-Class level of quality management regardless of its challenges. Companies are then placing quality at the forefront of a digital thread implementation to reduce manufacturing complexity while at the same time advance on the digital transformation journey.

It is for this reason that today many quality control software tools are being adapted to provide them with these capabilities to connect with the MES/SCADA manufacturing systems, in order to align manufacturing and quality aspects during the whole PLM.

From the Innovalia Metrology alliance (as one of the main lines of expertise of Innovalia), a metrological high-performance platform has been developed (M3 Software) for the capture and analysis of automatic scanning point clouds of various types of parts, for the reliable and efficient acquisition of 3D information about their dimensions, thus allowing advanced control dimensional quality.

The measurement operating process that this solution follows and that allows to obtain the maximum performance to work both online and offline with the dimensional information, is as follows: 1) Connect and measure, 2) Creation of measurement plans, 3) Powerful and comprehensive analysis for a wide range of geometries and dimensional and geometric tolerances (GD&T), 4) Measurement (scanning) process automation to reduce measurement time and 5) Generation of personalized measurement reports.

What it is necessary to take into account are the overall functionalities that this platform can provide not only for the quality managers, also to the production managers, thanks to working with a data model based on the QIF standard (ISO 23952:2020), considering a digital metrology workflow and agile management of heterogeneous products and massive quality data, covering the whole product lifecycle management process, starting from the product design process up to the advanced analysis and visualization of the quality information:

- **Loading the part design and generation of measurement programs.** M3 compatibility covers a wide spectrum of CAD formats used for metrology. Once the CAD file with PMI information is loaded, the workpiece measurement program begins to be developed. Once the program is performed, then the scanning routine can be automatized and also macros can be built in order to automatize in continuous parts measuring and results reporting.

Figure 5-1: M3 inspection program performing

- **Dimensional quality control data processing.** A homogenization and reduction of the amount of data captured is carried out for the elimination of atypical data, reduction of errors.
- **Obtaining the reference geometry**: For the determination of position and size, through the application of numerical algorithms of geometric adjustment and segmentation on the high-density three-dimensional point clouds resulting from the digitization of mechanical components.

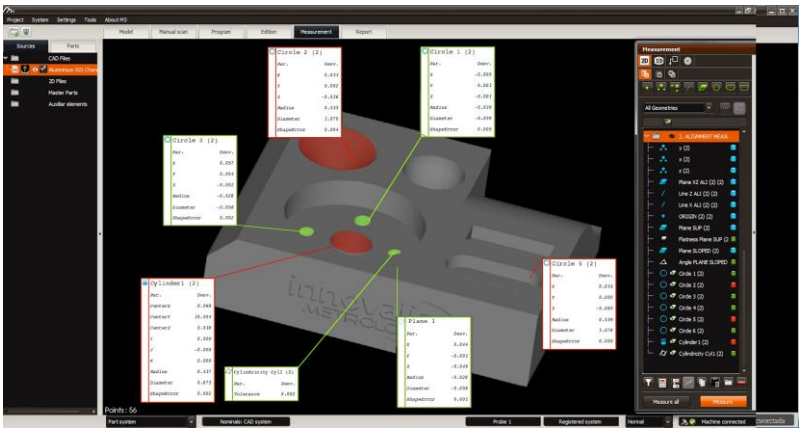


Figure 5-2: Demo part geometry references

- **Export dimensional quality control data results.** Considering the intention of obtaining a digital metrology covering the whole product lifecycle management process, it is important to be able to export this quality control results in a legible format (CSV, XML, DMO) to be exploited in further PLM steps.

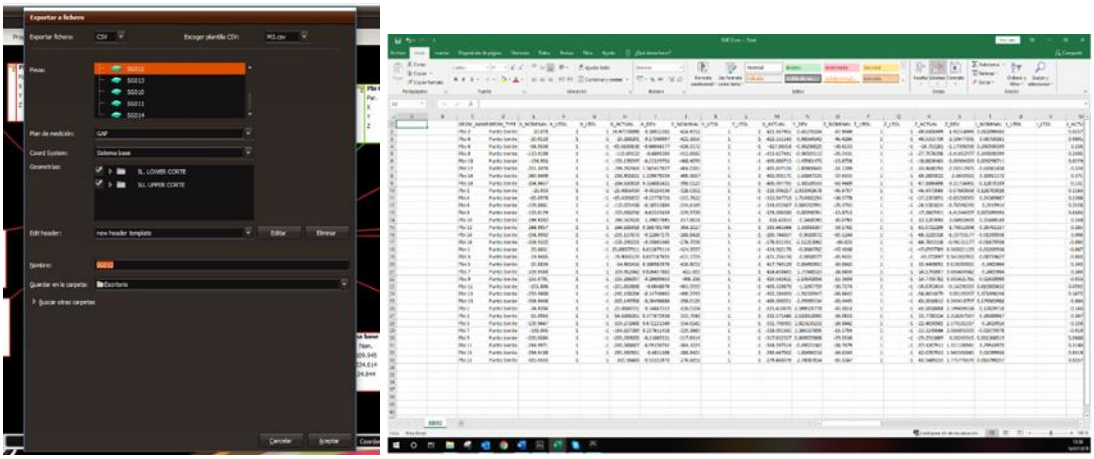


Figure 5-3: Example of extraction of measurement data to CSV format

- **Evaluation of the resulting deviation**: Through the comparison of the measurement carried out with the theoretical CAD model, the calculation of the existing surface deviations is carried out.

Figure 5-4: Demo part Colormapping

- **Identification of patterns and trends in the production process**: Through M3 Analytics, it is possible to obtain an early detection and precise evaluation of manufacturing errors in the production area. These advanced analytics will permit to improve not only the efficiency of the plants but the decision-making process, becoming flexible, dynamic, and easier.

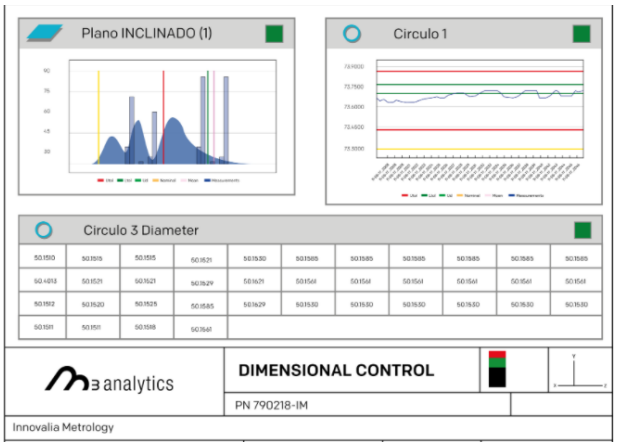


Figure 5-5: Statistical analysis through the M3 Analytics module

For all these functionalities to have a greater sense in a broader environment further the manufacturing site, even more considering the Eur3ka scope to provide support among a collaborative manufacturing environment, it is necessary the capability of these platforms in order to provide trusted data exchange systems, but also to have a space where you can share this information in an organized and private way where you can create a traceable environment for sharing product design data, part quality, and data set analysis.

5.1.2 ZDM Platforms

Zero Defect Manufacturing platforms aim to help factories to achieve the goal of zero defects, addressing the concept of connected factories with a high level of interoperability. To this end, ZDM platforms allow manufacturers to connect their manufacturing systems (MES, PDM, SCM, ERP, etc), and other computer-aided systems like CAD/CAM, CAE to benefit from the platform's features in order to improve the products, processes and production quality.

In this context, to have an operational solution in place quickly, Eur3ka will reuse results/concepts from other research projects, especially the Digital Reality in Zero Defect Manufacturing (**Qu4lity**)[17], the Big Data Value Spaces for COmpetitiveness of European COnnected Smart FacTories 4.0 (**Boost 4.0**)[18], which already includes Reference Architectures and components/services implementing functionalities and capabilities identified in these Reference Architectures and the **ZDM Software for Designing Quality Inspection Equipment** by Siemens. Focussing on the zero-defect concept, Eur3ka aims to support both process and product quality assurance in dedicated workflows in medical equipment manufacturing. In addition, Eur3ka will focus on integration activities and develop applications based on existing components, customising and improving them, suitable for Eur3ka pilots, as well as shaping and supporting the overall manufacturing environment.

Enabling technologies such as affordable sensors and actuators, cloud computing, artificial intelligence (AI), machine learning (ML), Deep Learning (DL), open-source software,

[17] https://qu4lity-project.eu/
[18] https://boost40.eu/

augmented reality (AR), mixed reality, virtual reality (VR), data streaming (such as Kafka and Storm) could help quality experts to implement their quality improvement plans and therefore contribute in Quality management. This is a key component of the Quality 4.0 paradigm which is about aligning the practice of quality management with the emerging capabilities of Industry 4.0, helping manufacturers to avoid unexpected quality defects, and assuring high level of quality, by alerting them of emerging product faults that can potentially cause product quality issues, and driving organizations toward operational excellence.

Therefore, some AI-based components developed in Qu4lity and Boost 4.0 will help Eur3ka in automated defect prediction, training AI systems to detect or predict defects on diverse surfaces by pre-fed data and real-time inputs provided by the production process and supporting in the development of virtual inspection mechanisms to identify functional and cosmetic defects in the production line. These solutions will be supported by emerging industrial data spaces enabling controlled and secure data exchange and data sovereignty.

In the following subchapters, Qu4lity and Boost 4.0 projects are introduced, presenting their objectives, their reference architectures and the components that have allowed their implementation.

5.1.2.1 Zero Defect Manufacturing background

Zero Defect Manufacturing is a way of thinking in the quality management systems (QMS) regarding the product and process quality. It is based on a simple but yet hard to achieve goal: Do right on the first attempts. For this reason, ZDM must be integrated into the production process right from the beginning rather than trying to address the issues at a later stage, and should follow a continuous improvement cycle based on standardized benchmarks. In fact, the standard Six Sigma methodology embraces ZDM as one of its core concepts, defining it as allowing a maximum 3,4 defects per million products, since achieving zero defects in a real context is practically impossible. For achieving this, the evolution of Industry 4.0 enabling data-driven innovation leads to an easier implementation of the ZDM concept due to the availability of the required amount of data for techniques such as machine learning to work properly [Psarommatis20b].

The Zero Defect Manufacturing can be implemented in two different approaches. The product-oriented ZDM and the process-oriented ZDM. The difference is that a product-oriented ZDM studies the defects on the actual parts and tries to find a solution while on the other hand the process-oriented ZDM studies the defects of the manufacturing equipment, and based on that can evaluate whether the manufactured products are good or not. The latter one lays within the predictive maintenance concept. In Figure 5-6, we illustrate these two approaches as one concept, i.e., the Zero Defect Manufacturing concept which comprises two start points, one for each approach.

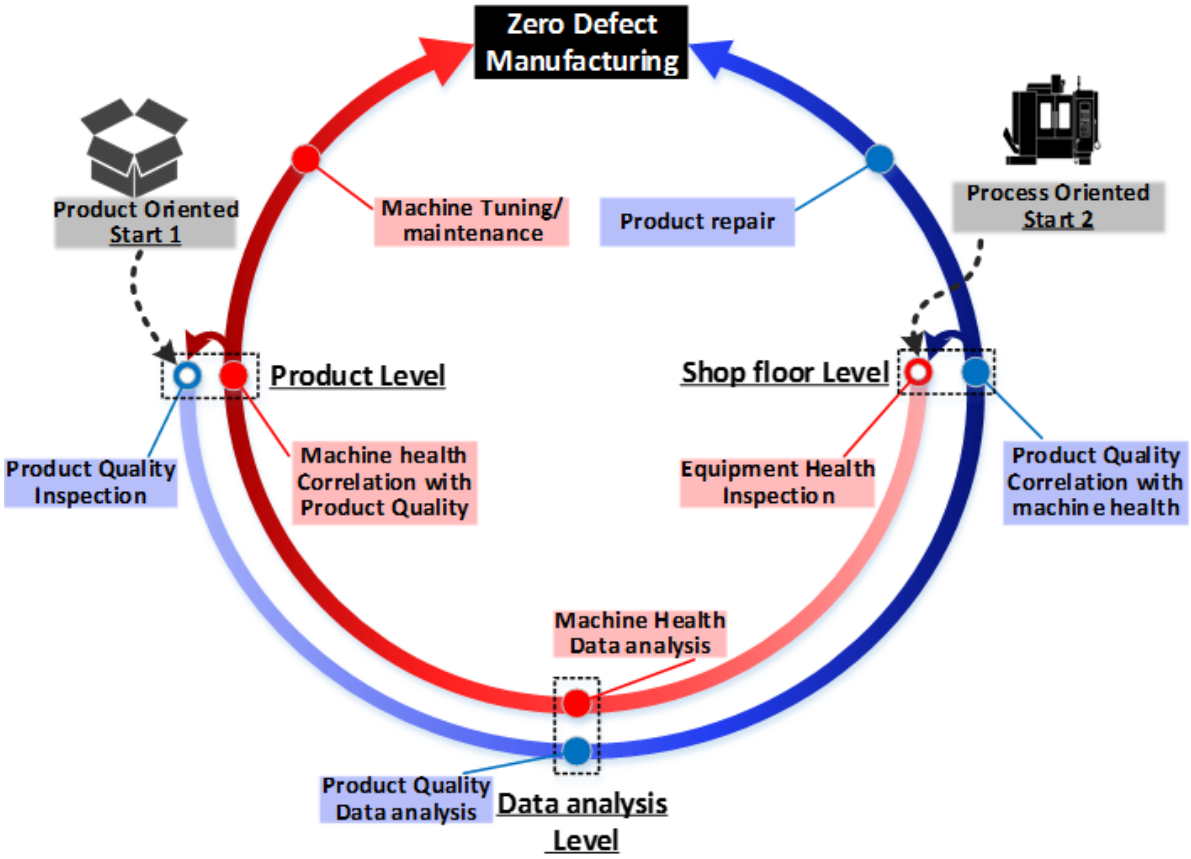


Figure 5-6: Zero defect manufacturing concept [Psarommatis20a]

The reasons why the ZDM thinking is attractive for companies are manifold. First, it can considerably reduce costs of the company's resources related to the treatment of defective products (Bai and Zhang, 2018). The ZDM process relies essentially on the fact that no useless element is present within a process. Useless element refers to anything that does not bring any added value to the product, e.g., defective machines and tools, inefficient employees, etc. Significant reduction of scrap production and therefore money expenditure can be realized with ZDM (Dong et al., 2017). Beyond that, the overall production chain should be continuously improved. Any possibility of system enhancement must also be meticulously and extensively assessed. In that way, product manufacturing is getting closer and closer to perfection [Eleftheriadis16}. This approach can also be motivated by increasing safety and customers' satisfaction, which might strengthen customer loyalty and soar the financial benefits of the company [Thangaiah18].

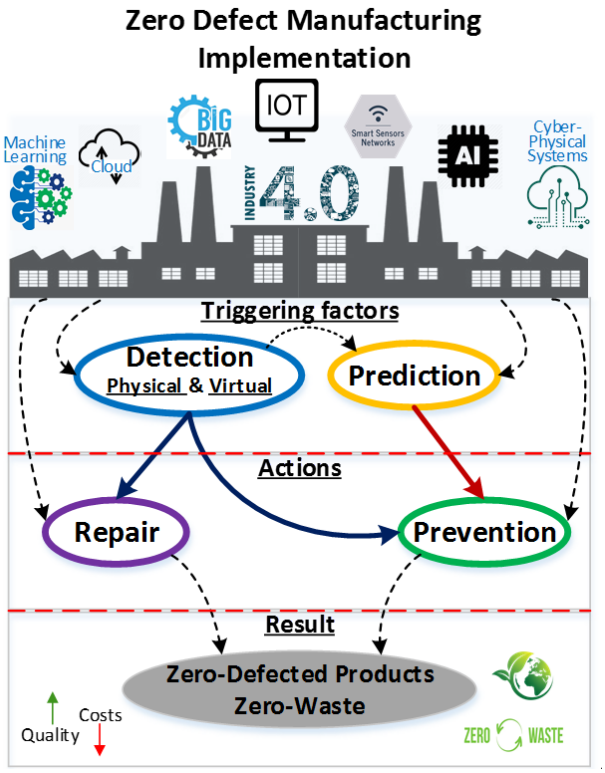


Figure 5-7: Zero defect manufacturing implementation [Psarommatis20a]

Currently, with the evolution of Industry 4.0, ZDM concept is easier to be implemented due to the availability of the required amount of data for techniques such as machine learning to work properly [Moutzis16], [Chien13], [Kuo13], [Choi12] but still a lot of effort is needed for better integration and coordination of the capabilities of each technology. Furthermore, the equipment that is required for such data recording used to be very expensive and companies were not investing on that [Ahuett-Garza18]. However, the landscape has changed now with computer power and data storage rising, while sensors price dropping significantly together with the new technologies that make the concept of ZDM possible. ZDM will be the new standard for companies towards more eco-friendly and more efficient production lines with zero defects. On that regard, in Figure 5-7 we illustrate how the ZDM concept can be implemented and also how the ZDM strategies are interconnected among them. The ZDM consists of four strategies: detection, repair, prediction, and prevention [Psarommatis18]. The prediction is though, a new aspect provided Those strategies are interconnected among them as follows. The following are applied in both product or process oriented approaches. If a defect is detected then it can be repaired, also the data gathered by the defect detection module is populated to specifically designed algorithms for predicting when a defect may occur and therefore be prevented. Here fits the phrase mentioned earlier “to do things right in the first time”. Defects, at both product and process levels, are more likely to occur at several stages of the product life such as raw material transformation, manufacturing and assembly. Defects that were generated at an early stage are also susceptible to be amplified and diffused along the following steps of the manufacturing process and might cause manufacturing issues and critical malfunctions. Defects that are coming from manufacturing operations are not always avoidable. One of the reasons is that they are intrinsic to the operation itself. A single defect in the manufacturing life might also be the result of the

accumulation of small defects that appeared in previous steps. If not treated or detected at an early stage of the manufacturing process life, defects continue to spread in the following life stages, namely the use phase. Use phase defects, are also caused by wrong or poor information regarding the use of the product from the manufacturer to the user. However, it is possible to reduce these inconveniences by gathering data and information regarding materials, manufacturing processes, tools and machines and also by using quality control strategies (Sinha and Anand, 2018). That way, several problems can be eliminated.

Traditional quality improvement methods such as LM, SS, L6S, TOC and TQM do not learn from defects. They just remove them. These philosophies are analyzing the past to improve in the future. Therefore, there is a loss of potential important information from the present. Not analyzing the present creates an inertia between the occurrence of an event and the identification of an improvement linked to this event [Psarommatis20b]. One major change of ZDM is on the flow of information. Indeed, ZDM treats real-time data to prevent product from defect. Doing this, ZDM combines several quality control applications concerning production lines, machinery, automation applications and supply chain processes. This is possible thanks to the development of IT systems and industry 4.0. This helps to anticipate defects in order to fix them before too late. It is crucial to reach a state of early detection in order to have a sustainable system [Yusup15]. Moreover, this flow of information helps to better connect the global supply chain [Pagliosa19], which is known to be critical success factor for an efficient QMS. Another aspect on the predictive aspect is to predict defect in the product but also in the process. In ZDM, the treatment of real-time data helps to dynamically monitor and tune the parameters in order to adapt the predictive maintenance. Downtime of a machine is known to be very costly. Reducing this downtime by a predictive maintenance of higher accuracy is a strong quality of ZDM [Dreyfus18].

5.1.2.2 ZDM design software background

Currently there are numerous of different technologies with different characteristics each, for implementing ZDM. Additionally, manufacturers re-configure production lines more frequently than ever in order to cope with the volatile and diverse demand and at the same time provide high quality products. To achieve high quality production manufacturers must implement a quality improvement / assurance methodology. Quality assurance design is a crucial step during the design phase and can significantly affect the profitability of a company [Wiendahl07]. Having an efficient quality assurance design will assure high product qualities without significant performance losses and less scraps. The quality assurance plan design is not a simple task, it depends on numerous factors that can significantly affect the production.

Considering the above manufacturers' needs, a tool that will assist them during the design or re-design of their manufacturing systems in terms of quality assurance. More specifically, ZDM design software will help manufacturers to analyse the product to identify the critical places for performing quality control and at the same time providing the required specification of the quality assurance equipment in order to achieve satisfactory KPIs. Further to that, the quantification of the impact of the implementation of quality assurance plan is performed through a ZDM oriented simulation engine.

5.1.2.3 Qu4ality

Qu4lity[19] is the biggest European project dedicated to Autonomous Qu4lity (AQ) and Zero Defect Manufacturing (ZDM) in the Industry 4.0, with the main objective to demonstrate in a realistic, measurable and replicable way an open, certifiable and highly standardised, SME-friendly and transformative shared data-driven ZDM product and service model for Factory 4.0 through 14 pilot lines.

Qu4lity also aims to build an autonomous quality model to meet the Industry 4.0 ZDM challenges, demonstrate how European industry can build unique and highly tailored ZDM strategies and competitive advantages through an orchestrated open platform ecosystem, ZDM atomized components and digital enablers across all phases of product and process lifecycle (engineering, planning, operation and production) building upon the Qu4lity autonomous quality model to meet the Industry 4.0 ZDM challenges.

Qu4lity defines a Reference Architecture (RA)[20] based on the most relevant outcomes of other Research and Innovation activities in the context of generic reference architectures for digital industries such as the Platform Industrie 4.0 initiative (RAMI 4.0), the Industrial Internet Consortium (IIRA) and the OpenFog RA. In addition, it also considers the adoption of the Digital Shopfloor Alliance Reference Framework as the main input to further enhance it for ZDM scenario, exploiting it adherence to standards and the openness toward the integration of multiple digital enablers.

As illustrated in Figure 5-8, the Qu4lity RA is designed as a Four-Tier architecture, composed of 4 main layers, Field, Line, Factory and Ecosystem layers, which are hierarchically stacked according to their scope with respect to the physical processes in the factory, and one Digital Infrastructures providing common services such as connectivity and distributed processing capabilities. Furthermore, the Qu4lity RA also identify three distinct Functional Domains, orthogonal to the Tiers, (Adaptive Digital Shopfloor Automation, Multiscale ZDM Processes and User-Centric ZDM) for grouping system functionality, and four Crosscutting Functions (Security, Digital Infrastructures and Digital Models) that are domain-agnostic. To better clarify the role of all these elements, they are mapped, whenever possible and relevant, to the corresponding concepts in RAMI 4.0. **The Qu4lity RA will be taken into account in the specification of the Eur3ka RA in WP2**.

[19] https://qu4lity-project.eu/

[20] Quality - D2.11 Reference Architecture and Blueprints (Version 1)

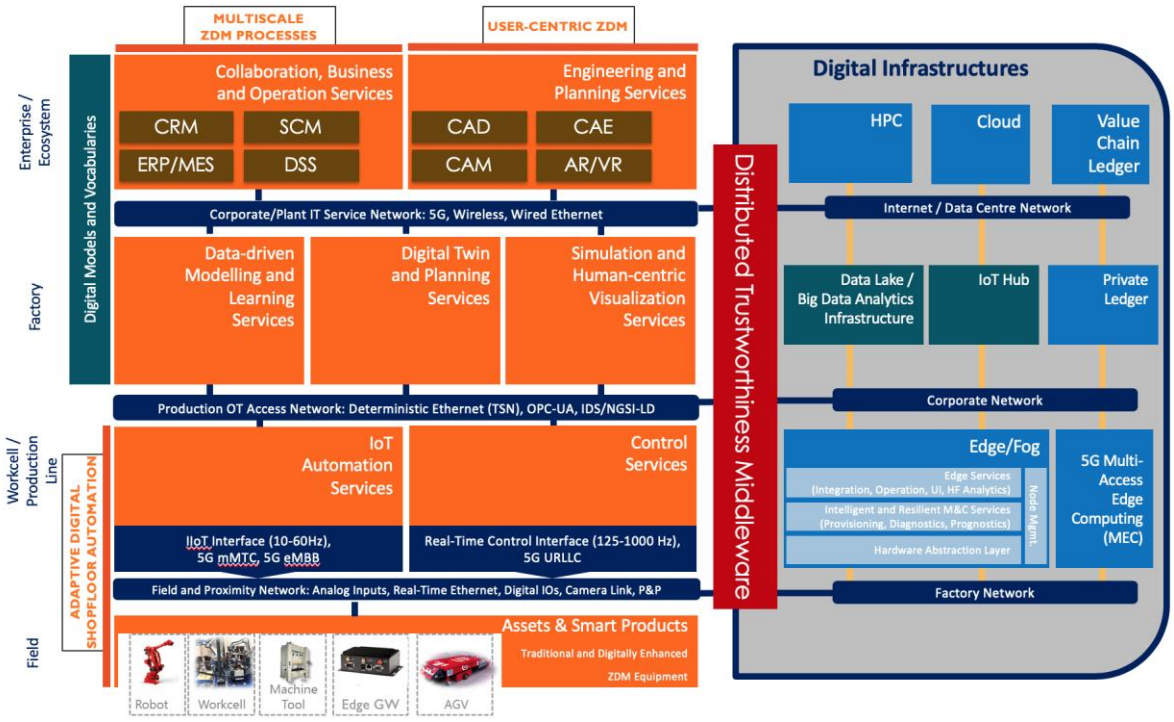


Figure 5-8: Qu4lity Reference Architecture

Besides the existing solutions identified to implement some functionalities of the Qu4lity Reference Architecture, in Qu4lity has been developed multiple specific components and digital enablers needed to implement critical functionalities required by pilots. In the following list are described the most relevant ones grouped by functionality.

Data Analytic Frameworks:

Interoperable ZDM framework for Big Data/AI Analytics and Cloud/HPC Analytics, combined with relevant Digital Models

This ZDM framework offers a Big Data and Analytics framework specifically tailored to Industrial IoT and Industry 4.0, providing a portfolio of solutions specifically tuned for high volumes of data specialized in Zero Defect Manufacturing and Industrial IoT Solutions as opposed to more generic similar initiatives.

The wider realm of industry 4.0, smart factories and Industrial IoT requires in most applications an infrastructure of Big Data and Analytics solutions combined with the relevant data models and libraries.

Failure Propagation Analysis Framework on Process Chain Level

This component is a Data Analytics Framework to analyse Intermediate Product Properties (IPP). The aim of this module is a characterization of IPP at every process step by applying suitable data analytics models. As a result, an analysis of IPP behaviour over the entire process chain can be conducted and used for the process control to reduce (pseudo) failures and improve the efficiency and availability of the equipment. By applying the knowledge

derived from the data on a simulation framework, different process control strategies can be derived to optimize the overall process chain.

Monitoring and optimisation of manufacturing processes:

M3MH

This component provides a software solution for accuracy in the measurement of pieces during the production process for assuring the quality as well as for ensure the precision of the machine tool during production, as it is essential to achieve high dimensional quality of the product.

This component offers a full measurement software within machine tool, allowing to perform measurement in the middle of machining for the generation of new machining alignment, what will significantly increase precision of the machining (e.g., to check the dimensions of operations performed such as length of a milled workpiece, or diameter of a drilled hole. It also provides Real-time tool monitoring and In-cycle gauging, automatic tool offset updates and reduced rework.

Pseudo Error Reduction Framework

The component is a Data Analytics Framework in charge to identify and analyse relevant product attributes that characterize the final product quality to automate quality tests. Therefore, the main objective is to improve the overall product quality rate as well as to increase the testing efficiency. The pseudo errors occur since the automated quality tests are programmed to control univariate product measurements, the mission is to reduce the pseudo error rate significantly by changing from predefined static testing parameters to a refined quality assessment procedure based on processing parameters and prior testing results. The component follows a closed-loop process that feeds back into the system with data and results and allows the system to investigate and identify failure sources.

FAlink-MAP

The aim of this component is the monitoring of machines in different plants around the world. The data obtained from the machines will be available to be displayed in the platform, giving information about the machines (forces, oil levels, temperatures…) to the end user, and can be all collected in a report, to be subsequently analysed to identify anomalies and extract valuable information that can improve the efficiency of the manufacturing and provide a better understanding of the manufacturing process.

eTRUE

The eTRUE component is an intelligent, adaptive deviation compensation system for automated mould manufacturing, facilitating the optimisation process chain for automated cells which are time consuming and require expertise which is difficult to find. This happens because equipment ages and optimal settings change and must be readjusted over time in order to get the maximum accuracy.

The component allows an effortless implementation of automated solutions for mould manufacturing, with a consequent reduction in costs and productivity improvement, mainly

due mainly due to their cloud database for data aggregation and automated process optimisation and coupled predictive maintenance capabilities which empowers it for process monitoring twin for zero defect manufacturing.

IKCLOUD+

IKCLOUD+ is a cloud infrastructure for manufacturing that allows inspecting, cleansing, transforming and modelling information and inferring key performance indicators from large amount of data provided and stored by manufacturing entities. The component tries to improve the efficiency of the manufacturing and flexibility by connecting and interoperate multiple IT systems. By allowing the communication of the different IT systems, it provides the means for managing and analyzing big amounts of data.

FURNACE4.0 Platform for hot stamping industrial furnace

The FURNACE4.0 platform consists of a Big Data solution implemented on a hot stamping furnace in order to obtain a more accurate control of the furnace operation to avoid problems related to crack formation on the hot stamping process and to obtain a more energy efficient system. The platform provides a more accurate control of the temperature of the pieces and therefore, a more optimized quality for such critical parts.

Collaborative ecosystems:

DIHIWARE

DIHIWARE offers Knowledge-driven services in a collaborative and innovation ecosystem, where providers and consumers interact together towards joint innovation by offering and requiring assets and services. The solution is offered as an integrated platform aiming to support both, the access to services and the collaboration services that will act as a one-stop-shop for SMEs where multiple services are offered and requested, allowing to find synergies, opportunities and valuable information and easily connect with the people from the ecosystem.

Additive Manufacturing simulation:

Design4AM

This is an innovative software for computer-aided construction of organically shaped parts in the context of Additive Manufacturing (AM), especially with multi-material design. It allows to predict by mechanical simulation the stability of the parts before they are manufactured. It allows the integration of modelling, simulation, and visualization of AM parts into a single framework.

The solution covers three important software facets of truly volumetric objects and integrates them into a single framework: intuitive volumetric modelling, mechanical simulation, and interactive visualization. The component can process parts with properties varying in space like smooth material transitions based on an innovative representation format and efficient data structures.

Additive manufacturing simulator for rapid time estimation

This component is a digital twin for metal additive manufacturing systems, and its main objective is to provide a reliable and fast estimation of processing/printing time to produce one or more parts on systems equipped with 2 independent lasers. To run the process, import post processing files from a CAM system as well as parameters setting from the real system and produces a detailed report. The simulation of additive manufacturing provides a rapid estimation of the processing time to print parts with minimal or no efforts for the end user without requiring modelling of processes, geometry etc., as the other tools available on the market require, because it needs just to import post processing files and machine parameters. Starting from them, this solution can estimate the processing time in a reliable and fast way.

Remote assistance and maintenance:

Pacelab WEAVR

Pacelab WEAVR is a powerful software suite to streamline the authoring, management and execution of extended reality (XR) applications for operations, maintenance and training. Pacelab WEAVR allows to create, deploy and execute a wide array of virtual, augmented and mixed reality solutions from the same set of technical data, creating a seamless and consistent experience from basic familiarization exercises to advanced, interactive field support. The suite provides an integrated set of modules including an editor platform, a server application for collaboration and content distribution, as well as a run-time environment empowered by mixed, virtual and augmented reality technology.

Nerve Blue

Nerve Blue is an industrial software platform that enables machine builders to offer services to customers for machines installed anywhere in the world. It offers an out-of-the-box experience, with an intuitive user interface and edge computing features that allow users to collect, store and analyse machine data, consolidate functions on one device, and remotely manage software. Machine builders can reduce system complexity and costs, improve machine performance, and offer new services to customers. The component offers: Workload consolidation, allowing to share computation resources between different operating systems and applications; Data Connectivity, providing three different ways to use the data, in the device, on a local server and in the cloud; Open interoperability due the open and interoperable characteristics of its edge solution; and finally a Centralized Management, providing visibility of installed devices and the possibility of interacting with them to carry out specific tasks such as software updates, monitoring, etc.

Decision support Systems and prediction:

Decision Support System (DSS) for ZDM

This component offers an integrated approach leveraging IIoT and predictive analytics, maintenance specific DSS and effective Maintenance Scheduling. To this end, it provides

interoperability with various systems, integration with ZDM Strategies, and considers heterogeneous sources of predictive analytics.

The DSS will manage the zero-defect processes by filtering out false alarms coming from predictive analytics and deciding mitigation actions to cope with defects. It may be combined with ZDM Strategies to control the propagation of defects and manage their occurrence in multi-stage production. It also incorporates semantic rules and a rule-based engine.

ARUL

The component can provide the most appropriate Remaining Useful Life (RUL) estimation form based on the analysis of the available data. It can provide valuable information regarding the deterioration rate of assets as the former is defined as the distance from the current time to the end of the useful life. The forms covered are: Degradation models, End of Life models and Run to Failure models.

To estimate the RUL of the equipment, the ARUL component uses a data-driven approach utilizing the Long Short-Term Memory (LSTM) deep learning algorithm, and can also provide combinations of model-driven approaches, proposing a weighting schema for the evaluation of their efficiency, to provide better estimations on an early stage, as soon the LSTM gets properly trained. Hence, both data- and model-driven approaches will be used to estimate accurately the RUL of the equipment, which is key in the improvement of the quality of the produced product and in the zero-defect manufacturing process in general.

Edge software and diagnosis algorithms for grinding machine

The software developed at the edge in the Danobat Box gateway incorporates diagnosis algorithms that allow diagnosis and prediction of problems in production. So, the main objective is to allow the provision of smart machines in the way to autonomous production in the customer factory. It will also be supported by intelligent services by the machine tool manufacturer. The component will facilitate an expert analysis-based o data for improvement of machine performance and provides mechanisms to avoid quality problems in the machining related to defective condition of main components of the machine and to avoid unexpected failures of components of the machine.

Data Integration and IEC61499:

MASAI

MASAI is a data integrator software for heterogenous resources focused on the manufacturing domain, acting as data collector for machinery available at shop floor level, offering a wide range of connectivity protocols. It allows integrating and collecting information from sensors and other data sources, normalizing that data, and processing it to provide aggregated and intelligent views of raw data to support the decision making. The solution could be installed close to the data sources and allows to monitor devices and offers interoperability with some manufacturing-oriented platforms like Siemens MindSphere, and it is interoperability with visualisation-oriented platforms like Atos Urban Data platform (AUDP) or Grafana.

FB_DLL

This component provides the possibility to implement basic or service IEC 61499 function blocks in a custom programming language that are compiled in a dynamical loadable library (DLL). The goal of this FB is to include external code written in a custom programming language into an IEC61499 application.

The FB_DLL function block implements an interface between a FB and arbitrary functions residing in a dynamically loaded library. It is a generic function block which means that the count of event ports and data ports can be defined.

5.1.2.4 Boost 4.0

Boost 4.0[21] is the biggest European initiative in Big Data for Industry 4.0 and aims at developing an open standardised and transformative shared data-driven Factory 4.0 model through 11 lighthouse factories. For this purpose, Boost 4.0 builds a European industrial data space to improve the competitiveness of Industry 4.0 and also demonstrate how European industry can build unique strategies and competitive advantages through big data across all phases of product and process lifecycle (engineering, planning, operation, production and after-market services) building upon the connected smart Factory 4.0 model to meet the Industry 4.0 challenges (lot size one distributed manufacturing, operation of zero defect processes & products, zero break down sustainable operations, agile customer-driven manufacturing value network management and human centred manufacturing).

Therefore, one of its main objectives has been guiding the European manufacturing industry in the introduction of Big Data in the factory, providing the industrial sector with the necessary tools to obtain the maximum benefit of Big Data, accelerating the adoption of industry 4.0 big data intensive smart manufacturing services, and addressing the data fragmentation between products and processes, enabling connectivity among them and leveraging the Factory 4.0 data value chain.

In order to achieve this, Boost 4.0 is aligned to global standards, adopting data models and open interfaces interoperable with the European Reference Architectural Model Industry 4.0 (RAMI 4.0), and providing also a Trusted Big Data Middleware integrating the four main open source European initiatives (International Data Space, FIWARE, Hyperledger and Big Data Europe) to support the development of open connectors and big data middleware. In addition, Boost 4.0 offers a Secure Digital Infrastructure, adapting and extending cloud and edge digital infrastructures to ensure high performance operation of the European Industrial Data Spaces, as well as offering Open Interfaces in order to be able to deploy big data pipelines for advanced analysis services and data visualization supported by the main digital engineering, simulation, operations and industrial quality control platforms. Finally, it also provides a European certification program for equipment, infrastructures, platforms and big data services for the operation in the European Industrial Data Space.

[21] https://boost40.eu/

Boost 4.0 defines a Big Data driven Reference Architecture (BD-RA)[22] aligned with the Big Data RA proposed by Big Data Value Association (BDVA) and harmonized with the Digital Factory Alliance (DFA) overall digital factory open reference model.

As shown in Figure 5-9, The Boost Big Data Reference Architecture is composed of 4 main structural layers: a) The integration layer in charge of data ingestion, b) The Information and Core Big Data layer, responsible for data management, processing, analytics and visualisation. c) The application layer, providing services to support business functionalities and expose the functionality of lower layers through appropriate services, and finally d) The business layer, which provide the overall business solution in Boost 4.0 project.

It defines also several horizontal layers that supplement the previous 4 layers with a set of cross-cutting aspects, in particular data sharing platforms, engineering and DevOps, Communications & Networking, Standards and Cybersecurity & Trust. These layers provide communication mechanisms and technologies for to transmit and receive data, to share data securely, to facilitate the development of Big Data solutions, and mechanisms for device and application registration, identity and access management, data governance and data protection, all supported by widely adopted standards.

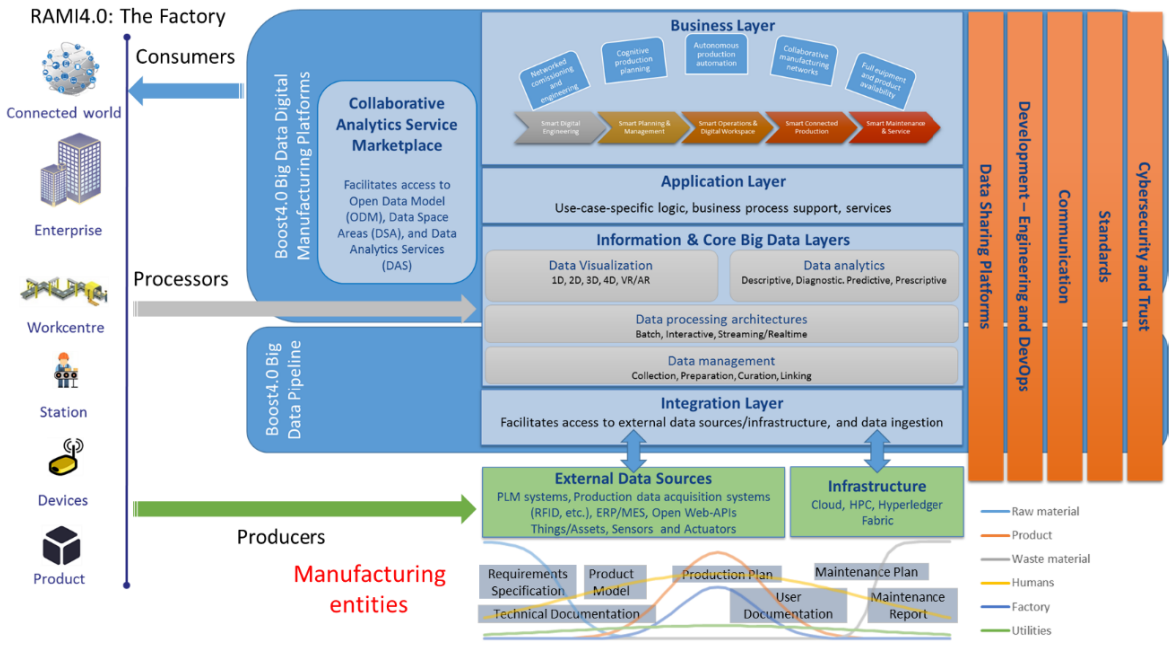


Figure 5-9: Boost 4.0 Universal Big Data Reference Architecture 4.0

The generic Boost 4.0 BD-RA is articulated and instantiated with the support of specific platforms, solutions and infrastructures that provide solution to the functionalities identified in the different layers defined in the BD-RA, which underpin the specific developments that will provide solutions to the specific project objectives and for requirements of the different pilots. **The Boost 4.0 RA will be taken into account in the specification of the Eur3ka RA in WP2**

[22] Boost 4.0 - D2.5 – BOOST 4.0 Reference Architecture Specification v1

The most relevant components and outcomes achieved in Boost 4.0 project are:

The European Industrial Data Space (EIDS)

It is a data space based on the IDS Reference Architecture Model (RAM) V3.0[23]. developed by the International Data Spaces (IDS) Association, with the aim to provide full control over data to companies, by coming up with the so-called IDS standard. This standard in addition of providing the technical solution, also provides mechanisms to create trust between the different participants in a data space, both the technical components (connectors, applications, etc.) and the participants are certified according to the IDS standard.

The EIDS has four main characteristics, which are the federated data architecture, allowing data to be non-integrated; no need for a common schema, by making integration at semantic level without affecting domain specific vocabularies; Data is treated as an economic asset increasing its value by sharing it; and the possibility to have ecosystems of data spaces allowing for scalability to have pools of cross-domain data.

The IDS Reference Architecture Model defines how existing technologies must be orchestrated to create data spaces that deliver data sovereignty via a trusted environment to its participants. For this there are some essential components that ensure interoperability and a trustworthy data exchange:

- **The Connector**, which is a dedicated communication server for sending and receiving data in compliance with the general Connector specification; There are different types of Connectors (Base Connector vs. Trusted Connector, or Internal Connector vs. External Connector).
- **DAPS** (Dynamic Attribute Provisioning Service), which issues Dynamic Attribute Tokens (DATs) to verify dynamic attributes of Participants or Connectors.
- The **Certificate Authority** (CA), a trusted entity issuing digital certificates (X.509 certificates); may host services to validate certificates issued.

The IDS Reference Architecture Model also defines optional roles in order to make the data space more effective for discovering data endpoints, app search and more. These are: The Vocabulary Provider, the Metadata Broker, the App store and the Clearing House.

The EIDS has implemented and uses the following components:

FIWARE EIDS CIM REST Connector

This component is in charge for providing REST APIs to allow access to the Industrial Data Space and it can be implemented with the FIWARE Context Broker providing the NGSI interface based on the NGSI-LD standard, covering the concepts of linked data and the semantic web. This connector allows participants in the Industrial Data Space to provide, consume, and subscribe to context information in multiple scenarios and involving multiple

[23] https://www.internationaldataspaces.org/wp-content/uploads/2019/03/IDS-Reference-Architecture-Model-3.0.pdf

stakeholders. Hence, the component offers an easy and seamless interoperability within the IDS when uses the FIWARE Smart Data Models.

Semantics: QIF Ontology

It is a standardized feature-based ontology of manufacturing metadata, built on XML technology, with the foundational requirement of maintaining traceability of all metadata to the product and all its components as defined in CAD/MBD. Then, QIF is a highly organized grammar and vocabulary for software systems to communicate manufacturing data structures.

The software vocabulary and grammar of QIF is defined by the QIF XML Schema Definition Language (XSDL) schemas.

Certification Authority

Data security and data sovereignty are the fundamental value propositions of the EIDS. Any organization or individual seeking permission to access the EIDS must certify the core components, like connectors, to securely exchange data with any other party which is part of the data space. The Certification Authority is in charge to certify that the EIDS core components provide the required functionality and an appropriate level of security. For this purpose, the IDS certification scheme defines three security profiles for the core components. From lowest to highest security requirements, there are: The Base Security Profile, the Trust Security Profile and the Trust+ Security Profile.

Applications and Platforms provided by the EIDS

This is a list of the applications/components offered by the EIDS.

- **RISC Data Analysis Platform for the Optimization of Flexible Machines Manufacturing:** This component is a combination of BD technologies and Semantics to process and store data. It is based on cluster computing and data analytics services.
- **ESI Hybrid Twin for Zero Defect Production:** Cloud platform dedicated to simulation solutions. Provides 3D remote visualizations and a vertical application framework.
- **Interactive Analytics for Smart injection Moulding:** This component provides a live monitoring of machine's behaviour. Graphical interface for mapping data with concepts of a generic data model. Also, it could be used for outliers detection.
- **ESI Platform for Cognitive Value Chain:** This component offers Big Data and visualization analytics. Use of ontology for the extraction of reliable training datasets for predictive maintenance.
- **Visual Components 4.0 and UNINOVA Analytics for inventory Optimization and Dynamic Production Planning:** This solution is a DB infrastructure for data management, storage and processing, offering visualisation services based on Grafana.

It also provides Data aggregation into a 3D Digital Twin exploiting the Connection with Visual Components Simulation Software.

- **Siemens Mindsphere Extensions for 3rd Parties:** This solution is a Cloud-based IoT platform for DB management and analysis with applications in various domains.
- **IBM Blockchain Application Platform for Industry 4.0:** This is a Blockchain based application for enabling traceability and fully visibility of transaction data related to the production of fabrics.
- **CERTH Cognitive Analytics Platform for Industry 4.0:** This is an EIDS compatible Cloud platform for BD analytics and advanced visualization. Offers real time models retraining and ensemble methods for predictive maintenance.
- **SAS Analytics Platform for Production Planning:** It is a powerful analytics platform with plenty of real-world applications and provides support of extensions through web services.
- **ATLANTIS DSS and Fraunhofer IEM analytics for Predictive Maintenance:** Complete solution EIDS compatible that provides data analytics services alongside with decision support mechanisms.
- **TRIMEK M3 Platform for Zero Defect Manufacturing:** A Metrology platform that provides BD analysis and visualizations for scanning processes.
- **I2CAT IoT Real Time Location System:** This is an IoT location monitoring system compatible with EIDS with high precision (1-2 cms).

5.1.3 Semantic Interoperability Frameworks

Semantic interoperability enables that computer systems manage/exchange data with common understanding by explicit and distributed meaning. As Industry 4.0 has been highlighted, it happens very often that manufacturing companies must consider data federation between various data sources. For instance, one of the pilots in Boost 4.0 is dealing with predictive maintenance. This pilot is exploiting not only machine operation data but also quality measurement data. However, the owner of machine operation data is different from the owner of quality measurement data, and each sort of data has its data format. To overcome this challenge, semantic interoperability is a priority requirement to enable data federation. It is accomplished by linking each data element to an ontology which provides the capability of machine interpretation with logic by shared vocabulary.

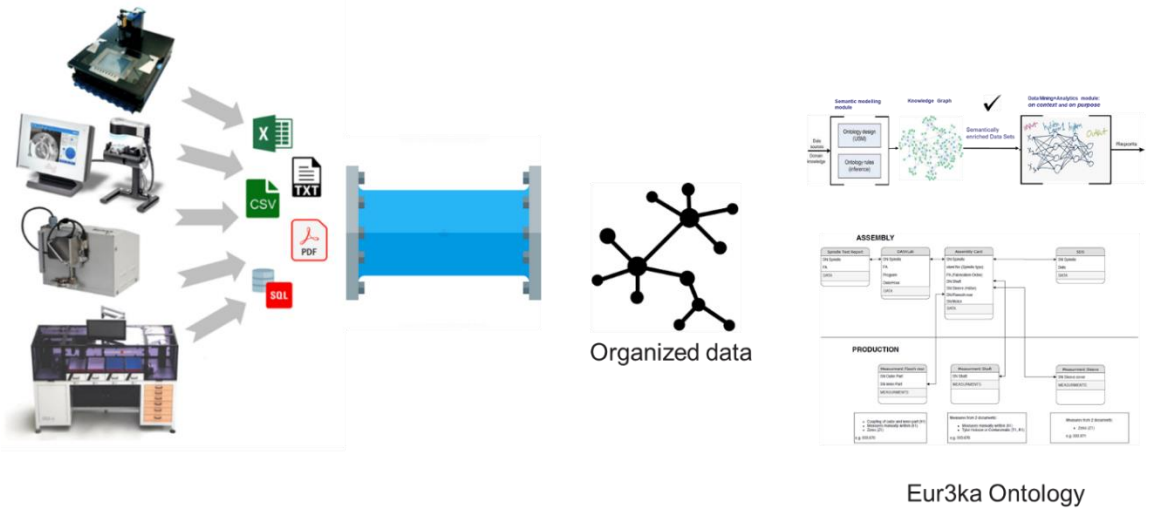


Figure 5-10: Semantic Interoperability Framework

Ontologies and their development have been highlighted for the last 20 years where ontology development has become an engineering discipline called “Ontology Engineering”. An ontology is defined as an “explicit, formal specification of a shared conceptualization of a domain of interest”. Ontologies can be meant to be machine-understandable meta-models which define the different kinds of concepts (classes) of a domain and their relations (object/data properties), which are based on the consensus knowledge across the members of the domain.

An ontology model, therefore, consists of primitive components which are concept, individual, relation, function, and axioms. There are a lot of languages for ontology representation such as KIF, OKBC, XML, RDF(S), XML-based languages: XOL, OIL, DAML+OIL, and Protégé and OntoEdit are well known as ontology management tools [56]. An ontology represents the following ideas together:

Semantic modelling can help to define the data and the relationships between entities.

- An information model provides the ability to abstract different kind of data and provides an understanding of how the data elements are related.
- A semantic model is a type of information model that supports the modelling of entities and their relationships.
- The total set of entities in our semantic model comprises the taxonomy of classes we use in our model to represent the real world.

According to World Wide Web Consortium (W3C), the semantic web is defined as a web that provides a common framework that allows data to be shared and reused across applications, enterprises, and community boundaries. The semantic web consists of the ontology frame that semantically integrates Internet information and enables a machine to reason and create new information through reading and understanding existing information. “Ontology Engineering is the set of activities that concern the ontology development process and the ontology lifecycle, the methods, and methodologies for building ontologies, and the tool suites and languages that support them. The ontology engineering is a general term for methodologies and methods for building ontologies. The main objective of ontology engineering has been to provide a basis for building models of all things in which computer

science is interested. The result of ontology engineering allows domain knowledge to be reused efficiently, and solving the problems from non-shared knowledge, prevents unnecessary waste of time and money, which is usually repeated. It will help Information System (IT) to operate with interoperability and standardization.

To exploit enabling technologies efficiently, businesses need to design a common data format and protocol which enables that computer systems manage/exchange data with common understanding by explicit and distributed meaning. With the increasing complexity of modern systems, manufacturing companies have industrial problems which are described as various industrial domains, and each domain has its own system with relevant data. However, various systems are not capable of communicating with each other if they use common data formats and protocols. To overcome this challenge, interoperability is a priority requirement to enable data federation, and especially, semantic interoperability as syntactic interoperability provides a common understanding for both machines and humans. It is accomplished by linking each data element to an ontology which provides the capability of machine interpretation with logic by shared vocabulary.

The ontologies are key tools to enrich semantic interoperability for effective knowledge sharing in development, deployment. Accordingly, IOF (Industry Ontology Foundry) was established, aiming at technical goals: 1) Creating a suite of open and principles-based ontologies, from which other domain dependent or application ontologies can be derived in a modular fashion, remaining 'generic' (i.e., non-proprietary, non-implementation specific) so they can be reused in any number of industrial domains or manufacturing specializations. 2) Providing principles and best practices by which quality ontologies can be developed that will support interoperability for industrial domains. 3) Instituting a governance mechanism to maintain and promulgate the goals and principles, and 4) Providing an organizational framework and governance processes that ensure conformance to principles and best practices for development, sharing, maintenance, evolution, and documentation of IOF ontologies.

IOF is a community of industry, academia, and research institutes. Its aim is to produce open-access ontologies for the manufacturing domain. In the current charter of IOF, its notional architecture that outlines different types of ontologies it will produce and curate is shown in Figure 5-11. In this architecture, five types of ontologies are indicated including 1) Foundation Ontology (FO); 2) Domain Independent Reference Ontologies (DIROs); 3) Domain Specific Reference Ontologies (DSROs); 4) Domain Dependent Ontologies (DDOs); and 5) Application Ontologies (AOs). The IOF intends to produce and curate the first three types. The division of ontologies into top-, middle and lower-levels is a division along the axis of generality – the content of top-level ontologies is *more general* than that of the ontologies at lower levels. This happens to foster interoperability, we re-use as much as possible IOF and other published ontologies.

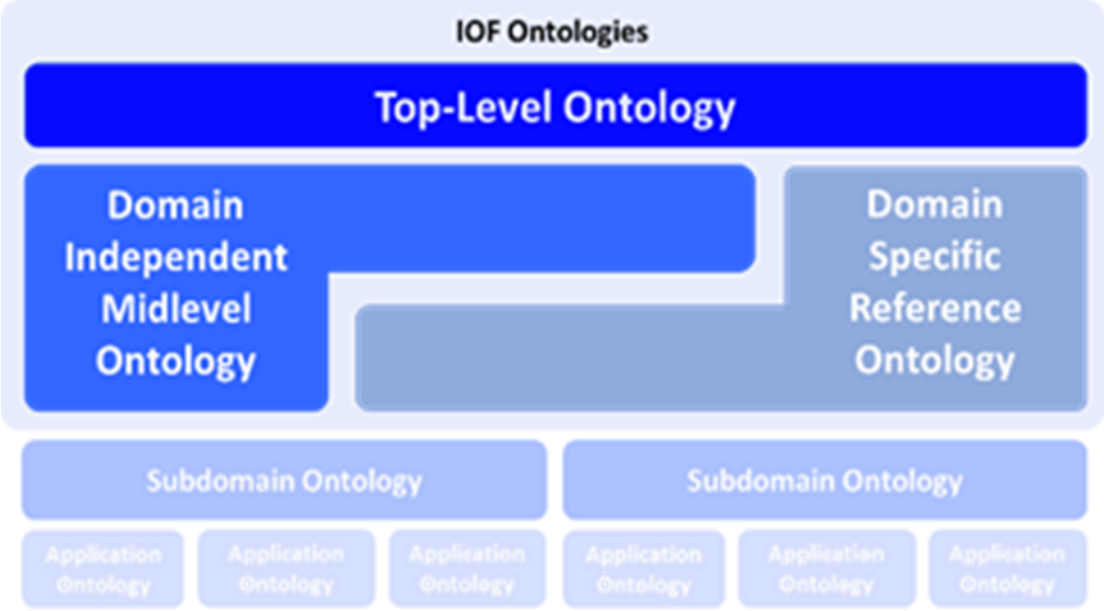


Figure 5-11: IoF Framework

Ontology population is the process of creating instances of an ontology that will stand for the various data sources it intends to describe and collect data from. This process is intended to receive and ontology and a list of data sources as inputs and link those data sources to the elements of the ontology. This is done by extracting, for each data source, which class in the ontology it corresponds to, and create an instance of that class that will represent this data source, that will consist of the class name and a unique identifier.

This process is an important preparatory work to be able to use the ontology to express data that will be collected from these data sources, and more specifically stored in a database. Combined with graph data, ontologies help express data in terms of entities and their relationships. It is possible to express the relationships between different entities as well as the relationship between an entity and a piece of information. Data will be expressed in the form of triples subject – predicate – object, and stored in a specific type of database called a triple store. The subject is the instance of a class, the predicate a relationship, and the object is either another instance of a class, or a literal value. Triples are expressed with the Resource Description Framework (RDF), a language that helps express data models with metadata. The instances and relationships are expressed with URIs (Unique Resource Identifier), which are the concatenation of the ontology's URI, the name of the class or the relationship, and in the case of instances, a unique id.

5.2 Specifications for Customization and Use in Eur3ka – Eur3ka Services

5.2.1 Eur3ka Digital Lean Quality Management Framework

As it has been commented previously on section 5.1.1, all the quality control software tools that are getting adapted to the nowadays manufacturing PLM requirements, still need to open their suitability in order to facilitate the PLM traceability in scenarios were a joint

collaboration between different partners is required. It is not just about to break silos along the manufacturing lifecycle, it is also necessary to break silos between stakeholders.

During crisis situations such as the current one, all production systems have been faced with the prevailing need to reinvent themselves or adapt based on the need for essential products or the shortage of raw materials. All those who on their own have not found a way to get ahead, have become trapped in, where joint solutions or collaboration plans had been conspicuously absent.

For that reason, Eur3ka is reinforcing the message that all these platforms need to incorporate solutions that allow the secure exchange of data between stakeholders. This is what in Eur3ka is approached through the Plug & Respond repurposing resource coordination framework.

From the Innovalia side, regarding the M3 Platform, through Eur3ka intends to work on both necessities that has been recently described:

1) On one side, M3 Platform intends to be adapted to the new QIF3.0 standard (ISO 23952:2020) requirements. QIF consists of an integrated set of information models for effective exchange of metrology data through the entire manufacturing product-quality lifecycle (product design, inspection, planning, execution, analysis and reporting) but also to use it throughout the PLM/PDM domain, supporting seamless exchange and sharing of metrology data across the manufacturing process. The main application area to be adapted is related to the measurement results area.

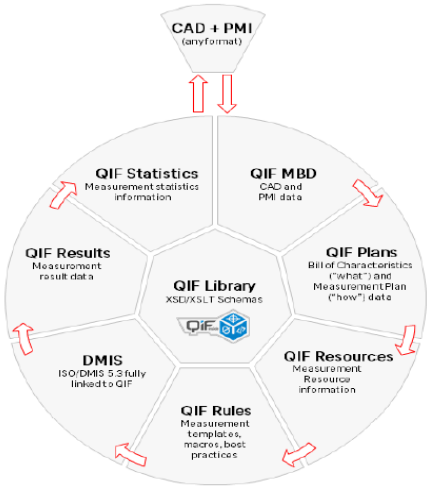


Figure 5-12: QIF entire model lifecycle

2) On the other side, M3 Platform intends to adapt the M3 Workspace to the current needs to allow the secure exchange of data with the platform customers, in order to have the chance to share with them part designs (from the customers) and quality control part dimensional analysis (from Innovalia). Currently, M3Workspace, consists of a metrological data platform oriented to customer management, which offers a wealth of information about Innovalia's metrology software (M3), such as tutorials focused on the interface handling, user queries or license management, among others. For this purpose, M3Workspace enables the extension of a network of contacts and allows access to different types of information, such as online webinars, guides and technical manuals for customers. With the

adaptation of this new functionality, M3 Workspace intends to provide a a customer-manufacturer collaborative space for sharing metrology data in a secure way during the manufacturing process, allowing the correct management and monitoring of the quality control process. Available data from different heterogeneous products, metrological sources and different locations will be integrated, managed, and stored in the M3 Workspace so as to be able to have access, conduct advanced data visualization and correlation. This secure data exchange will be carried out between the M3 IDS connector and the customer IDS connector.

Figure 5-13: M3 Workspace interface.

Table 5-1 provides the detailed specifications of the M3 workspace interface to be developed in Eur3ka.

Functional Overview: **Within Eur3ka, M3 Workspace intends to provide a customer-manufacturer collaborative space for sharing metrology data in a secure way during the manufacturing process, allowing the correct management and monitoring of the quality control process. This data exchange is carried out through the M3 IDS Connector integrated in M3 Workspace.**
Main Inputs: **M3 Workspace intends to be the secure shared space between Innovalia and their customers. It gathers customer product designs (CAD files [STEP, STL] with PMI information) or process manufacturing data (XML).**
Produced Outputs: **M3 Workspace is one of the components that compound the M3 platform, the metrological high-performance software owned by Innovalia whose greater functionality is for the capture and analysis of automatic scanning point clouds of various types of parts, for the reliable and efficient acquisition of 3D information about their dimensions, thus allowing advanced control dimensional quality.** **The dimensional analysis results can be formatted into an [XML or CSV file] but considering M3 Workspace as the main channel to securely exchange these results with Innovalia customers, this will be done through the IDS connector with [XML, JSON] formats considering the usage of the FIWARE OCB as the broker for the exchange.**
Security Mechanisms: **The data exchange is done through the M3 IDS connector, which includes a security mechanism following the DIN spec 27070 and ISO 62443-3 standards, based on an Authentication, Authorisation and Accounting (AAA) technology.**

Use of Containers: **The M3 IDS Connector can be started as a standalone application within a Docker container.**
Components Licensing**: M3 Workspace and the M3 IDS connector are components from the M3 Platform, a proprietary software owned by Innovalia.**

Table 5-1: Specifications of M3 Workspace – M3 IDS Connector

5.2.2 ZDM Platforms

Eur3ka will create a service for re-purposing manufacturing systems for producing products that are in high unexpected demand but with limited time to plan. Therefore, when a product is required to be produced using the Eur3ka service the ZDM design software will analyse the product and the available production sites and suggest the most efficient quality assurance plan for achieving the required KPIs and at the same time approach ZDM. The required input from the software is simple to ease its use by the manufacturers. It composed from the Bill of processes of the product under investigation and the characteristics of the manufacturing system. These characteristics concerns the machines involved in the production with their corresponding specification such as operational cost, energy consumption etc. Further to that, another input is the desired KPIs, manufacturers can select which KPIs wants to include in the analysis from a list of available KPIs from the ZDM oriented simulation package.

There are two different ways that manufacturers can utilize the results of the ZDM design software. The first is when a manufacturer wants to establish a product quality improvement process at certain manufacturing stages and asks several third parties to provide a solution for the problem that the manufacturer faces or when the manufacturer estimates that will phase quality issues, if the production is at the design stage. When the manufacturer has all potential solutions, they can evaluate them using the ZDM performance maps (which are produced by the software, for the specific case) and select the best solution between the available. The second way to use the results works the other way around. Based on the produced performance maps, the manufacturer selects a range of ZDM parameter combinations, where the performance of the manufacturing systems is at an acceptable level, and then asks a third party to provide a solution with those specifications. This approach entails the danger that the manufacturer might select parameter ranges that are impossible to implement. By using those graphs, manufacturers can easily evaluate and rank alternative solutions for implementing ZDM into their manufacturing systems. Furthermore, the evaluation process is significantly faster, and the results are repeatable and independent of the expertise of a single expert worker.

Table 5-2 provides the initial specifications of the Eureka ZDMap for new product design.

Functional Overview**: ZDMap software will be used in Eur3ka project when there is the need of a new product. ZDMap is capable of suggesting the most optimum quality control plan in order to achieve efficient Zero Defect Manufacturing. The suggestions of the software can also be used for re-purposing or investing if it is required, to quality control and assurance equipment in order to achieve the desired KPIs.**
Main Implementation Technologies**: Matlab (legacy version), Python (working edition)**

Main Inputs: **Since the data required by the software to operate are not many, in order to be practical for manufacturers to use Excel sheets are used, but they can be modified to fit project needs if there is the capability.**
Sample Inputs: Briefly the required input can be summarised below: (i) Product Bill of Materials; (ii) Product Bill of processes; (iii) Shop-floor details and layout; (iv) Estimated demand profile and orders characteristics such as average due date; (v) Estimated defect profile at certain manufacturing stages that is known (optional).
Produced Outputs: **The output of the ZDMap software is a set of graphs where manufacturers can use them for comparing alternative quality oriented equipment that third parties have proposed or in-house department proposed. Or they can use the suggested quality equipment specifications and ask a third party or the in-house quality department for equipment with the requested characteristics.**
APIs Information: **The software does not offer any API. APIs implementation will be considered as part of the Eur3ka implementation/customization.**
Security Mechanisms: **Currently, no security is implemented, since the software is running on a local machine at manufacture's site therefore it does not require security at this point since manufacturer does not expose his data.**
Use of Containers: **The software will run locally at the manufacturer site.**
Components Licensing: **Proprietary.**

Table 5-2: Specifications of ZDMap

In the scope of the Eur3ka pilots, the project will also implement quality testing techniques for PPE and CCE products. An example for PPE FF masks in the SEAC factory is provided in Table 5-3.

Functional Overview: **Seac, as a Pilot, will put at disposal of Eur3ka project the Quality Control tests, using its two testing machines: Ansti machine – CO2 testing machine. STAM will then cooperate in this pilot to set up an integrated and automated system to put together the relevant data from the test machines and exchange useful data with the Eur3ka platform.**
Main Inputs: **From the pilot point of view (SEAC), the inputs are the test they perform during the Quality Control procedures expressed in numbers and percentage; the measured values of these parameters are input for STAM's integration module. Referring to the required format, they weren't defined so far, but most probably csv or JSON format (according to the operations to be done later) will be OK.**
Produced Outputs: **At the time being, the output of SEAC's testing machines are a test report in pdf format. The aim of STAM cooperation is developing a system allowing the two machines to create one test report with data coming from both of them and send it to the Eur3ka platform. This test report will be given in a certain data format, according to the standard that will be decided at a project level.**
Deployment Architecture: **The "Local Integration System at pilot level" is our digital solution. It will be a software system to automatically collect data from testing and give them into a centralized Data Layer. This can be replicated on the other pilots, if needed. On the other hand, the test machines could be set up automatically with their thresholds according to some known parameters and information coming from the platform (e.g.: size of the mask, adult Vs child or other, certification**

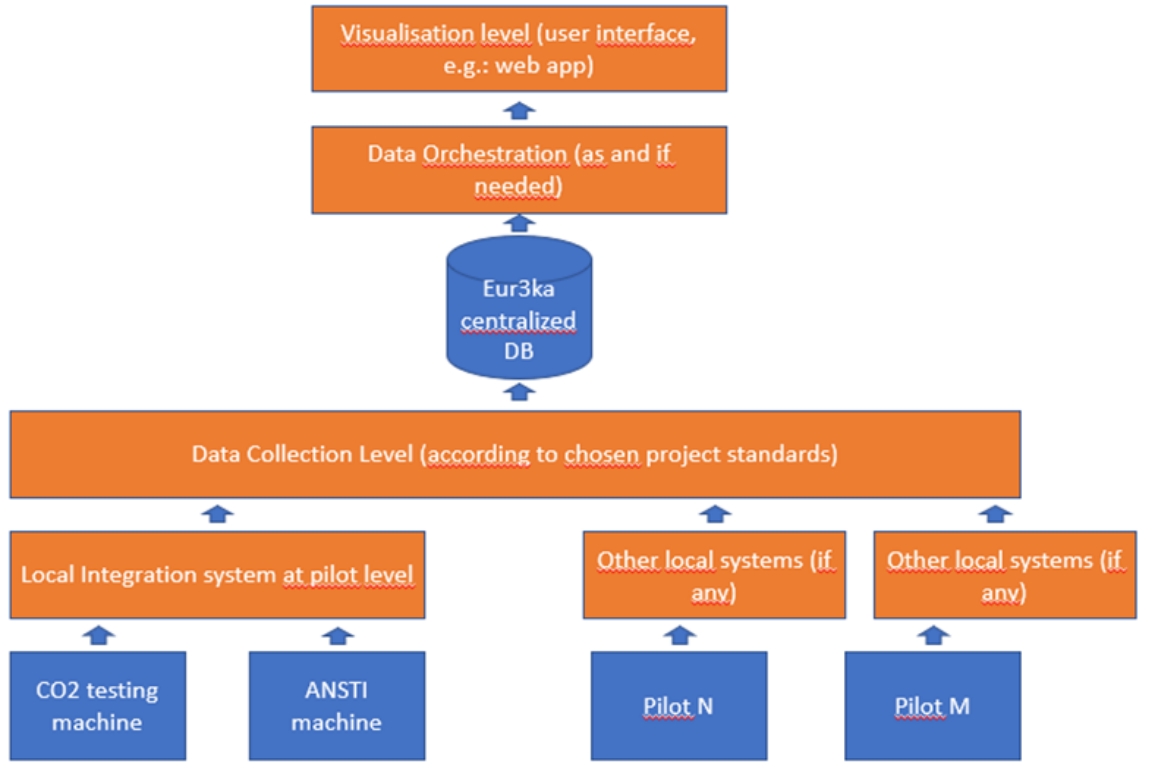
requirements, etc). This information should be available in a special Knowledge-Base that will be designed in the pilot and integrated in its Data Layer.

Components Licensing: **SEAC is currently running a proprietary software.**

Table 5-3: Specifications of Automation and Integration of Quality Tests for PPE FF Masks

5.2.3 Semantic Interoperability Frameworks

The development of the Eur3ka semantic interoperability framework is currently under development based on the following process:

1. Analyze and understand the product and domain of Eur3ka project.
2. Ontology needs to be understood and appreciated, but it should be properly grounded with an appropriate structure to avoid cross-pollination of terminologies.
3. The challenge is not in building various information technologies but to develop a common representation within Eur3ka domain.
4. Semantics for each term should be defined properly to avoid ambiguity between stakeholders (researchers and industries).
5. Eur3ka ontology should be intuitive so that it could be easily and appropriately implemented in industries.
6. Exclusiveness and exhaustiveness of the Eur3ka ontology will evolve over time.

Eur3ka ontology should be designed using BFO (Basic Formal Ontology)[24] as an upper ontology providing communication capability across various industrial domains such as maintenance, Supply Chain Management (SCM), and Production Planning and Scheduling

[24] https://basic-formal-ontology.org/

(PPS). BFO has been strongly validated as a part of ICE/ISO CD 21838-2 Information technology and it provides strong philosophical fundamentals.

Ontology design principles

1. use single nouns (except data) and avoid acronyms (except PPS and KPI).
2. ensure univocity of terms and relational expressions.
3. distinguish the general from particular.
4. provide all non-root terms with definitions.
5. use essential features in defining terms and avoid circularity.
6. start with the most general terms in the domain.
7. use simpler terms than the term you are defining (to ensure intelligibility)
8. do not create terms for universals through a logical combination.
9. structure ontology around iss_a hierarchy and ensure is_a completeness.
10. single inheritance.

Eur3ka ontology will share several classes with other ontologies relevant for manufacturing, such as Product, Service, Company, Resources, etc. Therefore, the objective will be not to further elaborate such generic classes in the manufacturing domain but to indicate those that of relevance for the scope of Eur3ka project in the manufacturing industry. These classes serve as 'interfaces' to other ontologies and will need to be harmonized with these ontologies under the scope of IOF.

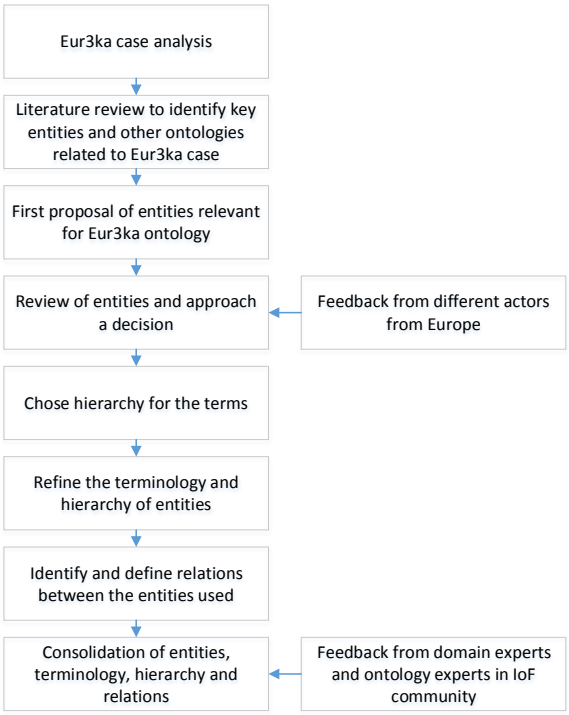


Figure 5-14: Ontology Development Workflows

6 Equipment Specification and Certification Framework

Eur3ka Resilient and Reliable Repurposing Manufacturing network envisions a fast and effective provision of PPE and CCE products to ensure short term preparedness for COVID19 specifically but also for future pandemic demands. To achieve a resilient and zero-defect setting across the five identified manufacturing repurposing assets, to have a highly certificated environment is exhorted.

The five manufacturing repurposed assets of Eur3ka (Built for Repurposing Manufacturing Equipment; Manufacturing as a Service Platform; Manufacturing Repurposed Data Space; Plug & Respond Factory Network; Digital Lean Production Continuity) are certifiable under the concept of 'Assets', which can take the form of: Sites, Manufacturing Equipment, Processes and Management Systems.

Thereby, the Eur3ka Certification Framework envisages a set of regulations and mandatory standards of necessary compliance for each of the 'Assets'. The aggregated certified 'Assets' will be used to provide a regulated product of warranted conformity to the European Market.

Certification provides a warranty of conformance for products, being mandatory to certify a product prior to introducing a new one in the market. This document provides a set of standards, regulations, and requirements that new products must meet so they can pass the certification process.

In this context, the following paragraphs of these section provide:

- A set of regulations and mandatory and optional standards focused on medical devices, in vitro diagnostic products, and personal protection equipment (PPE) products.
- Main requirements from regulation/standards to perform the certification process.

Requirements and regulations are provided at different levels, in including:

- Sites (e.g.: material incoming, delivery, manufacturing, packaging).
- Manufacturing equipment.
- Management systems.
- Products.

6.1 Applicable Standards and Regulations

6.1.1 Sites standards

Mandatory and optional (but highly advised) standards are listed in this section.

6.1.1.1 Mandatory

The following table displays mandatory standards that need to be met to have the medical devices certified. These standards are applicable in manufacturing processes at different abstraction levels.

Standard	Description
ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes
ISO 27001:2017	Information technology - Security techniques - Information security management systems - Requirements
GMP	Good manufacturing practices
21 CFR 820	FDA Regulation for medical devices: Quality System Regulations
21 CFR Part 11	FDA Regulation for medical devices: Electronic Records
Premarket 510(k)	FDA Regulation for medical devices: Guidance Documents for Premarket Notification by the FDA that Benefit Both FDA Reviewers and Device Sponsors
	FDA Regulation for medical devices: Data integrity and compliance with drug CGMP

6.1.1.2 No mandatory – guidelines

The following table list a set of standards that are optional, but are highly advised, as they can guide manufacturing processes:

Standard	Description
ISO/TC39/SC4 and SC5	Industrial automation systems and integration; Product Interoperability, integration, and architectures for enterprise systems and automation applications, development of many standards including ISO 20140 series of standards
ISO/DIS 22400-2	Automation systems and integration – Key performance indicators (KPIs) for manufacturing operations management: It is currently under development, and will include energy related KPIs
IEC 62264 / ISA 95	Standard that defines operations management in manufacturing plants. Its full name is “Enterprise-control system integration”
IEC 60812	Analysis for system reliability – Procedure for FMEA
ISO/ASTM 52901:2017 [ASTM F 42]	Additive manufacturing — General principles — Requirements for purchased AM parts

6.1.1.3 Working groups

The following table shows a list of groups that are working in the different subjects to create new standards.

Working groups	Description
ISO/IEC JTC 1 SC 42	Artificial intelligence
	Digital Twins: Automation systems and integrations - Digital Twin framework for manufacturing.
ISO/DIS 23247	The ISO 23247 defines a framework to support the creation of Digital Twins of observable manufacturing elements including personnel, equipment, materials, manufacturing processes, facilities, environment, products, and supporting documents.
ISO/TC 307	Blockchain and distributed ledger technologies
ISO/TC 184	Automation systems and integration

Working groups	Description
ISO/IEC JTC 1 SC 42	Artificial intelligence Digital Twins: Automation systems and integrations - Digital Twin framework for manufacturing.
ISO/DIS 23247	The ISO 23247 defines a framework to support the creation of Digital Twins of observable manufacturing elements including personnel, equipment, materials, manufacturing processes, facilities, environment, products, and supporting documents.
	Standardization in the field of automation systems and their integration for design, sourcing, manufacturing, production and delivery, support, maintenance and disposal of products and their associated services. Areas of standardization include information systems, automation and control systems and integration technologies. Industrial-process, measurement, control and automation
IEC/TC 65	To prepare international standards for systems and elements used for industrial process measurement, control and automation. To coordinate standardization activities which affect integration of components and functions into such systems including safety and security aspects. This work of standardization is to be carried out in the international fields for equipment and systems.
ISO/IEC JTC 1	Information technology
IEC/SyC	System Committee Smart Manufacturing

6.1.2 Equipment standards and regulation

The following table gather a set of standards necessary for manufacturing equipment certification. In Europe, medical product certification does not require to have the manufacturing equipment certified.

Standard /regulation	Description	Scope
Directive 2006/42/EC	Machinery Directive	machines
Directive 2014/30/EC	Electromagnetic Compatibility	machines, 3D printers
Directive 2012/19/EU	Waste electrical and electronic equipment (WEEE)	machines, 3D printers
Directive 2011/65/EU and 2017/2102	Hazardous substances in electrical and electronic equipment (RoHS II)	machines, 3D printers
EN ISO 13855: 2010	Safety of machinery - Positioning of safeguards with respect to the approach speeds of parts of the human body	machines
EN ISO 13857: 2008	Safety of machinery - Safety distances to prevent hazard zones being reached by upper and lower	machines
EN ISO 13849: 2008/AC:2009	Safety of machinery - Safety-related parts of control systems	Machines, 3D printers
EN ISO 14119: 2013	Safety of machinery - Interlocking devices associated with guards - Principles for design and selection	machines
EN ISO 4414: 2010	Pneumatic fluid power - General rules and safety requirements for systems and their components	machines
EN ISO 12100: 2010	Safety of machinery — Basic concepts, general principles for design — Risk assessment and risk reduction	Machines, 3D printers

Standard /regulation	Description	Scope
EN 614: 2006+A1:2009	Safety of machinery – Ergonomic design principles	machines
EN 60204: 2006/ AC: 2010	Safety of machinery - Electrical equipment of machines	Machines, 3D printers
EN 1037: 1995:+A1:2008	Safety of machinery – Prevention of unexpected start-up	machines
EN 61496: 2015	Safety of machinery - Non-contact protective devices	machines
EN ISO 13850: 2008	Safety of machinery. Emergency stop. Principles for design	Machines, 3D printers
ISO 14120: 2002	Safety of machinery - Guards - General requirements for the design and construction of fixed and movable guards	machines
OPC, OPC-UA, UMCM, IEC 62714, IEC 62264	Various communication protocols & standards	machines
DIN 27070	Communication architecture: control on data access and data usage (IDS)	machines
IEC 62368-1:2020	Hazard based safety standard	machines
EN ISO 10218: 2011	Robots for industrial environments - Safety requirements	robots
ISO TS 15066: 2016	Robots and robotic devices - Collaborative Robots	robots
EN ISO 11553	Safety of machinery - Laser processing machines	Laser machines
EN 60825	Safety of laser products	Laser machines

Standard /regulation	Description	Scope
EN 1127	Explosive atmospheres – Explosion prevention and protection	3D printers
EN ISO 19353	Safety of machinery – Fire prevention and fire protection	3D printers

6.1.3 Management systems standards

Software systems used for manufacturing management (for example, an ERP) must meet the following standards:

Standard	Description
ISO/IEC 27032:2012	Information technology — Security techniques — Guidelines for cybersecurity
-	FDA Regulation for medical devices: General principles of software validation; Final guidance for Industry and FDA staff
-	FDA Regulation for medical devices: Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software
21 CFR 10.115	FDA Regulation for medical devices: Off-The Shelf Software Use in medical devices
Premarket 510(k)	FDA Regulation for medical devices: Guidance Documents for Premarket Notification by the FDA that Benefit Both FDA Reviewers and Device Sponsors
DIN 27070	Communication architecture: control on data access and data usage (ids)

6.1.4 Product standards and regulation

6.1.4.1 Product specific standards

In the following table products have been grouped in 3 subsets according to the manufacturing complexity level, being 1 the easiest one. Also, the mandatory standards to be met in the product manufacturing process have been listed. To finish, the product type has been specified as well.

Manufacturing complexity level	Product	Standard	Type
1	Medical gloves	**EN 455-1:2000** Medical gloves for single use - Part 1: Requirements and testing for freedom from holes (MDD) **EN 455-2:2015** Medical gloves for single use - Part 2: Requirements and testing for physical properties (MMD) **EN 455-3:2015** Medical gloves for single use - Part 3: Requirements and testing for biological evaluation (MDD) **EN 455-4:2009** EN Medical gloves for single use - Part 4: Requirements and testing for shelf life determination (MDD) **EN ISO 374-5:2017** Protective gloves against dangerous chemicals and micro-organisms - Part 5: Terminology and performance requirements for micro-organisms risks	Protective personal equipment (PPE)
	Protective clothing	**EN 14126:2003** Protective clothing - Performance requirements and tests methods for protective clothing against infective agents **EN 14605:2009** Protective clothing against liquid chemicals - performance requirements for clothing with liquid-tight (Type 3) or spray-tight (Type 4) connections, including items providing protection to parts of the body only	Protective personal equipment (PPE)

Manufacturing complexity level	Product	Standard	Type
		EN 13795-1:2019 Surgical clothing and drapes - Requirements and test methods - Part 1: Surgical drapes and gowns **EN 13795-2:2019** Surgical drapes, gowns and clean air suits, used as medical devices for patients, clinical staff and equipment - Part 2: Test methods **EN ISO 13688:2013** Protective clothing - General requirements	
	Personal eye-protection	**EN 166:2001** Personal eye-protection – Specifications	Protective personal equipment (PPE)
	Surgical mask	**EN 14683:2019+AC:2019** Medical face masks - Requirements and test methods	Medical device
	PPE mask. Ex. FFP2 in Europe	**EN-149** Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking **EN 132** **EN 134** **EN 143** **EN 13274-7**	Protective personal equipment (PPE)

Manufacturing complexity level	Product	Standard	Type
		ISO 6941	
	Disinfectants	**EN 14476:2014 + A1:2015** Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of virucidal activity in the medical area - Test method and requirements	Biocidal products
2	RT-PCR kit (Diagnostic equipment)	**EN 14254:2004** In vitro diagnostic medical devices - Single-use receptacles for the collection of specimens, other than blood, from humans	Medical device - in vitro
3	Ventilator patient	**EN ISO 60601-2-12** Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance, **EN ISO 80601-1** Medical electrical equipment - Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators, **EN 794-3** Lung ventilators - Part 3: Particular requirements for emergency and transport ventilators **EN ISO 17510-1:2009** Sleep apnoea breathing therapy - Part 1: Sleep apnoea breathing therapy equipment (ISO 17510-1:2007) **EN ISO 17510-2:2009** Sleep apnoea breathing therapy - Part 2: Masks and application accessories (ISO 17510-2:2007) **EN 12342:1998+A1:2009** Breathing tubes intended for use with anaesthetic apparatus and ventilators	Medical device

Manufacturing complexity level	Product	Standard	Type
		EN ISO 8835-3:2009 Inhalational anaesthesia systems - Part 3: Transfer and receiving systems of active anaesthetic gas scavenging systems (ISO 8835-3:2007) EN ISO 8835-3:2009/A1:201 **EN ISO 5366-1:2009** Anaesthetic and respiratory equipment - Tracheostomy tubes - Part 1: Tubes and connectors for use in adults (ISO 5366-1:2000) **EN ISO 7376:2009** Anaesthetic and respiratory equipment - Laryngoscopes for tracheal intubation (ISO 7376:2009) **EN 13544-1:2007+A1:2009** Respiratory therapy equipment - Part 1: Nebulizing systems and their component **EN 13544-2:2002+A1:2009** Respiratory therapy equipment - Part 2: Tubing and connectors	

6.1.4.2 Product type specific standards and regulations

In the following table, the relevant European regulation for each product type is listed. The table also includes a link to the harmonised standards lists, and also the general standards to be met by each product type.

Product type	European directive / regulation	Harmonised standards	General standards
Protective personal equipment (PPE)	Regulation (EU) 2016/425	Harmonised standards for personal protective equipment	-
Biocidal products	Regulation (EU) 528/2012	Not found	-

Product type	European directive / regulation	Harmonised standards	General standards
Medical device - in vitro	Regulation (EU) 2017/746	harmonised standards for in vitro diagnostic medical devices	**ISO62304** - Medical device software — Software life cycle processes
Medical device	Directive 93/42/EEC	harmonised standards for medical devices	**ISO14971** - Medical devices - Application of risk management to medical devices **FDA Regulation for medical devices:** - Applying Human Factors and Usability Engineering to Optimize Medical Device Design - Class II Special Controls Guidance Document for Pharmacy Compounding Systems; Final Guidance for Industry and FDA - Establishment Registration and Medical Device Listing (21 CFR Part 807) - General principles of software validation; Final guidance for Industry and FDA staff **EN ISO 10993:2009** Biological evaluation of medical devices

6.2 Applicable requirements

In this subchapter, a list of general requirements has been listed from regulations/standards documents.

6.2.1 Site Certification requirements

6.2.1.1 Quality management system

6.2.1.1.1 ISO 13485

N	Description
1	
2	The organization shall document procedures for the validation of the application of computer software used in the quality management system. Such software applications shall be validated prior to initial use and, as appropriate, after changes to such software or its application.
3	Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled
4	Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience. The organization shall document the process(es) for establishing competence, providing needed training, and ensuring awareness of personnel.
5	Infrastructure The organization shall document the requirements for the infrastructure needed to achieve conformity to product requirements, prevent product mix-up and ensure orderly handling of product. The organization shall document requirements for the maintenance activities, including the interval of performing the maintenance activities, when such maintenance activities, or lack thereof, can affect product quality. As appropriate, the requirements shall apply to equipment used in production, the control of the work environment and monitoring and measurement.
6	Work environment The organization shall document the requirements for the work environment needed to achieve conformity to product requirements.
7	Contamination control As appropriate, the organization shall plan and document arrangements for the control of contaminated or potentially contaminated product in order to prevent contamination of the work environment, personnel, or product. For sterile medical devices, the organization shall document requirements for control of contamination with microorganisms or particulate matter and maintain the required cleanliness during assembly or packaging processes.
8	Planning of product realization: The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system.

N	Description
9	Design and development: The organization shall document procedures for design and development.
10	Purchasing: The organization shall document procedures to ensure that purchased product conforms to specified purchasing information.
11	Production and service provision: Production and service provision shall be planned, carried out, monitored and controlled to ensure that product conforms to specification.
12	Traceability: The organization shall document procedures for traceability. These procedures shall define the extent of traceability in accordance with applicable regulatory requirements and the records to be maintained Control of monitoring and measuring equipment: The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements.

6.2.1.1.2 GMP

N	Description
1	Manufacturing facilities must maintain a clean and hygienic manufacturing area.
2	Manufacturing facilities must maintain controlled environmental conditions in order to prevent cross-contamination from adulterants and allergens that may render the product unsafe for human consumption or use.
3	Manufacturing processes must be clearly defined and controlled. All critical processes are validated to ensure consistency and compliance with specifications.
4	Manufacturing processes must be controlled, and any changes to the process must be evaluated. Changes that affect the quality of the drug are validated as necessary.
5	Instructions and procedures must be written in clear and unambiguous language using good documentation practices.
6	Operators must be trained to carry out and document procedures.
7	Records must be made, manually or electronically, during manufacture that demonstrate that all the steps required by the defined procedures and instructions were in fact taken and that the quantity and quality of the food or drug was as expected. Deviations must be investigated and documented.
8	Records of manufacture (including distribution) that enable the complete history of a batch to be traced must be retained in a comprehensible and accessible form.
9	Any distribution of products must minimize any risk to their quality.
10	A system must be in place for recalling any batch from sale or supply.
11	Complaints about marketed products must be examined, the causes of quality defects must be investigated, and appropriate measures must be taken with respect to the defective products and to prevent recurrence.

6.2.2 Equipment Certification requirements

Some of the specifications included in Directive 2006/42/EC are:

N	Description
1	The machinery manufacturer must perform a risk evaluation. To do that, essential requirements about health and security must be established.
2	Materials and products: The materials used to construct machinery or products used or created during its use must not endanger persons' safety or health. In particular, where fluids are used, machinery must be designed and constructed to prevent risks due to filling, use, recovery or draining.
3	Lighting: Machinery must be supplied with integral lighting suitable for the operations concerned where the absence thereof is likely to cause a risk despite ambient lighting of normal intensity.
4	Design of machinery to facilitate its handling Machinery, or each component part thereof, must: - be capable of being handled and transported safely, - be packaged or designed so that it can be stored safely and without damage.
5	Ergonomics: Under the intended conditions of use, the discomfort, fatigue and physical and psychological stress faced by the operator must be reduced to the minimum possible, taking into account ergonomic principles.
6	Operating positions: The operating position must be designed and constructed in such a way as to avoid any risk due to exhaust gases and/or lack of oxygen.
7	Seating: Where appropriate and where the working conditions so permit, workstations constituting an integral part of the machinery must be designed for the installation of seats.
8	Safety and reliability of control systems: Control systems must be designed and constructed in such a way as to prevent hazardous situations from arising. Above all, they must be designed and constructed in such a way that: — they can withstand the intended operating stresses and external influences, — a fault in the hardware or the software of the control system does not lead to hazardous situations, — errors in the control system logic do not lead to hazardous situations,

N	Description
	— reasonably foreseeable human error during operation does not lead to hazardous situations.
9	Control devices must be: — clearly visible and identifiable, using pictograms where appropriate, — positioned in such a way as to be safely operated without hesitation or loss of time and without ambiguity, — designed in such a way that the movement of the control device is consistent with its effect, — located outside the danger zones, except where necessary for certain control devices such as an emergency stop or a teach pendant, — positioned in such a way that their operation cannot cause additional risk, — designed or protected in such a way that the desired effect, where a hazard is involved, can only be achieved by a deliberate action, — made in such a way as to withstand foreseeable forces; particular attention must be paid to emergency stop devices liable to be subjected to considerable forces.
10	Starting: It must be possible to start machinery only by voluntary actuation of a control device provided for the purpose.
11	Stopping: Normal stop: Machinery must be fitted with a control device whereby the machinery can be brought safely to a complete stop. Operational stop: Where, for operational reasons, a stop control that does not cut off the energy supply to the actuators is required, the stop condition must be monitored and maintained. Emergency stop: Machinery must be fitted with one or more emergency stop devices to enable actual or impending danger to be averted. Some exceptions applied.

6.2.3 Product Certification requirements

6.2.3.1 Personal protection equipment (Level 1 of complexity)

6.2.3.1.1 General requirements

N	Description
1	Ensure the traceability of PPE throughout the whole supply chain.
2	Manufacturers shall ensure that it has been designed and manufactured in accordance with the applicable essential health and safety requirements set out in Annex II
3	EU declaration of conformity: The manufacturer shall draw up a written EU declaration of conformity for a PPE model
4	In order to ensure compliance with the essential health and safety requirements laid down in the Regulation, it is necessary to lay down appropriate **conformity assessment procedures** to be followed by the manufacturer.
5	The **technical documentation** shall include at least the following elements: (a) a complete description of the PPE and of its intended use; (b) an assessment of the risks against which the PPE is intended to protect; (c) a list of the essential health and safety requirements that are applicable to the PPE; (d) design and manufacturing drawings and schemes of the PPE and of its components, sub-assemblies and circuits; (e) the descriptions and explanations necessary for the understanding of the drawings and schemes referred to in point (d) and of the operation of the PPE; (f) the references of the harmonised standards referred to in Article 14 that have been applied for the design and manufacture of the PPE. In the event of partial application of harmonised standards, the documentation shall specify the parts which have been applied; (g) where harmonised standards have not been applied or have been only partially applied, descriptions of the other technical specifications that have been applied in order to satisfy the applicable essential health and safety requirements; (h) the results of the design calculations, inspections and examinations carried out to verify the conformity of the PPE with the applicable essential health and safety requirements; (i) reports on the tests carried out to verify the conformity of the PPE with the applicable essential health and safety requirements and, where appropriate, to establish the relevant protection class; (j) a description of the means used by the manufacturer during the production of the PPE to ensure the conformity of the PPE produced with the design specifications;

N	Description
	(k) a copy of the manufacturer's instructions and information set out in point 1.4 of Annex II; (l) for PPE produced as a single unit to fit an individual user, all the necessary instructions for manufacturing such PPE on the basis of the approved basic model; (m) for PPE produced in series where each item is adapted to fit an individual user, a description of the measures to be taken by the manufacturer during the fitting and production process to ensure that each item of PPE complies with the approved type and with the applicable essential health and safety requirements.
6	Non-compliant records

6.2.3.1.2 Health and safety requirements

Some of the specifications included in EN149 are:

N	Description
1	Visual inspection: it must include the CE marking and manufacturer information
2	Package: mask must be protected against mechanical damages and pollution before use.
3	Material: it must support handling and use during the period of time which was designed for.
4	Good skin compatibility: materials must not cause skin irritation.
5	Flammability: material must not be a danger for the wearer and must be fire-resistant.
6	Carbon dioxide content in the inhalation air must not exceed 1% in average.
7	Head harness: it must be designed to easily attached and removed.

More specifications must be found in the Annex II of Regulation (EU) 2016/425.

6.2.3.2 Medical device in vitro (Level 2 of complexity)

Specifications must be found in Regulation 2017/746.

6.2.3.2.1 General requirements

N	Description
1	The **traceability** of devices by means of a Unique Device Identification system (UDI system) based on international guidance should significantly enhance the effectiveness of the post-market safety-related activities for devices, which is owing to improved incident reporting, targeted field safety corrective actions and better monitoring by competent authorities. It should also help to reduce medical errors and to fight against falsified devices. Use of the UDI system should also improve purchasing and waste disposal policies and stock-management by health institutions and other economic operators and, where possible, be compatible with other authentication systems already in place in those settings. The **UDI system** should apply to all devices placed on the market except devices for performance studies, and be based on internationally recognised principles including definitions that are compatible with those used by major trade partners. In order for the UDI system to become functional in time for the application of this Regulation, detailed rules should be laid down in this Regulation and in Regulation (EU) 2017/745 of the European Parliament and of the Council (12).
2	EU declaration of conformity: The manufacturer shall draw up a written EU declaration of conformity for a PPE model
3	All parties involved in the application of this Regulation shall respect the **confidentiality of information** and data obtained in carrying out their tasks in order to protect the following: (a) personal data (b) commercially confidential information and trade secrets of a natural or legal person, including intellectual property rights unless disclosure is in the public interest; (c) the effective implementation of this Regulation, in particular for the purpose of inspections, investigations or audits.
4	**Technical documentation** - Device description and specification, including variants and accessories - Information to be supplied by the manufacturer (a) the label or labels on the device and on its packaging, such as single unit packaging, sales packaging, transport packaging in the case of specific management conditions, in the languages accepted in the Member States where the device is envisaged to be sold; (b) the instructions for use in the languages accepted in the Member States where the device is envisaged to be sold. - Design and manufacturing information - General safety and performance requirements - Benefit-risk analysis and risk management - Product verification and validation

6.2.3.2.2 Health and safety requirements

N	Description
1	Devices shall achieve the performance intended by their manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose. They shall be safe and effective and shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art.
2	Manufacturers shall establish, implement, document and maintain a risk management system.
3	Chemical, physical and biological properties: Devices shall be designed, manufactured and packaged in such a way as to minimise the risk posed by contaminants and residues to patients, taking account of the intended purpose of the device, and to the persons involved in the transport, storage and use of the devices. Particular attention shall be paid to tissues exposed to those contaminants and residues and to the duration and frequency of exposure. Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by the unintentional ingress of substances into the device, taking into account the device and the nature of the environment in which it is intended to be used.
4	Infection and microbial contamination Devices and their manufacturing processes shall be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the user or, where applicable, other persons
5	Devices incorporating materials of biological origin Where devices include tissues, cells and substances of animal, human or microbial origin, the selection of sources, the processing, preservation, testing and handling of tissues, cells and substances of such origin and control procedures shall be carried out so as to provide safety for user or other person. In particular, safety with regard to microbial and other transmissible agents shall be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process. This might not apply to certain devices if the activity of the microbial and other transmissible agent are integral to the intended purpose of the device or when such elimination or inactivation process would compromise the performance of the device.
6	Construction of devices and interaction with their environment If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system, shall be safe and shall not impair the specified performances of the devices. Any restrictions on use applying to such combinations shall be indicated on the label and/or in the instructions for use.
7	Protection against radiation Devices shall be designed, manufactured and packaged in such a way that exposure of users or other persons to radiation (intended, unintended, stray or scattered) is reduced as far as possible and in a manner that is compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for diagnostic purposes.
8	Electronic programmable systems — devices that incorporate electronic programmable systems and software that are devices in themselves

N	Description
	Devices that incorporate electronic programmable systems, including software, or software that are devices in themselves, shall be designed to ensure repeatability, reliability and performance in line with their intended use. In the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks or impairment of performance.
9	Devices connected to or equipped with an energy source Devices where the safety of the patient depends on an internal power supply shall be equipped with a means of determining the state of the power supply and an appropriate warning or indication for when the capacity of the power supply becomes critical. If necessary, such warning or indication shall be given prior to the power supply becoming critical.
10	Protection against mechanical and thermal risks Devices shall be sufficiently stable under the foreseen operating conditions. They shall be suitable to withstand stresses inherent to the foreseen working environment, and to retain this resistance during the expected lifetime of the devices, subject to any inspection and maintenance requirements as indicated by the manufacturer.
11	Protection against the risks posed by devices intended for self-testing or near-patient testing Devices intended for self-testing or near-patient testing shall be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to the intended user and the influence resulting from variation that can be reasonably anticipated in the intended user's technique and environment. The information and instructions provided by the manufacturer shall be easy for the intended user to understand and apply in order to correctly interpret the result provided by the device and to avoid misleading information. In the case of near-patient testing, the information and the instructions provided by the manufacturer shall make clear the level of training, qualifications and/or experience required by the user.

6.2.3.3 Medical device (Level 3 of complexity)

6.2.3.3.1 General requirements

N	Description
1	CE marking 1. Devices, other than devices which are custom-made or intended for clinical investigations, considered to meet the essential requirements referred to in Article 3 must bear the CE marking of conformity when they are placed on the market.
2	Clinical investigations:
3	The **technical documentation** must allow assessment of the conformity of the product with the requirements of the Directive. It must include in particular: - a general description of the product, including any variants planned, - design drawings, methods of manufacture envisaged and diagrams of components, sub-assemblies, circuits, etc.,

N	Description
	- the descriptions and explanations necessary to understand the abovementioned drawings and diagrams and the operations of the product, - the results of the risk analysis and a list of the standards referred to in Article 5, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the Directive if the standards referred to in Article 5 have not been applied in full, - in the case of products placed on the market in a sterile condition, description of the methods used, - the results of the design calculations and of the inspections carried out, etc.; if the device is to be connected to other device(s) in order to operate as intended, proof must be provided that it conforms to the essential requirements when connected to any such device(s) having the characteristics specified by the manufacturer, the test reports and, where appropriate, clinical data in accordance with Annex X, - the label and instructions for use.

6.2.3.3.2 Health and safety requirements:

N	Description
1	The devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.
2	The solutions adopted by the manufacturer for the design and construction of the devices must conform to safety principles, taking account of the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer must apply the following principles in the following order: - eliminate or reduce risks as far as possible (inherently safe design and construction), - where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated, - inform users of the residual risks due to any shortcomings of the protection measures adopted.
3	The characteristics and performances referred to in Sections 1, 2 and 3 must not be adversely affected to such a degree that the clinical conditions and safety of the patients and, where applicable, of other persons are compromised during the lifetime of the device as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use.
4	The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer.
5	Any undesirable side-effect must constitute an acceptable risk when weighed against the performances intended.
6	The devices must be designed and manufactured taking special attention to: - the choice of materials used, particularly as regards toxicity and, where appropriate, flammability, - the compatibility between the materials used and biological tissues, cells and body fluids, taking account of the intended purpose of the device.

N	Description
7	The devices must be designed, manufactured and packed in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to the patients, taking account of the intended purpose of the product. Particular attention must be paid to the tissues exposed and to the duration and frequency of exposure.
8	The devices must be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures; if the devices are intended to administer medicinal products they must be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these products and that their performance is maintained in accordance with the intended use.
9	Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product and which is liable to act upon the body with action ancillary to that of the device, the safety, quality and usefulness of the substance must be verified.
10	The devices must be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the device.
11	Infection and microbial contamination The devices and manufacturing processes must be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties. The design must allow easy handling and, where necessary, minimize contamination of the device by the patient or vice versa during use. Tissues of animal origin must originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues.
12	Construction and environmental properties If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system must be safe and must not impair the specified performances of the devices. Any restrictions on use must be indicated on the label or in the instructions for use.
13	Devices with a measuring function Devices with a measuring function must be designed and manufactured in such a way as to provide sufficient accuracy and stability within appropriate limits of accuracy and taking account of the intended purpose of the device. The limits of accuracy must be indicated by the manufacturer.
14	Protection against radiation Devices shall be designed and manufactured in such a way that exposure of patients, users and other persons to radiation shall be reduced as far as possible compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.
15	Medical devices connected to or equipped with an energy source Devices incorporating electronic programmable systems must be designed to ensure the repeatability, reliability and performance of these systems according to the intended use. In the event of a single fault condition (in the system) appropriate means should be adopted to eliminate or reduce as far as possible consequent risks.
16	Information supplied by the manufacturer Each device must be accompanied by the information needed to use it safely and to identify the manufacturer, taking account of the training and knowledge of the potential users.

7 Business Continuity Framework

7.1 Elements of a BCF - Background Assets and Technologies

7.1.1 Factory Risk Assessment

During the COVID19 pandemic, factories have to operate under several restrictions that are aimed at ensuring the continuity of production tasks in ways that safeguard the safety of employees. Furthermore, manufacturing enterprises must adhere to restrictions imposed due to measures against COVID19. In this context, they must identify the processes or activities that might ease the spreading of the virus and plan for remedial actions to minimize the likelihood of spreading. This might for example lead to the implementation of social distancing measures, as well as to the radical reduction of physical activities that involve close human interaction and sharing of physical tools. Furthermore, it is important to identify the workers that are at risk of being infecting and to take measures to protect them. Special provisions must be taken for workers that are vulnerable and susceptible to COVID19 implications.

To identify these risks, manufacturing organizations must establish a risk assessment process for COVID19. Specifically, a COVID19 risk assessment is aimed at:

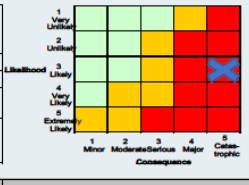
- Identify and document the risk factors that could cause damage to the workforce and the enterprise. The COVID19 pandemic is associated with several known risk factors concerning the health and safety of the employees, yet there are also other risks that concern supply chain operations, contractors and more.
- Grading the risk through assessing their likelihood of occurrence and their potential impact on the enterprise (e.g., on enterprise assets). The grading process is important in order to prioritize the risk based on their importance and their potential for damaging the manufacturing enterprise.
- Specify appropriate mitigation actions for eliminating the risk or controlling it in cases where it cannot be eliminated. Typical risk control actions include for example the implementation of social distancing measures (see for example Figure 7-2), the reengineering of production processes towards a safer direction (e.g., to reduce sharing of tools), the implementation of staggering shifts, the exploitation of PPE for workers, and the provision of handwashing facilities.

The risk assessment process can therefore drive organizational and technological processes, such as the planning and allocation of shifts, as well as the implementation of organizational measures that boost manufacturing flexibility despite COVID19 restrictions.

The Eur3ka Plug n' Response (PnR) framework must therefore support organizations in their COVID19 risk assessment processes. Furthermore, it should use the outcomes of these processes in the reengineering of organizational processes (e.g., shifts allocation, reskilling of employees) towards meeting stringent flexibility requirements.

In this direction Eur3ka can leverage background work on risk assessment that has been carried out by institutional actors in Europe (e.g., the Health and Safety Executive (HSE) governmental organization in the UK), as well as risk assessment methodologies developed by the project partners (e.g., SIEMENS see for example the form at Figure 7-1).

Assessment Title (Task, process, equipment or facility)	COVID-19	Task/ process owner	Site
Location	All sites	Date	Mar-20
		Date for next review	Last reviewed 29/04/2020
Prepared By (Team)			
	COVID-19 controls in line with government guidelines and site control measures and actions.		



Steps, parts or sections	Hazard	Effect (Who/what affected AND how)	Existing Controls (inc practices/ procedures)	Initial Risk: Likelihood	Initial Risk: Cons	Initial Risk: Risk Level	Additional Controls/Opportunities (inc practices/ procedures)	Residual Risk: Likelihood	Residual Risk: Cons	Residual Risk: Risk Level
GOV GUIDELINES	COVID - 19	Contracted COVID-19 or passing on the virus - all persons	1. Only go outside for food, health reasons or work (where this absolutely cannot be done from home). 2. Stay 2 meters away from other people. 3. Wash your hands as soon as you get home. (HR) have developed protocol flowcharts for employees and managers to follow with regards to actions to take. These have been communicated to all managers and employees.	3	3	Medium	Monitor Gov guidelines and Siemens Guidelines	3	3	Medium
		Contracted COVID-19 or passing on the virus - all persons	Symptoms. 1. A new continuous cough - this means coughing a lot more than an hour, or 3 more coughing episodes in 24 hours (if you usually have a cough, it may be worse than usual). 2. A high temperature - this means you feel hot to touch on your chest or back. 3. Shortness of breath	3	3	Medium	Follow current government guidelines if you suspect these symptoms.	3	3	Medium
Communications	COVID - 19	All COVID-19	SCC/ECC regular updates including strategic management, CV19 status and actions, CV- questions and answers. EHS Meetings to review the effectiveness of CV-19 controls. QMM regular CV19 meetings to review the Siemens and Government guidelines/compliance. Regular Siemens meetings. Compliance and strategy. Comms 20, ppt slides, notice boards, mental health, Q&A. HR and EHS on the ground - open door policy - emails etc. Noticeboards. Electrium/Siemens intranet.	1	3	Low	Monitor external communications	1	3	Low

Figure 7-1: Snapshot of the Risk Assessment Form Provided by SIEMENS UK

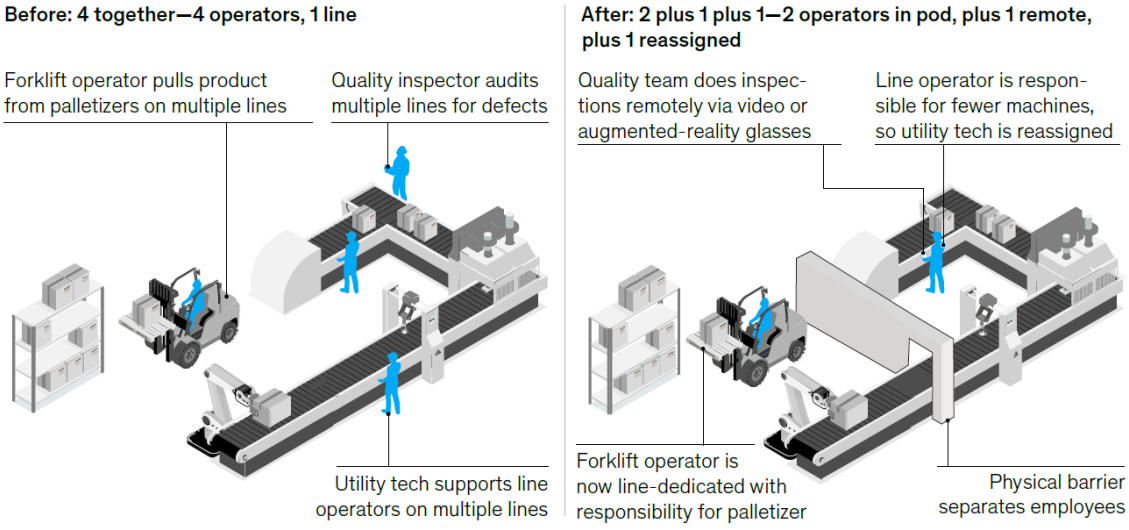


Figure 7-2: Example of Shopfloor Physical Distancing [Furtado20]

7.1.2 Shifts Allocation

During COVID19 times, plants must operate subject to several restrictions, where are imposed by government or corporate policies. Some of these restrictions are directly related to the staffing of production processes such as the number and availability of employees to work on specific processes. As plants must operate with lesser workers, ensuring an adequate number of employees with proper skills for various processes becomes challenging. In this context, shift allocation processes must be revisited and revised. The goal of the revisions is not only to ensure the allocation of shifts subject to COVID19 restrictions. Rather, there is also a need for identifying risk mitigation actions that could alleviate shift allocation and production continuity challenges. Overall, the following processes and functionalities should be considered in the broader context of shift allocation and human resources management:

- **Assessing employee skillsets**, towards identifying shortages in certain skills that challenge production continuity.
- **Identification of retraining and upskilling requirements**, as a means of mitigating shift allocation and skills shortage challenges.
- **Ensuring conflict avoidance** towards supporting production continuity in the light of COVID19 related restrictions.
- **Scheduling of tasks and breaks** under certain corporate and governmental policies, including their constraints.
- **Management of leaves and time-off**, considering applicable policies and restrictions.
- **Management of shift coverage**, including scheduling of positions based on the available skills.
- **Supporting scenarios where operation with limited capacity might be required**, for reasons such as physical distancing rules and unplanned absences due to COVID19 Infections.
- **Provision of dynamic reports about the COVID19 conditions of employees and the status of the operations**.

Baseline shift allocation functionalities are provided by most mainstream ERP systems such as SAP (i.e., based on SAP's Time and Attendance Management by Workforce Software) and Microsoft Navision (i.e., as part of the Resources Allocation module). Furthermore, there are many stand-alone tools that solve the shift allocation problem and provide user interfaces towards end users specified above. All of them introduce a pay as you go model with different available features according to selected plan. Some of the most characteristic examples of such SaaS (Software-as-a-Service) systems follows:

- **Connecteam (https://connecteam.com/)**: It provides the means for communicating, operating, and training non-desk employees with the help of an employee app. It is easy to use, customizable, and scalable.
- **mHelpDesk (https://www.mhelpdesk.com/)**: Mhelpdesk is a cloud-based service management software solution. It provides enterprises (notably SMEs) with visibility over service tickets, scheduling, and billing in one elegant solution.
- **Shiftboard (https://www.shiftboard.com/)**: It is workforce scheduling software for mission-critical industries. It helps enterprises manage workforce scheduling complexity with precision and ease. The software offers a COVID19 module, which emphasizes the

management of shifts under dynamically changing conditions such as those driven by the pandemic.

- **TSheets (https://www.tsheets.com/)**: TSheets is a web-based and mobile time tracking and employee scheduling application. Its emphasis is on the digital transformation of conventional paper timesheet-based processes.
- **Homebase (https://joinhomebase.com/)**: Homebase is a software system that helps enterprises to manage their hourly teams. It supports functionalities like employee scheduling, time clocks, team communication, hiring, onboarding, health screenings, and compliance.
- **Deputy (https://www.deputy.com/)**: Deputy's Open Shifts solves for this by enabling managers to ensure the most suitable employees are selected for a shift - effectively matching the right skill set for the position. Furthermore, the product democratizes open shifts policies, allowing all employees to claim open shifts advertised by the manager.
- **StaffJoy (https://www.staffjoy.com/)**: Staffjoy is a workforce scheduling platform. It has been released as an opensource platform and is the only solution currently free that provides on premises deployment, but there is currently very minimum contribution from the community. There is no official documentation, yet its GitHub page provides some basic instructions for deployment.

Most of these tools fall short when it comes to supporting allocations in the light of COVID19 restrictions, as well as in order to support safe working procedures and dedicated production continuity. For instance, most of them do not provide support for defining continuity between departments or defining department area in (m^2), so that employees' shifts can be optimized. The Eur3ka business continuity framework will include a smart shift allocation functionality based on an interactive web application targeted for both plant managers and for employees (staff workers), i.e., supporting both stakeholder types in planning shifts and communicating relevant information to them.

7.1.3 Situational Awareness for Manufacturing Ecosystems Monitoring

Many manufacturing business ecosystems can benefit from a set of (near) real-time monitoring components intended to increase business continuity, contributing to the creation of increased ecosystems of data and information. Such trusted data spaces can be further analyzed and exploited to improve the resilience of the monitored digital infrastructures and business ecosystem, through the construction of the so-called Situational Awareness. Situational Pictures provide an understanding of relevant events and the ability to observe the state of the systems (the single component/system and progressively up to the set of all infrastructures at the relevant level of the considered ecosystem, e.g., plant, corporate, supply chain, …) in an integrated manner, also in relation to objectives, constraints and acceptable risks associated with monitoring.

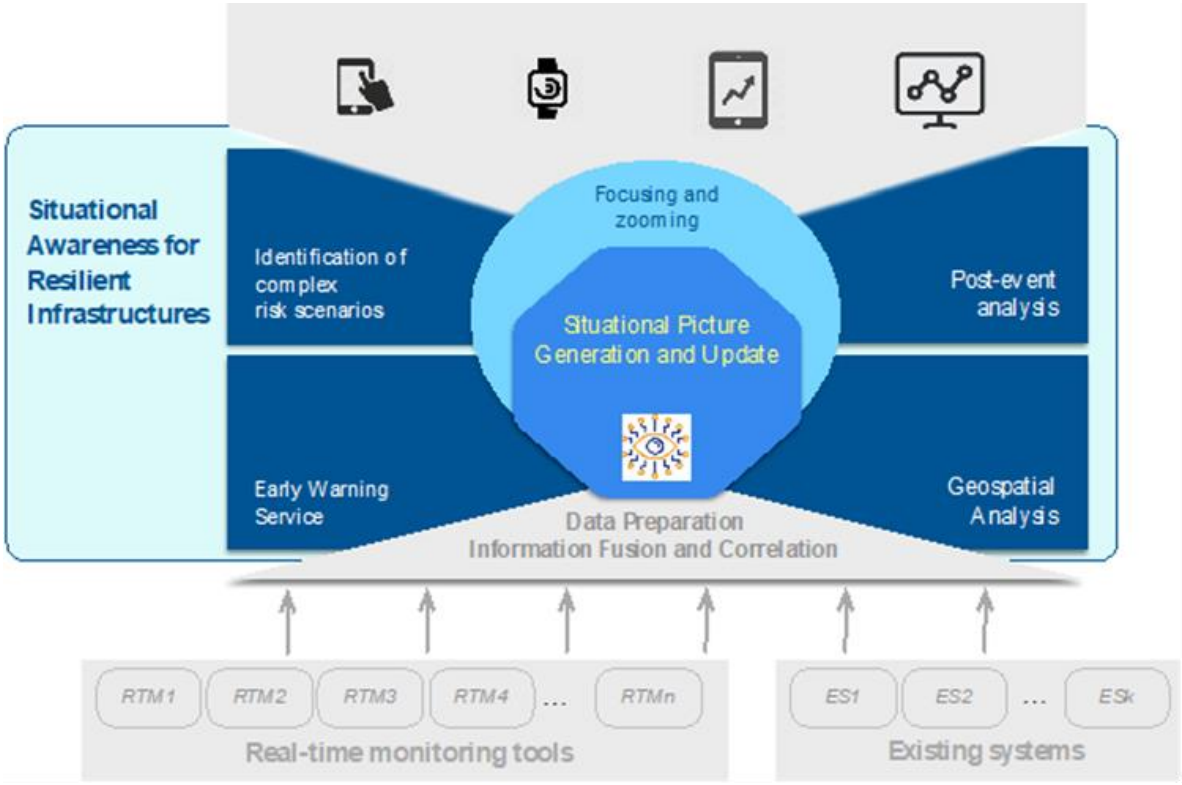


Figure 7-3: Conceptual Architecture for Building Situational Awareness Solutions

7.1.4 Remote Manufacturing Support during COVID19 Times

The mobility limitations as well as the interpersonal distance requirements which COVID19 implies, have pushed the development of virtual commissioning technologies into new limits. While the Boost 4.0 project has focused on enhancing these commissioning technologies through the reuse of the datasets along the engineering release process, COVID19 has added new requirements towards remote reprogramming and support, which eliminates the contact between the operators and ensures the security distances. Specifically, work allocation in the factory layout must be organized in the virtual environment, keeping security distances between the plan operators, maximizing productivity.

Additionally, in a limited mobility environment (i.e., where physical/social distancing is obligatory), the virtual environment needs to provide the more interactive support through VR and AR technologies which allow the operators to be trained in new production requirements as well as support during the execution of their tasks and help in the maintenance.

7.1.5 Workforce Training

To validate the People, dimension of Pilots, five main data science job profiles, four professions due to the COVID19 pandemic, and their related competencies have been defined.

7.1.5.1 Data Science Roles

Related to skills in Industry 4.0, a structured repository of 100+ technical and managerial skills 4.0 covering five areas[25] necessary to define Industry 4.0 strategies, and design, manage and enable Industry 4.0 processes and business models which are:

- Smart product-service design management
- Smart supply chain management
- Smart operations management
- IT-OT integration management
- Data science management

In the case of "**Data science management**," five main job profiles and their related competencies validation are defined[26] as illustrated in Figure 7-4.

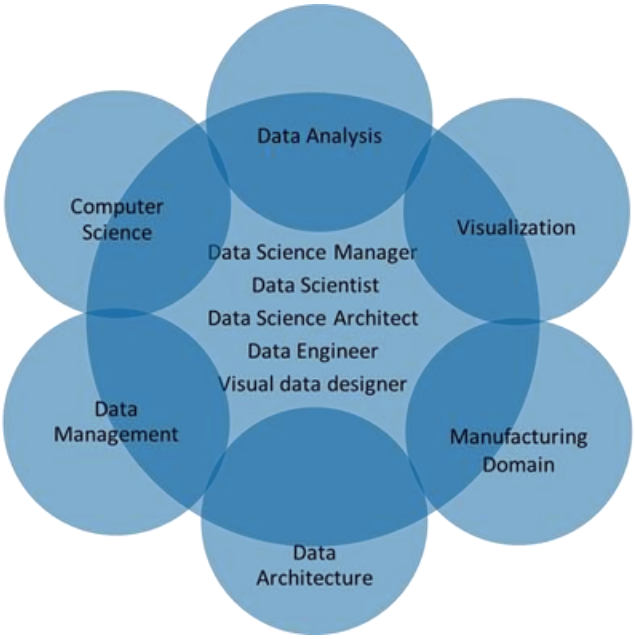


Figure 7-4: "Data science management," main job profiles and their related competencies

Data Science Manager

Data Science Managers propose, plan, and manage functional and technical evolutions of the data science operations within the relevant domain.

Top related skills for this position are as follow:

- knowledge about data processes
- knowledge about business processes

[25] Osservatorio Industria 4.0 - Politecnico di Milano
[26] Osservatorio Industria 4.0 - Politecnico di Milano

- knowledge about performance indicators
- communication with domain experts
- ability to manage the data science team and resources.
- ability to develop and execute the data strategy according to business objectives.

Data Scientist

Data scientists find, interpret, and merge data sources, manage large amounts of data, ensure consistency of datasets, and create visualizations to aid in understanding data. Build mathematical models, present, and communicate data insights and findings, and recommend ways to apply the data.

Top related skills for this position are as follow:

- ability to identify and interpret relevant data sources.
- ability to use a programming language (R, Python)
- knowledge about advanced mathematical and statistical models
- use of machine learning.
- use of Bayes classifier.
- use of Deep Learning techniques
- use of Operational Research methods
- use of optimization algorithms.
- knowledge about domain-specific processes
- ability to communicate with domain experts.

Data Science Architect

Data Science Architect designs and maintains the architecture of data science applications and facilities.

Top related skills for this position are as follow:

- ability to integrate data universe.
- knowledge about big data architectural standards
- ability to select software platforms for big data (Hadoop, Data Lake)
- ability to select hardware platforms for big data (performances, costs, scalability, flexibility)/

Data Engineer

Data Engineers build, manage, and maintain data pipelines.

Top related skills for this position are as follow:

- ability to develop data models and workflows.
- ability to use cloud computing.
- knowledge about data storage and query languages
- ability to maintain security, quality, integrity, safety, and availability of data.
- ability to integrate new data technologies into existing systems.

Visual Data Designer

Data Visualization Designers create custom visualizations from complex data sets in a compelling way.

Top related skills for this position are as follow:

- ability to create infographics (maps, charts, diagrams)
- ability to visualize the huge and complex volume of data.
- ability to understand complex information.
- ability to develop insightful and engaging data analytics view.
- ability to develop vector graphics, scientific illustrations, and icons (maps, charts, diagrams)
- ability to develop interface and interaction to increase user experience.
- user experience analysis, design, and evaluation.

7.1.5.2 Professions due to the COVID19:

More than twelve (12) months have passed since Europe's countries placed strict and far-reaching locks into place to slow down COVID19 spread and save the lives of its people. These initiatives have had an unprecedented effect on industries, employees, and businesses. Whole factories were shut down temporarily and while these constraints have begun to be steadily relaxed by nations, it was impossible to return to life and work early, as we knew.[27] Researchers speculate about the evolving world after the COVID19 pandemic,

[27]https://skillspanorama.cedefop.europa.eu/en/analytical_highlights/covid-19-and-jobs-which-skills-makedifference#_summary

but they must accept that places of work would not be like the previous ones. Here are eight competencies that we expect to be important for post-coronavirus staff and businesses.[28]

- **Leadership:** Team leaders and managers must be able to inspire, empower and promote remote collaboration.
- **Emotional intelligence:** There is complexity and difficulties in post-COVID19 world, and businesses will need emotional intelligent leaders to help their workers navigate through these challenging times.
- **Technology skills:** Technologies such as the robotics, augmented reality, the artificial intelligence and IoT will enable companies to resist pandemics in the future. People who can help companies exploit these technologies will be indispensable.
- **Digital and coding skills:** people with skills in digital marketing, web development, web design and coding can be invaluable in helping companies stay afloat during difficult times.
- **Adaptability:** It is also about regularly learning new skills and upgrading old skills to keep you competitive on the job markets, not just the acceptance of changes in your work duties.
- **Creativity and innovation:** Many businesses have been role models for creating ways of delivering services online or rapidly moving their output. Human creativity is crucial in a post-coronavirus environment.
- **Data literacy:** Enterprises need data literacy experts who can interpret and propose solutions based on knowledge.
- **Critical thinking:** Companies need to rely on critical thinking to make informed decisions by false news and misinformation inundating the internet. There will be great demand for media literacy and the opportunity to interpret knowledge from multiple sources critically.

[28]https://ec.europa.eu/eures/public/news-articles/-/asset_publisher/L2ZVYxNxK11W/content/8-essential-skills-to-succeed-in-a-post-covid-19-world

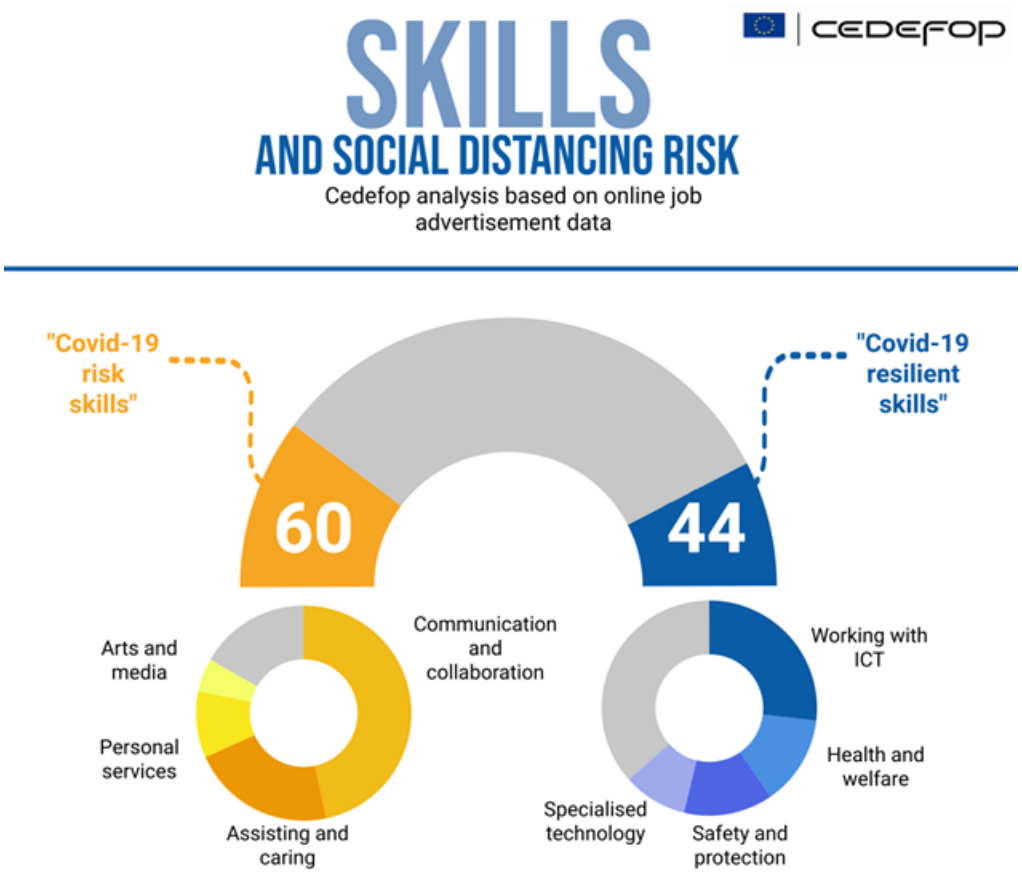


Figure 7-5: Skills and social distancing risk

Figure 7-5 depicts Skills and social distance risks in COVID19 Pandemic duration, out of 104 skills, 60 were highly dependent on the relationship between people and society, mostly in areas of “communication, collaboration and creativity”, “assisting and caring for others”, “providing personal services” or “performing arts and media content production”.

44 skills consider as mostly resilient to social distancing, as they have either high potential to be done remotely, such as in areas like “working with ICT”, “working with special technology” (such as medical or audio-visual equipment) or are necessary for provision of basic services such as in areas like “provision of health and welfare services”, “provision of safety and protection services”, “provision of food supply services”, or “packaging and delivery”. [29]

Based on categorized skilled in previous paragraphs and related to COVID19 pandemics circumstance. four job profiles and their related competencies validation are defined:

[29]https://skillspanorama.cedefop.europa.eu/en/analytical_highlights/covid-19-and-jobs-which-skills-makedifference#_summary

Remote Workers

A remote employee is employed by a company but works outside of a traditional office environment. This could mean working from a local coworking space, home, or city across the world.[30]

Based on structured repository of **100+ technical and managerial skills 4.0**, regarding to definition of remote workers, we can mention " **Remote Maintenance Supervisor**" who will need to have the following skills:[31]

- Ability to program and interact with collaborative robots.
- Ability to use and interact with systems and sensors.
- Ability to understand and use mathematical models.
- Ability to select and use industrial analytics.
- Ability to perform scenario analysis to evaluate and prepare for possible interventions (simulations, classifiers, etc.).
- Ability to interpret 3D digital models.
- Ability to use virtual and augmented reality goggles.

Operator 4.0

- Ability to use virtual and augmented reality goggles.
- Ability to use exoskeletons and other wearable devices.
- Ability to use applications to increase sensory, physical, and cognitive abilities.
- Ability to understand and use mathematical models.
- Ability to use analytical or scientific software (e.g., SPSS, MATLAB)
- Ability to select and use industrial analytics.
- Ability to perform scenario analysis to evaluate and prepare for possible interventions (simulations, classifiers, etc.).
- Ability to interpret quantitative data and graphs (KPIs).
- Ability to use computer-aided process planning (CAPP).
- Ability to interpret 3D digital models.
- Ability to use additive manufacturing technologies.

[30]https://www.remoteyear.com/blog/whatisremotework#:~:text=A%20remote%20employee%20is%20someone,a%20city%20across%20the%20world.

[31] JOBS & SKILLS 4.0: QUALE EVOLUZIONE PER PROFESSIONI, COMPETENZE E FORMAZIONE? Osservatorio Industria 4.0

Repurposing supervisor

The area of design and industrialization refers to the development of new products and services, and to the design of their life cycle: from the production phase to the phase of acquisition and use, until the end of their useful life and the beginning of any phase of **reuse, remanufacturing or recycling**.

According to the vision of Industry 4.0, this technical area also evolves or continues an already ongoing transformation towards the digitization of processes and product-services. Products become objects equipped with the ability to sense, process, and communicate to constitute platforms for service delivery.

Innovation is spurred by the availability of innovative materials and process technologies. The design considers the whole life cycle of the product-service. Through digital techniques of three-dimensional modelling, virtual prototyping, and simulations, it is possible to proceed quickly in the various iterations, verifying and validating the project with respect to feasibility, experience of use, maintainability, recovery or recycling at the end of life.[32]

According to the explanations given in the previous paragraphs, there is a need for a supervisor in the Repurposing field in every business; Repurposing is transforming products or their components to suit a second purpose after their first has expired. [33] Repurposing supervisor can organize the purposeful creation (or rescue), management, support, and governance of reusable assets.[34]

Repurposing supervisor (Adapted from The Designer 4.0 skills)[35]

- Ability to identify opportunities for new/alterative applications of existing components, products, machines, etc.
- Knowledge and ability to use and Re-use (new) materials.
- Ability to innovate and engineer the product in 3D printing perspective.
- Ability to use 3D printers.
- Ability to design around new materials/processes or used material/processes (e.g., light polymerization, extrusion accretion, compounding of granular material, layered lamination)
- Ability to define the business model around the product-service.
- Knowledge about Reduce, Reuse and Recycle Wastes[36].

[32] JOBS & SKILLS 4.0: QUALE EVOLUZIONE PER PROFESSIONI, COMPETENZE E FORMAZIONE? Osservatorio Industria 4.0

33 Design for Repurposing A sustainable design strategy for product life and beyond by Darinka Aguirre BSc Industrial Design, University of Monterrey, Mexico 2006; https://core.ac.uk/download/pdf/55286555.pdf

34 https://www.pmi.org/disciplined-agile/process/reuse-engineering

35 JOBS & SKILLS 4.0: QUALE EVOLUZIONE PER PROFESSIONI, COMPETENZE E FORMAZIONE? Osservatorio Industria 4.0

36 https://www.skillsyouneed.com/ps/managing-waste.html

Resilience Manager

The fundamental importance of a business's ability to operate during a crisis, whether that's major IT outages, cyber-attacks, or geo‑political incidents, is well understood. Almost overnight, COVID‑19 became the single greatest threat to the continuity of many businesses. The maturity of an organization's operational resilience now has the very real potential to dictate whether an organization will survive.[37]

Therefore, flexibility and resilience in management and engineering is extremely critical due to make the plan in different crises; The following job profiles have been considered in view of the importance of this issue.

Resilience Manager (Adapted from The Supply Chain Manager 4.0 Skills)[38]

- Ability to anticipate business requirements and end-user needs.
- Ability to understand the impact of emerging technologies on business (e.g., distributed systems, virtualization, big data).
- Ability to rapidly adapt technological innovations to business and Supply Networks (e.g., data-driven analytics and scenario simulation/modelling, advanced network analysis).
- Ability to redesign the production process end-to-end, improving it with the introduction of new technologies 4.0.
- Ability to foresee elements of flexibility when necessary in redesigning production processes.
- Ability to select and adopt track and trace technologies for logistics.
- Ability to interact with smart warehouses equipped with automated picking systems and autonomous vehicles.
- Ability to collaborate with other players (including those from outside the company) and integrate them into the value chains.
- Ability to engage and dialogue with stakeholders, trade unions first and foremost, to better manage change related to the introduction of new technologies.

7.1.6 Financial Impact Assessment

Eur3ka aims to generate positive outcomes for the society on both short and long terms. One of the main goals of Eur3ka is to provide manufacturing companies with the right tools

37 https://assets.kpmg/content/dam/kpmg/au/pdf/2020/covid-19-guide-to-maintaining-business-resilience.pdf

38 JOBS & SKILLS 4.0: QUALE EVOLUZIONE PER PROFESSIONI, COMPETENZE E FORMAZIONE? Osservatorio Industria 4.0

to understand how to operate in more flexible and resilient manner to face possible disruptive external changes. In particular, the Eur3ka Resilient and Reliable Repurposing Manufacturing network studies how to innovate and digitalise factories with the aim to support sudden demand peaks of Vital Medical Supplies and Equipment (PPE/CCE). This goal needs to be backed by a solid financial impact assessment tool to stimulate the adoption of these solutions underlying the economic benefits too. Therefore, to really understand the financial impacts, a scorecard to perform a financial impact assessment has been developed based on the most diffused financial indicators (e.g., taken from [Arnaboldi15]). In this section are reported those concerning the financial impact assessment of assets and technologies that need to be backed also by sustainable indicators to evaluate the sustainable performances of the new solutions along their lifecycles.

Several changes are required to be put in place to be flexible and reliable. To measure the financial impacts on these changes and stimulate the undertaking of this direction, the first element to be monitored is the **Growth of profit** trend and thus, it is required to evaluate whether the trend is positive or not. Indeed, PPE and CCE can be produced together or instead of the traditional products with the support of specific technologies and, to evaluate whether this choice can be sustainable from an economic point of view, the trend needs to be monitored. In addition, this measurement needs to be benchmarked with similar realities operating in the same context to really estimate the **Profitability** of the investment.

The values to be comparable require to be translated into percentages. Among the most diffused financial indicators, the **Net Profit Margin** is adopted to evaluate the profit generated over the revenues obtained. Indeed, while the denominator is represented by the revenues generated, the numerator must consider the overall amount of revenues generated, from which subtract the operating cost for the selling of goods/services, the expenses, the interests and the taxes. This value, if monitored, guarantees to have under control the outcomes from the modifications happened at factory level and supply chain level, which are both required for the update production of PPE and CCE within factories.

The net profit is estimated from the net operating income, that is the same value without considering the costs, which is especially important to monitor the **Return on Investment (ROI)**. The ROI indicator indeed is estimated as the net operating margin (thus the revenues before interests and taxes) over the invested capital. This indicator allows to verify across the years the return on what has been invested in the project to evaluate how to proceed according to the status.

The estimation of the return on investment is strictly connected to other indicators which allow to evaluate the investment profitability in advance. Among all, it will be used the **Net Present Value (NPV)**, and the **Pay Back Time (PBT).** The **NPV** allows to estimate, on the long run, the potential value that the investment will have by looking at the net cash flow updated over the cost of the capital along the asset useful life. Thus, for an investment to be acceptable, this value needs to be greater than 0. Instead, the **PBT** allows to monitor the time required to have positive returns from the investment, thus the time required to have a balance between the initial expense for the investment and the cash flow generated. Actually, the investment can be acceptable also only if the **Internal Rate of Return (IRR)** is estimated to be greater than the cost of capital. Considering the need to react even faster than usual, the estimation of these indicators needs to give positive returns quite fast to

highlight the usefulness of the countermeasures undertaken throughout the solutions proposed and developed in this research project in guaranteeing high level of flexibility within the updated factories.

In addition, all these indicators allow to have a long-term view over the possible scenarios and their potential returns. This stimulates the reliability and flexibility of factories even in normal situations and not only driven by a pandemic or an emergency situation. This long term, view supports the competitive advantage of companies being reactive fast against external needs of change.

To sum-up, Table 7-1 reported below depicts the scorecard to be used for the financial impact assessment of the introduction of the technological solutions defined by the Eur3ka project.

Indicator Name	**Formula**	**Why to use**
Net Profit Margin	$Net\,\mathrm{Pr}ofitM\,\mathrm{arg}in = \frac{R - C - Int - Taxes}{\mathrm{Re}venuew}$ R = revenues [€] C= operating and other expenses + costs of goods sold [€] Int = Interests [€] Taxes = Taxes [€]	To monitor the profit over the revenues
ROI	$ROI = \frac{NetOperatingIncome}{Investment^{T}}$	To monitor the investment
NPV	$NPV = \sum_{t=1}^{T} \frac{CF_t}{(1+k)^t} + \frac{V_T}{(1+k)^T} - I_0$ I_0 = initial investment [€] CF_t = cash flow in period t [€] V_T = residual value of the investment [€] k = cost of capital [%/year] T = useful life [years]	To forecast the outcomes from the investment
PBT	$\sum_{t=0}^{PBT} \frac{NCF_t}{(1+k)^t} = 0$ NCF_t = NCF= net cash flow in period t = $CF_t - I_t$ [€] k = cost of capital [%/year]	To evaluate the time required to balance the costs and revenues from the investment

IRR	$\sum_{t=0}^{T} \frac{NCF_t}{(1+IRR)^t} = 0$ NCF= net cash flow in period t = $CF_t - I_t$ [€] T= useful life	To evaluate the equivalent interest rate for an investment

Table 7-1: Financial Impact Assessment Indicators

7.2 Specifications of Eur3ka Business Continuity Framework Services

7.2.1 Factory Risk Assessment

Eur3ka will develop a manufacturing COVID19 risk assessment tool based on best practices and recommendations of health and safety organizations in Europe, as well as based on relevant experience of project partners. The tool will provide guidance that will help manufacturers continue their production operators in ways that ensure the safety and health of the workers. The tool will provide the means for accessing risks in the following areas:

- Workplace social distancing.
- Physical activities that can lead to infection like sharing of tools.
- Support for Remote Work.
- Implementation.
- Assessment of Groups of people may be at more risk in case they get infected.
- Assessment of Groups of people that are likely to have adverse outcomes if infected with COVID19.

The main value propositions of the Eur3ka COVID19 tools when compared to available risk assessment forms will be:

- The production of an on-line tool for risk assessment, including capabilities for collecting data, structuring it and sharing it with other modules of the Eur3ka Business Continuity Framework.
- The inclusion of a list of actionable recommendations (including mitigation actions) for each main risk area.

7.2.2 Shifts Allocation Specifications

The Eur3ka shift allocation tool will assign available staff workers to shifts per sector in the facility. To achieve maximum isolation between staff workers, they will be divided into groups and each group will be assigned to a unique shift in a specific sector of the department. Employees will not be allowed to work in different sectors during their shift. Each shift will be 8-hour long and according to the production needs there will be 2-3 daily shifts per sector. Personnel will be assigned shifts in each sector according to their profession and skills, i.e., employees that fit the sector's required profession will have higher cardinality to be selected. Shift allocation will be applied every two weeks. To balance the activities, each group of

employees rotate their shift every week, (i.e., if a group works on the morning shift during a week, in the next week the same group will have to work on the afternoon shift). To achieve maximum productivity per sector, a minimum number of working hours will be set to our solution model with respect to the maximum contractual number of working hours per week. The key objective function of the solution will be to minimize the sum of the deviations from the contractual number of working hours for each worker. Deviations apply additional costs to the organization (positive deviations will lead to extra costs, negative ones lead to missing hours in an employee's schedule that need to be paid).

The solution model will follow the MILP (Mixed-Integer Linear Programming) formulation and linear dynamic programming solvers will be applied in order to define the optimal solution to the shift allocation problem among a large space of solutions. The solution will follow the constraints described above. The following equations provide an initial mathematical formulation of the problem.

$$\textbf{min}\,\boldsymbol{\Delta}: \sum_{e \in E} \sum_{w \in W} \boldsymbol{\delta}_{ew}^{-} + \boldsymbol{\delta}_{ew}^{+} \qquad 1)$$

$$\textbf{s.t.} \quad \sum_{a \in A} \sum_{s \in S} \boldsymbol{x}_{se}^{wa} = \mathbf{1} \qquad 2)$$

$$\sum_{a \in A} \sum_{w \in E} \boldsymbol{x}_{se}^{wa} = \mathbf{1} \qquad 3)$$

$$\sum_{e \in E} \boldsymbol{y}_{se}^{wa} \geq \boldsymbol{\tau}_{sa} \qquad 4)$$

$$\sum_{a \in A} \sum_{s \in S} \boldsymbol{y}_{se}^{wa} + \boldsymbol{\delta}_{ew}^{-} - \boldsymbol{\delta}_{ew}^{+} = \boldsymbol{h}_{e}^{max} \qquad 5)$$

$$\boldsymbol{x}_{se}^{wa} \leq \boldsymbol{c}_{ea} \qquad 6)$$

Specifically, the equations can be interpreted as follows:

1) The objective function that needs to be minimized. (Minimizes the total deviation between the amount of weekly contractual hours of each worker and the actual working hours.

2) Each employee must be weekly assigned to exactly one shift and one sector (A=>set of sectors, s=>set of Shifts)

3) Each employee must work in exactly one sector per shift (A=>set of employees)

4) Ensure that the working hours for every shift in each sector are respected.

5) Ensure that the actual working hours per week for a specific employee after subtracting the deviations must be equal to the contractual hours.

6) Ensure that each employee that is selected for a specific shift is aligned with the sectors required qualifications (c_{ea} ε {0,1}, where 1 represents that employ is qualified and 0 represents that the employee does not fill the requested qualifications for a specific sector) .

To solve the above optimization problem alternative open-source Integer optimization solvers will be examined and used. Specifically, the Google OR-Tools library will be exploited, as it is easily customizable to fit the needs of the formulated shift allocation solution. The library will be integrated and provided solutions will be exposed through REST API to the visualization layer (Single Page Web applications).

The solutions provided will be evaluated by calculating the vertex degree of corresponding graphs representing employee interactions per sector (i.e., it is assumed that all employees working in the same sector per shift have interaction), this will be the contagion risk factor. The formulated problem can use bellow data model and table relationships for database persistence.

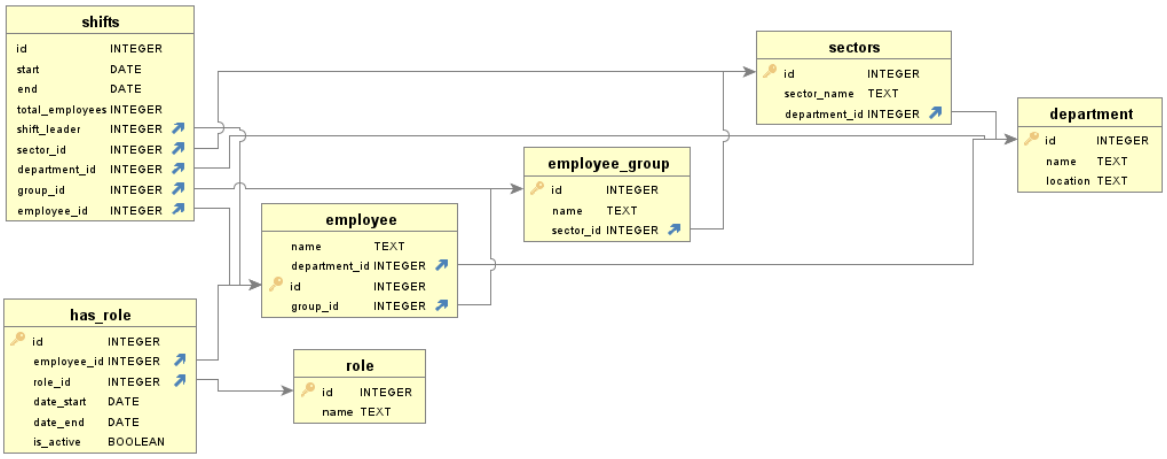


Figure 7-6: Simplified Version of the Shifts Allocation Data Model

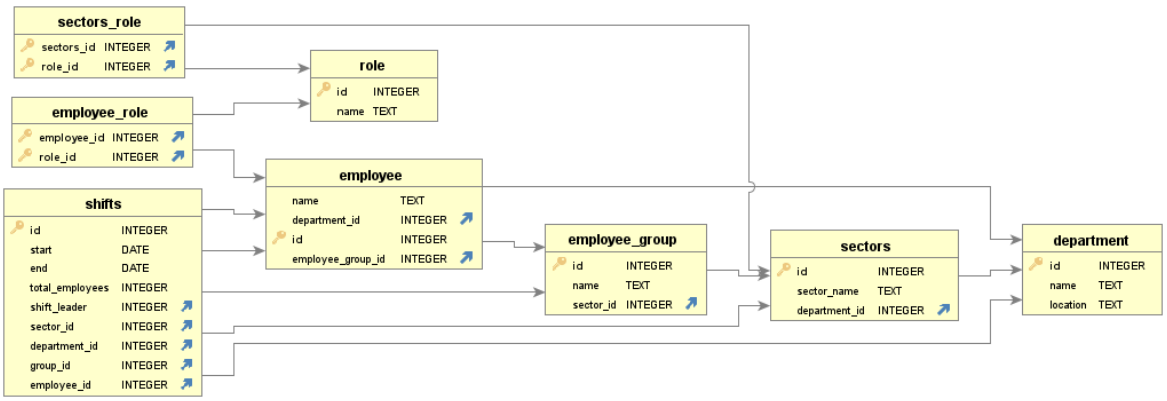


Figure 7-7: Database Schema for allocating personnel to sectors taking into account their profession

Infection Scenario

In case of infection during a shift, all employees that were working in the same group will be isolated (as part of the contact tracing procedure), until they receive a negative test. In the meanwhile, the facility operator will need to decide if the shift allocation will be re-executed or the sector that the event took place will be shouted down for decontamination. If so, the shift whose employee group reported infected personnel will be skipped making the sector

non-functional for at least 8 hours. After that, the sector will be again operational from the next shift having totally different group of employees.

7.2.3 Situational Awareness Services

Eur3ka intends to support the modular and incremental creation of Situation Awareness solutions, built on top of a series of data analysis tools, based on (big) data analytics techniques, Artificial Intelligence, graph intelligence and correlation of information to build services offering the so-called Situational Pictures, to be further integrated with other Eur3ka tools and platforms.

To this end innovative multi-level situational awareness models will be further analyses and refined, which include in an integrated way information relating to all the relevant aspects for the integrated assessment of the digital infrastructures underlying the monitored manufacturing businesses. This information model constitutes the enabling layer to determine, analyze and manage the risk, at the different levels and components of the monitored infrastructures intended as a complex System of Systems.

Furthermore, as part of a situational awareness creation service, for the continuous monitoring of the resilience and business indicators of the monitored ecosystem, techniques and solutions will be integrated to obtain an effective early warning in the event of possible accidents or threats. In this sense, a "focusing" and "zooming" mechanism and related intelligent functions will be defined and designed to focus on specific entities. Therefore, this module implements a multi-level surveillance and situational awareness approach in which the monitoring services will be “activated” more on specific areas and data sources / flows according with the perceived level of risks and received high-level signals.

Any manufacturing business ecosystem is, in fact, characterized by multiple components and subsystems highly interconnected from a technical, technological, functional, organizational and process point of view. This interconnection turns into dependencies at the level of vulnerability that can generate cascading threats and accidents (think about the effect of a lack of raw material in a supplier that certainly impacts a multiplicity of its customers). In this context, Eur3ka will integrate and offer services based on “model-based” simulation in order to focus at least on the following dependencies: interaction between multiple events and threats that may represent a more complex situation; analysis of the cascading effects between the various elements of the same system or the same business manufacturing ecosystem; analysis of the effects on cascade between different dependent manufacturers and between their manufacturing infrastructures and the different elements and subsystems of the whole business ecosystem.

Finally, dealing with information from situational awareness will support post-event analysis in order to analyse what happened in the past and at the same time deduce useful insights for improving the performance of the entire monitoring system in the near future. These services will be based on big data analytics of prescriptive descriptive type.

7.2.4 Remote Manufacturing Support

Eur3ka will further practically develop and implement the work initiated in BOOST 4.0 for virtual commissioning targeting remote repurposing of manufacturing lines, enhancing programming techniques. The virtual models will be extended to integrate existing production systems which have not been digitalized, in this way the programming capabilities will be deployed (Figure 7-8). In parallel to the development of virtual models, support skills will be added.

Figure 7-8: Virtual Model Example

Once the virtual models are available, the 3D simulation and visualization will allow to optimize the plan design process, validating production scenarios. Developed technologies in LIAA (Lean Intelligent Assembly Automation)[39] project targeting human-robot cooperation will be adapted to improve the work schedules and interpersonal distance between the operators (Figure 7-9).

The virtual environment combined with VR and AR technologies will provide the learning environment for training the employees in production and support tasks, as well as, collaborative environment between employees.

[39] https://cordis.europa.eu/project/id/608604

:

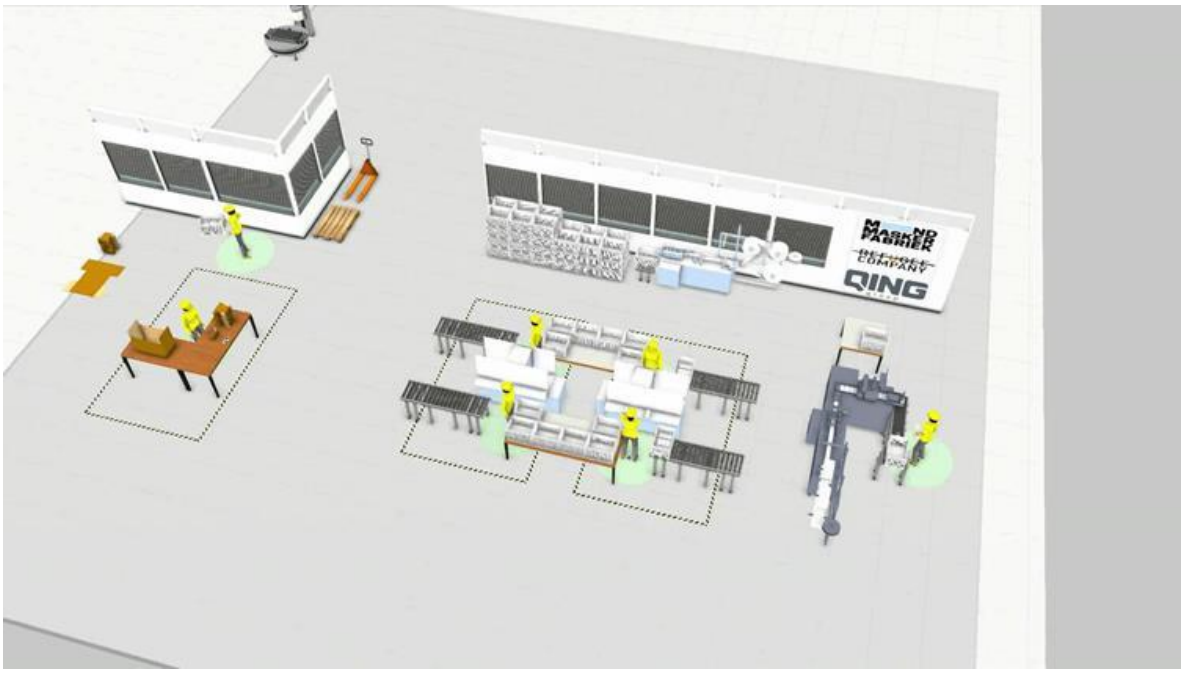


Figure 7-9: Example of 3D Simulation and Virtualization Environment

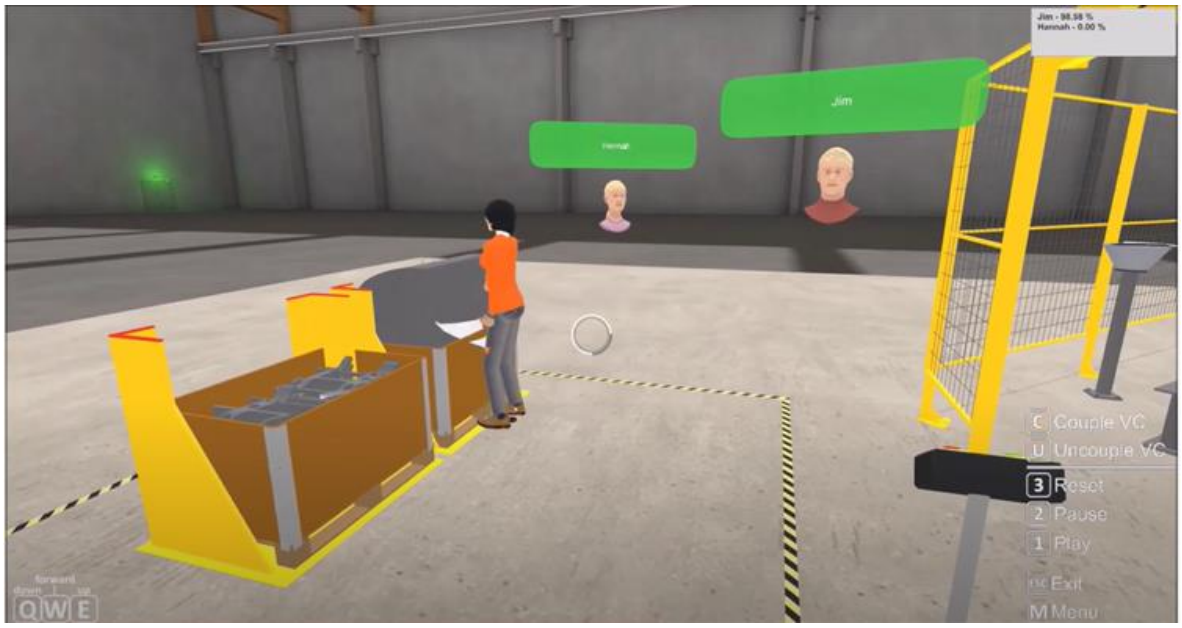


Figure 7-10: Learning and Collaboration Environment

7.2.5 Workforce Training

To determine the priority and importance of the mentioned skills for each job profile in the project's Pilots (discussed earlier in 7.1.5), online questionnaires were designed and can be used. Figure 7-11 is an example of the questionnaire's view - this example is related to " Data Science Manager".

Figure 7-11: Example of the questionnaire's view - Data Science Manager

Boost 4.0 BIG DATA FOR FACTORIES

FIL YOUR FUTURE

Pleas specify if the skills are possessed by the company itself or by the BOOST partners collaborating in the pilot.

Pleas also specify how the skills gaps evidenced have been filled by training courses up- re-skilling, by hiring new personnel, by opening new collaborations

Pease indicate with YES/NO if a job profile is needed in your pilot. if YES, rank from 1 to 5 the skills reported for that specific profile
(1 = basic level required in the pilot, 5 = expert)

Job Profiles and related skills	Needed (M36)	Possessed (M36	Comments
Data Science Architect			
ability to integrate data universe			
knowledge about big data architectural standards			
knowledge and ability to select software platforms for big data (Hadoop, Data Lake)			
knowledge about hardware platforms for big data (performances, costs, scalability, flexibility			
Data Science Manager			
knowledge about domain-specific processes			
knowledge about business processes			
knowledge about performances indicators			
communication with domain experts			
Data Scientist			
knowledge about programming language (R, Python)			
ability to identify and interpret relevant data sources			
knowledge about advanced mathematical and statistical models			
knowledge and use of machine learning			
knowledge and use of Bayes classifier			
knowledge and use of Deep Learning techniques			
knowledge and use of Operational Research methods			
knowledge and use of optimization algorithms			

Table 7-2: Big data roles and competencies questionnaire – Example from H2020 Boost4.0 Project

Besides, to validate the People dimension for Pilots, a questionnaire can be designed in the form of a table (see the example in Table 7-2 from the Boost 4.0 project) concerning the aforementioned job profiles, which the pilots completed according to their situations.

In the first column of this table, all the jobs related to "Data science management"," professions due to the COVID19," and the skills required for them were mentioned, and in the second and third columns, pilots indicate whether they needed these skills in their company or were currently using them. To display this information, a numerical range between 1 and 5 has been used, which one depicts "basic level required" and five shows "expert level required".

In the last column of this table, the pilots specify if the skills are possessed by the company itself or by the project partners' collaboration. In addition, they specify how the skills gaps evidenced have been filled: "by training courses," "up-re-skilling," "hiring new personnel," "opening new collaborations".

7.2.6 Financial Impact Assessment

Eur3ka will develop a scorecard to monitor the financial impact assessment on the services proposed. In particular, the financial impact assessment will be performed according to the scenario undertaken. Considering that services are developed through the interaction with the users, in all the scenarios their satisfaction needs to be evaluated since it impacts on the overall financial performances. Actually, the services deployment, regardless the scenario under consideration, require an initial investment which will be assessed by using the financial impact indicators reported above in the previous section (e.g., ROI, NPV, IRR, PBT). These indicators will allow to monitor the returns after the investments and to evaluate the potentialities and benefits of new investments. Below, a detailed overview of the different scenarios is given. Note that the four scenarios presented in following paragraph, map to the reference scenarios presented in Section 3.

7.2.6.1 SCENARIO 1: Rapid reconfiguration and continuity of production line operation

The first scenario aims to cope with changes in production orders and to solve lack in modernisation, digitalization, and modelling and simulation problems providing both Virtual Commissioning (VC) for a safe and secure reconfiguration of production lines and also Digital Twins (DT) and digital Personas solutions for flexible/modular highly automated production lines.

VC is defined as the early development and validation of programmable logic controller (PLC) code using a virtual simulation model. It usually starts during the engineering process, which enables the model to detect inconsistencies and errors in the construction.

- As VC can be done in parallel to the production and assembly process, valuable time in the pending commissioning process can be saved by optimization loops.
- VC enables a safer commissioning and reconfiguration, given that previous detected errors are solved in prior to the real commissioning.
- Regarding the virtual model, it is possible to combine it with components of the real machine to test their future function, which results in a hybrid simulation. This brings advantages regarding performance, reliability and usability.
- One main advantage of VC is the possibility to verify the planned cycle time of the production system.

All these issues will feed the financial impact assessment and cost distribution modelling. In particular, the adoption of VC in existing engineering processes brings two main aspects to take into account:

- The monitoring of the initial modelling process which might cause most of the difficulties.
- the monitoring of implementation costs which might be higher at the beginning, as well as the considerable complexity of VC in general, that need to be balanced with the positive returns.

Focusing on human-machine interaction, VC and DT:

- can be used to identify risky system design or behaviour as well as to introduce workers to new machines in a safe, virtual space.
- to further achieve a risk assessment, they can conduct human simulation, not only focusing on planned human behaviour but also foreseeing possible accidents.
- Offer the possibility to virtual employee training.

The Eur3ka enablers, such as Digital Automation Platforms, DTs for production processes and business continuity frameworks, can solve most of the implementation problems, allowing to save money and mitigate risks which will be assessed through the financial impact assessment scorecard.

7.2.6.2 SCENARIO 2: Reliable repurposing of production processes.

In the second scenario, Eur3ka solutions aims to help manufacturers that want to switch the production to different products, in particular PPE and CCE.

In fact, about the possibility of expanding production to life saving medical equipment, the main aspects to be monitored are:

- Sharing manufacturing knowledge: any general manufacturing businesses, to convert production into a technically complex and highly regulated one, needs a significant amount of information, training, know-how, design information, machining templates, software, quality assurance and other protocols for good manufacturing practice in the medical device industry.
- Sharing regulatory approvals with the new entrants: for safety reasons, medical devices are subject to robust regulations and approval processes. Given the urgency, the quickest solution for increasing manufacturing capacity is for new manufacturers to rely on existing, approved manufacturing procedures, quality assurance programmes and certificates of conformity held by existing medical device manufacturers.

In this context, Eur3ka supports manufacturers providing Certification Frameworks, Digital Quality management and assistance in the Product Design and Engineering. The financial impact assessment has to take into account the benefits of such investment, that can cover the lack of know-how in the initial phase and during the entire operation.

7.2.6.3 SCENARIO 3: Resilient Smart Supply Networks

The third scenario reflects the supply chain challenges and the need to create more resilient networks. Investments are required to enhance the data sharing based on trusted relationships and to exchange manufacturing resources based on the real needs from the market to match the offer with the demand. These challenges require modifications affecting the long-term since new relationships might be created or already existing ones might be strengthened thanks to the introduction of new solutions.

The scorecard developed by Eur3ka will monitor the financial impact on the following aspects:

- The choice to establish stronger partnerships with specific suppliers to increase the supply chain resilience;
- The reshoring of part of the production avoiding to be bounded by transportations problems and other restrictions which might arise;
- The introduction of interoperable systems to enhance the interaction and alignment among the actors' systems belonging to the supply chain;
- A stronger engagement of consumers to align the offer with the market demand

7.2.6.4 SCENARIO 4: Resistant on-demand remanufacturing networks

The fourth scenario encounters the emerged need of increasing an on-demand manufacturing and remanufacturing network. Therefore, the introduction of new technologies, such the Additive Manufacturing, allows the on-demand production which is highly required in a context where the resilience capacity is fundamental for the survival of the business activity.

The scorecard developed by Eur3ka will monitor the following aspects:

- The financial impacts after the investment in the additive manufacturing technologies which will cover not only the asset itself but also the ad hoc training of the workforce. Therefore, the several costs that will be encountered will be justified by the potential to become;
- The financial impact registered due to different internal and external logistics management caused by the introduction of the on-demand production;
- The financial impacts due to the introduction of a reverse logistics network

All these scenarios must be sustainable not only from an economic point of view, but they need to cope also with the social and environmental sustainability. Thus, further accurate analysis need to be performed. Among all, as proposed in the extant scientific literature [Garcia-Muiña18], the Life Cycle Assessment (LCA) can be performed to assess the environmental impact of the new solutions at both factory level and network level based on ISO 14040:2006 (framework) and ISO 14044:2006 (requirements and guidelines). Second, to estimate the social impact determined by the introduction of the new solutions, the Social Life Cycle Assessment (S-LCA) is adopted to involve the internal and external stakeholders,

and last to empower the traditional financial indicators with a lifecycle perspective the Life Cycle Costing (LCC) allows to estimate the required costs along the entire lifecycle of the new solution. In addition to the life cycle thinking-related indicators, other indicators can be used to assess the sustainable performances such as: the energy and material consumption within the organization, and the ratio of renewable sources of energy usage over the energy consumed to guarantee high level of sustainability covering all the three sustainable pillars. Concerning the social impact, still in accordance with the financial aspects, another indicator that will be assessed is the Social Return of Investments (SROI) [Millar13]. This indicator will allow to assess the social returns on stakeholders after the investments performed according to the scenario under analysis.

As can be guessed, concerning not only the indicators but also the possible revenues related to such investment, setting up a prompt-response manufacturing system can have various advantages, some of which are helpful in a crisis increasing resilience, and others in boosting the manufacturing process in ordinary situations in a proactive way. Some of these benefits can be:

- **Prompt response in order to increase resilience**. This would allow the manufacturing of the product volumes necessary to tackle any possible situation swiftly and successfully, with all the tools necessary to fight important humanitarian and emergency crises. Such a mechanism has an immediate impact on public health, on the mortality rate and, in the medium term, on the economy.
- **Significant improvement in preparedness and resilience** not only for the internal needs but also in the context of European and international collaboration, opening new business opportunities.
- **Activation of supply chains suitable for the purpose**, such as production technologies that are easily reconfigurable and adaptable to different contexts.

In conclusion, the change in the factory internal processes and supply network capacities due to the PPE production means not only the development of diagnostic equipment and/or clinical care equipment, but implies also a transformation and revision of regulatory and collaborative manufacturing networks. These represent future opportunities for the factories and can be take into account for a long term financial assessment of the project.

8 Conclusions and Future Outlook

This deliverable has provided the initial specifications of most of the Eur3ka manufacturing plug and response services, which are destined to facilitate manufacturers to survive and excel in times of crises that cause major disruptions in their strategy and operations, such as the COVID19 pandemic. The various services have been provided in varying degrees of maturity and detail, given that the specifications of some of the services are still on-going. The deliverable has also provided a taxonomy of the services in terms of their functionality and their ability to support the Eur3ka scenarios. Specifically, the provided specifications of the Eur3ka services aim at enabling manufacturers to address four main scenarios, including:

- Rapid reconfiguration and continuity of production line operations.
- Reliable repurposing of production processes.
- Resilient smart supply networks.
- Robust on-demand remanufacturing networks.

These four scenarios are addressed by the Eur3ka pilots, while being representative of what most manufacturers had to do following the COVID19 pandemic outbreak. The description of the four scenarios was derived based on a thorough review of the state of the art and start of practice regarding how manufacturers addressed the pandemic and its implications. Moreover, the scenarios considered a review of various real-life case studies of manufacturing repurposing during the COVID19 pandemic, including case studies of the factories of the consortium (e.g., SEAC) and cases studies of third-party manufacturers that were contacted and interviewed in the scope of the present deliverable.

Different types of services were specified to address the above-listed scenarios, including flexible production services, industrial data spaces services for the COVID19 supply chains, services supporting flexibility in the supply chain, digital quality management services that facilitate product design, semantic data interoperability services that ease exchange of data in the scope of trusted supply chains, on-demand (re)manufacturing services based on novel technologies like 3D printing, as well as a rich set of digital twins technologies. Emphasis was paid in the specification of services that identified certification requirements and boost compliance to them. Moreover, a pool of production continuity services was specified, including services for plant risk assessment, shifts allocation, training and reskilling, remote manufacturing support, as well as financial impact assessment of manufacturing repurposing operations. Most of the specified components and services are based on background IP (Intellectual Property) and developments of the partners, including partners' products and developments in other R&D projects. Hence, in several cases Eur3ka services were specified as extensions or enhancements to existing products, components, and services. This is part of the project's strategy to provide high-TRL developments within the two year timeframe of the project.

In addition to providing the initial specifications for the above-listed services, the deliverable has also introduced (even at high level) a set of services integration concepts, which will be

considered in the platform specification and platform integration activities work in other work packages of the project, notably WP2 and WP4. Overall, the present deliverable will be provided as input to both above work packages, towards driving relevant activities such as the specification of the Eur3ka P&R reference architecture, as well as the integration of the Eur3ka platform. Besides, the present document has integrated and presented the manufacturing and business context of digital manufacturing services during the COVID19 crises, which is useful inputs to other activities of the project, such as the services requirements and the exploitation strategy specifications.

The detailed specification of the Eur3ka services and their integration points to other modules of the Eur3ka platform will be provided in the second deliverable of WP3 (D3.2), which will be effectively the second version of this deliverable. D3.2 will illustrate the technical details of each one of the Eur3ka services, including details on their integration. This final specification will incorporate also feedback from the initial prototyping and use of the services in lab environments. This feedback will enable the fine-tuning of the definitions provided in this deliverable, along with the more detailed specifications of the services.

9 References

[Arnaboldi15] Michela Arnaboldi, Giovanni Azzone and Marco Giorgino, “Performance Measurement and Management for Engineers”, ISBN-13: 978-0128019023, ISBN-10: 0128019026

[Czifra20] G. Czifra and Z. Molnár, “Covid-19 and Industry 4.0,” Res. Pap. Fac. Mater. Sci. Technol. Slovak Univ. Technol., vol. 28, no. 46, pp. 36–45, 2020, doi: 10.2478/rput-2020-0005.

[Keller14] M. Keller, M. Rosenberg, M. Brettel, and N. Friederichsen, “How Virtualization, Decentrazliation and Network Building Change the Manufacturing Landscape: An Industry 4.0 Perspective,” Int. J. Mech. Aerospace, Ind. Mechatron. Manuf. Eng., vol. 8, no. 1, pp. 37–44, 2014.

[David18] J. David, A. Lobov, and M. Lanz, “Leveraging Digital Twins for Assisted Learning of Flexible Manufacturing Systems,” in 2018 IEEE 16th International Conference on Industrial Informatics (INDIN), Porto, Jul. 2018, pp. 529–535, doi: 10.1109/INDIN.2018.8472083.”

[Dreyfus18] Dreyfus, P. A., & Kyritsis, D. (2018). A framework based on predictive maintenance, zero-defect manufacturing and scheduling under uncertainty tools, to optimize production capacities of high-end quality products. IFIP Advances in Information and Communication Technology, 536, 296–303. https://doi.org/10.1007/978-3-319-99707-0_37

[Factory2Fit18] Factory2Fit 2018, D4.1 Virtual Factory Platform, available at https://factory2fit.eu/wp-content/uploads/2018/10/Factory2Fit-D4.1-Virtual-factory-platform-%E2%80%93-Executive-Summary.pdf

[Furtado20] Vivek Furtado, Tom Kolaja, Curt Mueller, and Julian Salguero, “Managing a manufacturing plant through the coronavirus crisis Manufacturers can follow three guiding principles to keep their workers safe while preparing for increased uncertainty and long-lasting changes to the work environment”, Mckinsey Operational Practice, Report, April 2020.

[Garcia-Muina18] Garcia-Muina, F., Gonzalez-Sanchez, R., Ferrari, A. M., & Settembre-Blundo, D. (2018). The paradigms of Industry 4.0 and circular economy as enabling drivers for the competitiveness of businesses and territories: The case of an Italian ceramic tiles manufacturing company. Social Sciences, 7(12). https://doi.org/10.3390/socsci7120255.

[IDSA-RAM19] Industrial Data Spaces Association, Reference Architecture Model, Version 3.0 April 2019, available at: https://www.internationaldataspaces.org/wp-content/uploads/2019/03/IDS-Reference-Architecture-Model-3.0.pdf

[IFR2020] Executive Summary World Robotics 2020, available at: https://ifr.org/img/worldrobotics/Executive_Summary_WR_2020_Industrial_Robots_1.pdf

[Johansson09] B. Johansson et al., “Enabling Flexible Manufacturing Systems by Using Level of Automation as Design Parameter,” in Winter Simulation Conference, 2009, pp. 2176–2184, Accessed: Jun. 19, 2014. [Online]. Available: http://dl.acm.org/citation.cfm?id=1995754.

[Kumar20] Aalok Kumar, Sunil Luthra, Sachin Kumar Mangla, Yiğit Kazançoğlu, “COVID-19 impact on sustainable production and operations management”, Sustainable Operations and Computers, Volume 1, 2020, Pages 1-7, ISSN 2666-4127,Reference 1

[Links20] Links, P. (2020) Covid-19: International Manufacturing Policy Responses - A preliminary review of international approaches to supporting the manufacturing supply chains and workforce. University of Cambridge. Available at: https://www.ciip.group.cam.ac.uk/reports-and-articles/covid-19-international-manufacturing-policy-respon/download/2020-04-07-COVID19A.pdf.

[López-Gómez20] López-Gómez, C. et al. (2020) COVID-19 Critical Supplies: The Manufacturing Repurposing Challenge, United Nations Industrial Development Organization. Available at: https://www.unido.org/news/covid-19-critical-supplies-manufacturing-repurposing-challenge (Accessed: 27 November 2020).

[Malik20] A. A. Malik, T. Masood, and R. Kousar, “Repurposing factories with robotics in the face of COVID-19,” Sci. Robot., vol. 5, no. 43, pp. 17–22, 2020, doi: 10.1126/scirobotics.abc2782.

[Marco20] M Marco, M.L. Di Baker, P. Daszak, P. de Barro, E.A. Eskew, C.M. Godde, T.D. Harwood, M. Herrero, A.J. Hoskins, E. Johnson, W.B. Karesh, C. Machalaba, J.N. Garcia, D. Paini, R. Pirzl, M.S. Smith, C. Zambrana-Torrelio, S. Ferrier Sustainable development must account for pandemic risk Proc. Natl. Acad. Sci. USA (2020), 10.1073/pnas.2001655117

[Mesa15] J. Mesa, H. Maury, R. Arrieta, A. Bula, and C. Riba, “Characterization of modular architecture principles towards reconfiguration: a first approach in its selection process,” Int. J. Adv. Manuf. Technol., vol. 80, no. 1–4, pp. 221–232, 2015, doi: 10.1007/s00170-015-6951-3.

[Millar13] Millar, R. and Hall, K. (2013) Social Return on Investment (SROI) and performance measurement: the opportunities and barriers for social enterprises in health and social care. Public Management Review. 15(6), pp. 923-941. 1471-9037.

[Netland20] Netland, T. (2020) A better answer to the ventilator shortage as the pandemic rages on. Zurich.

[Okorie20] O. Okorie, R. Subramoniam, F. Charnley, J. Patsavellas, D. Widdifield, and K. Salonitis, “Manufacturing in the Time of COVID-19: An Assessment of Barriers and Enablers,” IEEE Eng. Manag. Rev., vol. 48, no. 3, pp. 167–175, 2020, doi: 10.1109/EMR.2020.3012112.

[Pagliosa19] Pagliosa, M., Tortorella, G., & Ferreira, J. C. E. (2019). Industry 4.0 and Lean Manufacturing: A systematic literature review and future research directions. Journal of Manufacturing Technology Management. https://doi.org/10.1108/JMTM-12-2018-0446

[Psarommatis20a] Psarommatis, F., May, G., Dreyfus, P.-A., & Kiritsis, D. (2020). Zero defect manufacturing: state-of-the-art review, shortcomings and future directions in research. International Journal of Production Research, 7543, 1–17. https://doi.org/10.1080/00207543.2019.1605228

[Psarommatis20b] Psarommatis, F., Prouvost, S., May, G., & Kiritsis, D. (2020). Product Quality Improvement Policies in Industry 4 . 0 : Characteristics , Enabling Factors , Barriers , and Evolution Toward Zero Defect Manufacturing. Frontiers in Computer Science, 2(August), 1–15. https://doi.org/10.3389/fcomp.2020.00026

[Sean20] Sean, O. (2020) How GM and Ford Switched Out Pickup Trucks for Breathing Machines, The Verge.

[Shaik14] A. M. Shaik, V. V. S. K. Rao, and C. S. Rao, "Development of modular manufacturing systems—a review," Int. J. Adv. Manuf. Technol., vol. 76, no. 5–8, pp. 789–802, 2014, doi: 10.1007/s00170-014-6289-2.

[Wiendahl07] Wiendahl, H. P., ElMaraghy, H. A., Nyhuis, P., Zäh, M. F., Wiendahl, H. H., Duffie, N., & Brieke, M. (2007). Changeable Manufacturing - Classification, Design and Operation. CIRP Annals - Manufacturing Technology, 56(2), 783–809. https://doi.org/10.1016/j.cirp.2007.10.003

[Yusup15] Yusup, M. Z., Wan Mahmood, W. H., Salleh, M. R., Muhamad, M. R., & Saptari, A. (2015). Synthesizing the domain of lean practices in manufacturing operations: A review. In Jurnal Teknologi (Vol. 77, Issue 1, pp. 153–162). Penerbit UTM Press. https://doi.org/10.11113/jt.v77.4133

[Zhong17] R. Y. Zhong, X. Xu, E. Klotz, and S. T. Newman, "Intelligent Manufacturing in the Context of Industry 4.0: A Review," Engineering, vol. 3, no. 5, pp. 616–630, 2017, doi: 10.1016/J.ENG.2017.05.015.

Horizon 2020
European Union Funding
for Research & Innovation

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 101016175