D5.1

First Integration PlugFest & Validation

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D5.1 First Integration PlugFest & Validation

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Disclaimer

Executive Summary

This document provides an overview of all Eur3ka project pilots, in terms of their early-stage implementation and the preparation of the infrastructures that will allow the validation and continuous assessment and/or pre-certification of the reused lines, equipment and digital manufacturing platforms for the product categories considered.

Specifically, Eur3ka project aims to demonstrate the reusability of manufacturers, with two broad families of pilot projects: (1) Digital Modular Rapid Repurposing for Medical Products, and (2) On-demand additive Manufacturing of Medical Supplies and Components. These pilots are based on the four manufacturing Grand Scenarios that fit the challenges raised during the COVID-19 outbreak.

- *Pilot Family 1: Digital Modular Rapid Repurposing for Medical Products (Section 3)*
    1. Fast configuration and deployment of medical and pharma lines
    2. Testing Facilities for PPE FF Masks
    3. Before & After COVID-19: Building a New Value Chain

- *Pilot Family 2: On-demand additive Manufacturing of Medical Supplies and Components (Section 4)*
    4. Additive Manufacturing at Danish Technological Institute
    5. Open 3D Printing Catalogue for Professional Additive Manufacturing Network
    6. Crowd Production and Validation

In this document, the relevant information for each pilot is summarised:

- General objectives
- Involved partners
- Current state (as-is)
- Future state (to-be)
- Expected results
- Proof of concept (PoC)

These pilots are mapped to the identified Grand Scenarios and the main services and components linked to each of them (Section 2), as the basis for integrating the pre-defined services in the Global Manufacturing Response Initiative (MGRI) Plug & Respond platform of the Digital Factory Alliance (DFA), to coordinate efforts in case of manufacturing processes or supply chain disruptions. In addition, all components, technologies and services deployed in the pilots are linked to the Eur3ka reference architecture, and they will be validated and verified within the Eur3ka certification framework, which is described in detail in section 5.

This deliverable shows the initial results of the pilots up to M14, the final results of which will be shown in the following deliverable D5.2 (M20).

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Definitions and acronyms

AM	Additive Manufacturing
AMN	Additive Manufacturing Network
API	Application Programming Interface
AR	Augmented Reality
CA	Consortium Agreement
CAD	Computer Aided Design
CCE	Clinical Care Equipment
DFA	Digital Factory Alliance
DoA	Description of Action
DNA	Deoxyribonucleic Acid
EC	European Commission
EU	European Union
FEA	Finite Element Analysis
FF	Full-Face
GA	Grant Agreement
GS	Grand Scenario
HMI	Human Machine Interface
KPI	Key Performance Indicator
IDS	Industrial Data Space
MaaS	Manufacturing as a Service
MAL	Manufacturing Autonomy Level
MGR	Manufacturing Global Response Initiative
P&R	Plug&Respond
PC	Project Coordinator
PCR	Polymerase Chain Reaction
PoC	Proof of Concept
PPE	Personal Protection Equipment
QMS	Quality Management System
R&D	Research and Development
RNA	Ribonucleic Acid
RTO	Research Technology Organization
SME	Small and Medium Enterprise
TC	Technical Coordinator
TH	Trial Handbook
UDI	Unique Device Identification
V&V	Validation & Verification
VC 4.0	Visual Components 4.0
VR	Virtua Reality
WHO	World Health Organization
WP	Work Package

1 Introduction

1.1 Scope and Purpose

The COVID-19 health crisis has demonstrated the major impact of globalisation on the manufacturing sector, as the outbreak caused an unprecedented large-scale disruption in manufacturing production and in the supply chain of manufactured goods. The closure of some countries' borders and the disruption of transport routes had a global impact. Prior to the pandemic, China accounted for 28% of manufacturing output and, as a result, European factories could not fully compensate for the shortfall.

For this reason, it is vital to reuse local factories to keep supply chains functioning, and so the Eur3ka project aims to help small and medium-sized enterprises to be prepared to reuse their machinery to manufacture a new product within 48 hours in the event of another crisis.

Additionally, European factories may not be able to meet the full demand, so local 3D printing networks are critical to start production quickly, especially of less complex devices (e.g., masks and glasses), but also for more complex ones, for which setting up a new production line would take longer. The Eur3ka project will demonstrate that it is possible to coordinate and establish strategic cooperation between 3D printing companies to help Europe's medical suppliers become more resilient, filling gaps in the supply chain when demand spikes or transport routes are disrupted.

One of the main challenges addressed in this project is the certification scheme. Medical products cannot be supplied without the authorisation of medical authorities, so Eur3ka aims to establish a pre-certification system for companies that need to certify changes in machinery, the production process or the skills of the workforce, as well as the final product.

Specifically, the re-use changes arising from the pilots will be verified and validated (V&V) to ensure the quality of the new developments. On the one hand, verification will ensure that the requirements of each phase are met. On the other hand, validation will examine and verify that the specifications, the developments or the pilots themselves meet the requirements and/or needs of the end user.

The scope of the V&V process is broad and involves different activities throughout the entire system development process. Some of these activities are:

- Design and implementation of test environments
- Coordination of test processes and definition of test tasks
- Formal documentation reviews
- Code reviews
- Implementation of quality and security standards
- Test design and execution: functional, load, performance and security testing

Finally, to facilitate collaboration between partners and accelerate this phase in a secure and reliable way, Eur3ka is working on the development of a community (the Digital Factory Alliance) to connect existing networks of health and government agencies, IT companies, manufacturing companies and bodies such as the World Economic Forum. The pilots will

serve as a reference for the need and proper functioning of this type of resilient and reliable reuse manufacturing network.

1.2 Methodological Approach

The development of the pilots will be carried out over three different waves, as represented in Figure 1. The whole development process will be followed by the Eur3ka validation and verification framework.

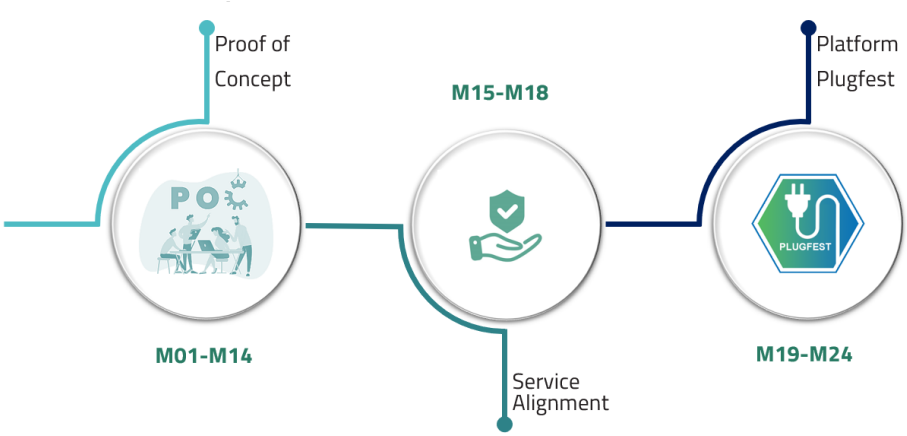

Figure 1. Pilot Timeline

1.2.1 First wave – Proof of Concept Development (M01-M14)

During the initial phase, use cases have been defined and related stakeholders have been involved in order to demonstrate the feasibility of deploying the proposed services and enablers within the Eur3ka concept to address the main challenges of the identified Grand Scenarios related to disruptions in the manufacturing sector. The Proof of Concept (PoC) includes the overall ambition of the trial, referring to the partial and global vision of the trial, the initial results obtained and the expected results to be obtained in terms of refinement and specification of components and services to be tested, new functionalities, etc. This phase has also defined the certification framework to address the verification and validation of the pilots' repurposing actions in the context of Eur3ka project. Accordingly, this deliverable is based on the PoC of the trials.

The Trial Handbook

The Trial Handbook (TH) is a key instrument to procure uniformity to the trials, with the aim of facilitating the collection of technical and business information, and in general, to organise and document all pilot results in a coherent way. That is, the TH is a single document for each pilot that serves to define in detail the processes carried out, ensuring that all the pilots are at the same level of development and facilitating the coordination of activities during the planned schedule. The applicability of this methodology has been successfully demonstrated in the first phase of the use cases‘ development.

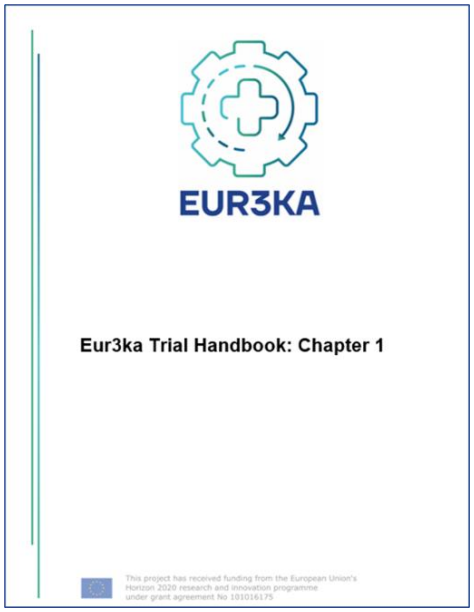

Figure 2. Eur3ka Trial Handbook

During the project, each demonstrator is going to complete and be responsible for its own TH and of the gathered information. Nevertheless, in order to improve the coordination and alignment of the activities of each demonstrator, the TH provides a common structure to gather and present data of all of the six demonstrators of Eur3ka. This approach will also:

- Facilitate the work within the different demonstrators
- Prevent overlapping among tasks
- Avoid duplication of effort by focusing all contributions from demonstrators in the TH

This iterative approach is the most suitable method when dealing with the definition of requirements, no matter the type of project it has been attempted.

Moreover, in the proposed approach, another trusted method for data acquisition has been defined on the basis of the methodology of Wellington created in "Research Methods for the Social Sciences". The Wellington methodology follows a 4-step method:

1. Brainstorming: jumbled, unjudged list of ideas, questions, areas of interest.
2. Classifying and categorising: areas, topics, questions, are grouped into classes or categories.
3. Creation of the guide: selection and judgement on which areas/questions will actually be explored.
4. Interview schedule: the phrasing of all questions into meaningful language, i.e., removing ambiguity; careful sequencing of questions, etc.

The revision of the Wellington methodology relies on the adaptation of the steps to the real requirements centred on Eur3ka demonstrator's ecosystem. Thus, the steps to be followed are:

- Conceptual design. Approach discussion and agreement.
- Classifying and categorising the content.
- Creation of the template.
- Circulation of the template to Eur3ka demonstrators.

- Organization of meetings with the demonstrators to explain the content required in each section.

The TH has been filled in after several meetings among the Eur3ka partners involved in the demonstrators, where a careful analysis of the relevant information to be collected has been carried out. The collected information is incorporated into a master document called chapter. As the project progresses, more chapters will be created, depending on the needs of both the demonstrators and the technical workpackages of the Eur3ka project. It is important to note that all TH chapters will be stored in the Eur3ka project Microsoft Teams repository, in this way partners who need information from Eur3ka use cases can consult it. For instance, in the case of this deliverable D5.1, information from chapter 1 of the TH has been used. For the other deliverables, different chapters will be used, as shown in Figure 3.

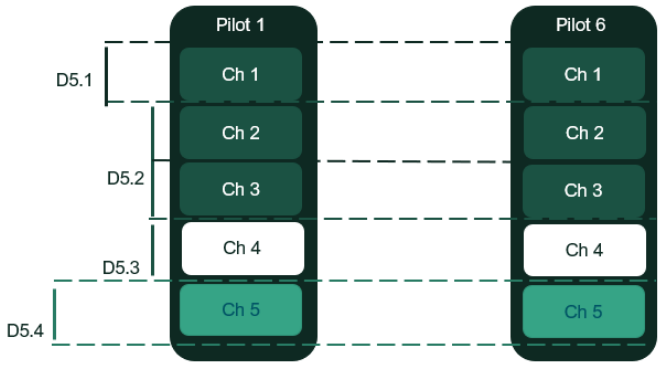

Figure 3. Possible linkage between the deliverables and chapters of the Trial Handbook

The table of contents of the first chapter is shown in Figure 4.

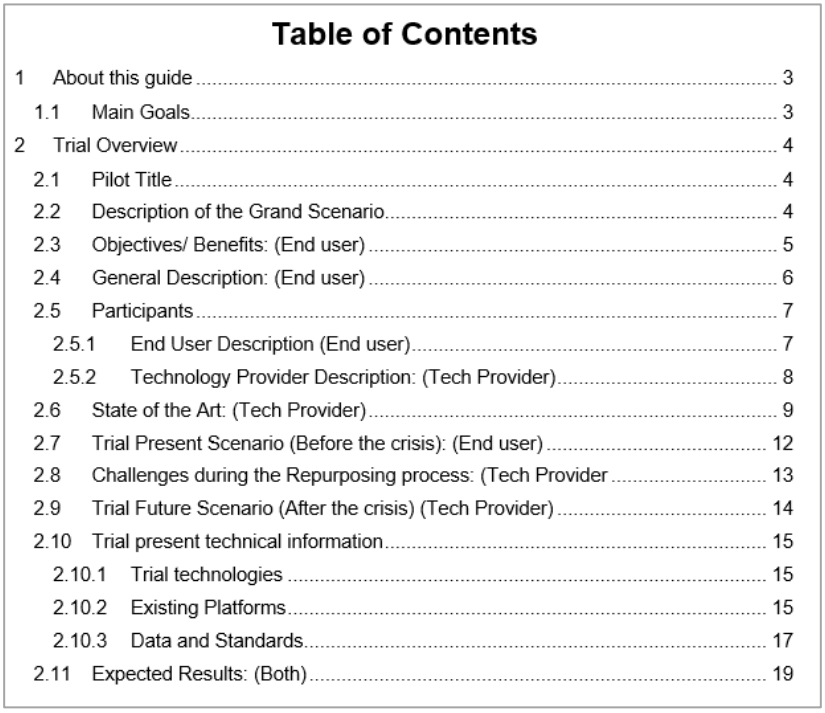

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Figure 4. Table of content of the first chapter of the Trial Handbook

1.2.2 Second wave - Alignment with Eur3ka services (M15-M18)

During the second phase, the trials will be focused on alignment with Eur3ka services, deploying the necessary components and technologies suggested in WP3 and WP4, and aligned with the WP2 Reference Architecture blocks, in order to face the repurposing challenges. In this phase, the certification framework will also be refined in line with emerging needs.

Therefore, the pilots are going to demonstrate their capability to deliver the previously identified services (i.e., D3.1) to overcome the challenges related to each Grand Scenario.

1.2.3 Third wave - PlugFest (M19-M24)

The third and final wave will be dedicated to the integration of the trial services into the Manufacturing Global Response Initiative (MGRI) Plug&Response platform of the Digital Factory Alliance (DFA) (Figure 5), which is further detailed in D2.2, after testing and approving in Eur3ka framework. The final aim of the project is to provide both a coordination and manufacturing repurposing management platform for Plug&Respond (P&R) for fast response to global value chain disruptions and outbreaks. Thus, the pilots will demonstrate that Eur3ka offers a unique and trusted capability to collectively connect and respond to sudden demand in a coordinated and effective manner in the event of a crisis, such as the COVID-19 health crisis.

The MGRI P&R platform will cover 4 main functionalities:

1. Identify user immediate needs, functioning as a direct contact channel.
2. Trusted and agile method to search for suitable assets.
3. Provide access to technology and know-how to users.
4. Prepare and improve for this type of environment between global contingencies.

Figure 5. MGRI Plug & Respond MaaS Network

More specifically, the main characteristics of MGRI (P&R) platform will be to:

- Guarantee digital production continuity and workforce qualification.
- Reinforce resilience and foster growth in the territory with strong digital and industrial repurposing policies.
- Enhance response and overall basic goods availability.
- Monetise spare production capacities and CAPEX investments.
- One stop shop to product & process quality certification.
- Operate through an interoperable, secure and trusted cloud and data space infrastructures locally provided to the DFA federation.
- Increase production capacity on-demand with low CAPEX.
- Fast response to demand peaks.
- Benefit from additional business opportunities through production repurposing strategies.
- Reduced risks through production diversification.
- Expert support in factories repurposing modernisation and digitization for increased resilience to value chain disruption.

1.2.4 Validation and Verification Framework

All the phases will be carried out within a certification framework to address the repurposing processes in the Eur3ka context. The validation and verification (V&V) structure establishes, in cooperation with regulators, the validation environment for the continuous validation of product conformity processes, as well as the rapid validation procedure for system validation in case of crisis affecting the manufacturing process and supply chains.

1.3 Linkage with other Deliverables

The first stages of WP5 aim at defining the scope and establishing the goals of the pilots, based on the Grand Scenarios and functionalities of the Eur3ka manufacturing platform

described in D3.1 "*Early Rapid Medical CCE/PPE Production Specifications & Eur3ka R3 Service Definition"* and D3.2 *"Final Rapid Medical CCE/PPE Production Specifications & Eur3ka R3 Service Definition".*

Additionally, the pilots will be completely aligned with the Eur3ka platform services and technical enablers described in D4.3 "*EUR3KA R3 Cognitive Digital Twin Services – First release*", which are at the same time mapped toward the Eur3ka Reference Architecture defined in D2.1 *"Eur3ka Manufacturing Repurposing Reference Framework & Data Management Plan".*

1.4 Structure of the Document

The rest of the document is structured as it follows:

- Section 2 defines the framework in which the pilots are set up, in relation to the Grand Scenarios, the main components and services deployed and the mapping in the Reference Architecture.
- Section 3 and Section 4 present the pilots build under Eur3ka repurposing framework, with the aim of enhancing the repurposing capacities. The general scope of the pilots is shown, as well as the work done so far and the main upcoming actions.
- Section 5 is devoted to the initial scope and working lines for the Verification and Validation (V&V) scheme, which will be developed as an efficient and flexible Certification Scheme in the framework of Eur3ka.
- Section 6 draws the main conclusions and the future outlook for further developments and services alignment.

2 Coverage Strategy

2.1 Mapping of Grand Scenarios with Main Services

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 (GS) have been 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).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. For this aim, it is necessary to increase the levels of modernisation, collaboration and coordination among (I) factory and cross-factory manufacturing processes, (II) supply network processes and (III) regulatory processes.

On this basis, some essential services have been identified to respond to the challenges for a more resilient and reliable repurposing network of manufacturers. The following Table 1, which is included in deliverable D3.2, shows the main services related to each GS (“M” means that the service is mandatory for supporting the scenario, and “O” optional).

Eur3ka Transformation Scenarios	Production Line Reconfiguration	Digital Quality 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 production processes	O	M		M		M	M	O
S3: Resilient smart supply networks				M	M		M	O
S4: Robust on-demand			M			O	O	O

remanufacturing networks								

Table 1. Mapping of Eur3ka main services with the Grand Scenarios

The Table 2 shows the main services that each pilot is deploying, according to the corresponding GS.

Eur3ka Transformation Scenarios	Production Line Reconfiguration	Quality 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	P1			P1		P1		P1
S2: Reliable repurposing of production processes	P2	P2				P2	P2	
S3: Resilient smart supply networks				P3				P3
S4: Robust on-demand remanufacturing networks			P4/P5/P6			P4/P6		

Table 2. Mapping of the pilots with the main services according to the GS

From this table, it can be concluded that, for example, the initial objective of pilot 1 is to develop and implement a fast and reliable simulation library to **reconfigure a production line**. Virtual commissioning technologies will be further developed in Eur3ka to validate the design in the **digital twin**, reducing the resources (time and material) needed for commissioning and ramp-up of the line in the operational space. In addition, virtual models will facilitate the **certification process**. Validation and certification methodologies will be developed to accelerate the certification process in the virtual scenario. Finally, to maintain **business continuity**, virtual training and remote support will be implemented, as well as a manufacturing repurposing skills framework.

Accordingly, the following subsections describe the scope of each GS (the descriptions in italics are based on deliverable D3.2), and the linkage of the pilots to each of them.

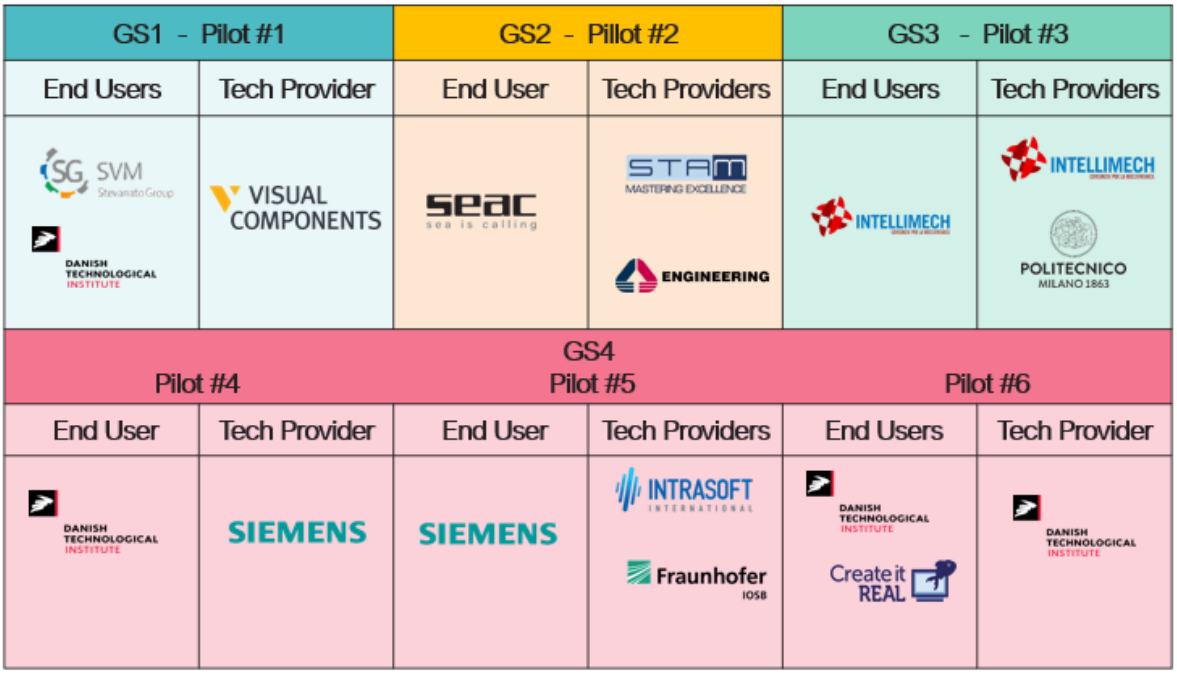


Figure 6. End User(s) and Tech Provider(s) of the pilots classified according to the corresponding Grand Scenario

2.1.1 GS1. Rapid Reconfiguration & Production Line Continuity (Reconfiguration of Production)

"GS1 is focused on the reconfiguration of production lines forced by the disruptions on the supply chains and changes in the customers´ demand. This scenario considers to maintain business continuity based on a shift allocation smart solution tool, risk assessment tools to evaluate the risk of the repurposing of the reconfiguration of the production lines, as well as the use of virtual commissioning technologies for repurposing production lines."

Pilot #1

This pilot related to GS1 is focused on the pharma and medical supply industry, which is characterised by the required high level of customization, as well as total quality solutions.

SVM provides a wide range of modular solutions for the pharma industry, which requires a high level of customization for the end user, that is, an ad hoc design. This modularity provides a high level of flexibility for the configuration of the production cell and the extensibility for future production demands.

The solutions provided by SVM target complex assembly problems typically characterized by tight tolerances, challenging geometries, and rigorous in-process quality controls. SVM modular solutions are engineered to meet the current market needs and deliver precision assembly of a wide variety of medical devices, including pen injectors, auto-injectors, nasal sprays, inhalers, and wearables.

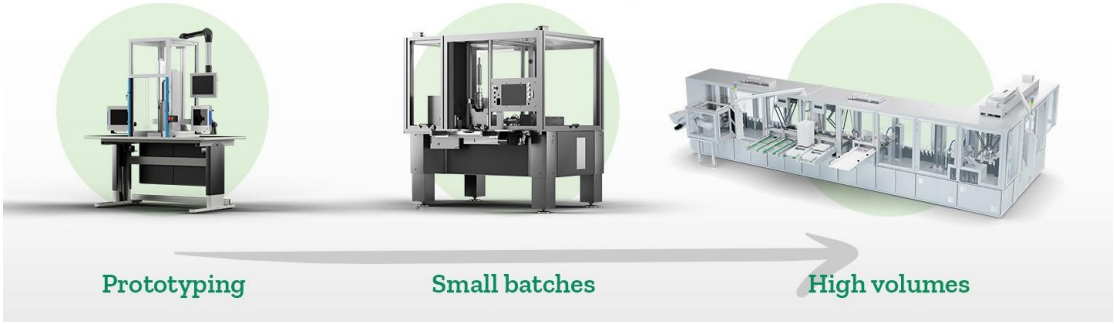


Figure 7 Pilot 1 properties

2.1.2 GS2. Reliable Repurposing of Production Processes (Repurposing of Products)

"GS2 pictures cases where manufacturing enterprises decide to make changes in the products they produced, to which end the production processes are repurposed. In this situation, Eur3ka project highlights the necessity to have quality manage system (QMS) to meet quality objectives in the new or modified products, or to give support on the improvement of the flexibility capacity of the manufacturing systems."

Pilot #2

In the case of pilot 2, SEAC needed to be capable of a rapid repurposing action in order to respond properly to a sudden high demand for personal protective equipment.

To do this, SEAC focuses on achieving the following goals:

- Rapid reconfiguration and continuity of production line operation
- Reliable repurposing of product
- Resistant on-demand remanufacturing networks
- Resilient smart supply networks

The need to re-configure production lines during pandemic situations is based on two main reasons: reduction of orders/personnel and need for social distancing among operators. This, during the first wave of COVID-19, was done by the manufacturing company, but without relying on standard methods/tools/platforms. Within Eur3ka, the re-configuration of the production lines will be modelled and simulated with reduced production capacity and reduced (or null) workforce presence. This will allow virtual commissioning of a safe and secure reconfigured Production Line Digital Twin and Digital Personas.

Another important need for SEAC is readiness for a quick repurposing to produce different products, caused by the high demand of PPE and CCE, while a low demand of their original products. This, contrary to what happened and thanks to Eur3ka, will rely on New Product Design, Engineering, Simulation as well as increased Manufacturing Automation, Quality Management and Medical Certification. The goal is to improve the quality and certification KPIs (time cost quality) of existing products.

Still, in regard of guaranteeing readiness for quick repurposing, resistant on-demand remanufacturing networks are needed. This scenario focuses on the execution of the order (usually a "one-of-a-kind" product) through an on-demand Additive Manufacturing network. This network will rely on the information sharing from manufacturer (Production Capabilities, Certification Levels) to manufacturer (CAD, specifications, constraints "no duplication"). For this purpose, Eur3ka will provide IDSA Data Sovereignty principle. Additional constraints about access and usage rights must be added and implemented, maybe also in a selective way.

Finally, a sudden necessity for re-configuring the production lines, for political or market reasons, can create problems to manufacturing supply chains. In order not to interrupt essential supplies to manufacturing companies, resilient smart supply networks are needed. The solution would be to provide Manufacturing as a Service in a network of trusted companies that share data in a common/shared Data Space. This will be achieved during Eur3ka project through IDSA Data Sovereignty principle, Industrial Agreement and a trusted pan-European federated networking and computing infrastructure.

The experiment's Test Bed is the repurposing of SEAC's diving FF (Full-Face) mask into a medical FF mask.

Figure 8. Medical FF mask

2.1.3 GS3. Resilient Smart Supply Networks (Reshoring of Supply Chain)

"GS3 highlights the value of establishing smart supply chain networks that can flexibly adapt to large scale disruptions to supply chain operations. Such supply chain networks must support the fast, trusted and secure exchange of information across the various stakeholders involved. Based on the exchange of this information more flexible and resilient supply chain operations can be supported."

Pilot #3

Pilot 3 refers to supply chain interruptions due to disruptive events, such as pandemics, or supply chain modifications, which can be driven by social (re-shoring), political (sovereignty), or market reasons. Specifically, this pilot is based on the necessity raised during the pandemic to support the health service in filling gaps in the supply of medical equipment, commonly exploiting collaboration among different companies, including raw material

suppliers as well as companies dealing with raw materials conversion, packaging and distribution. In this context, the rapid establishment of trusted supply chain networks has been one of the main challenges to overcome.

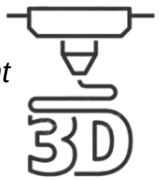
As a consortium of 42 high-tech enterprises, Intellimech could collect and compare different experiences from several industries acting in the Lombardy region. This pilot will provide an overview of the adopted measures, identified risks and lessons learned. More specifically, one use case will be anonymously illustrated as a virtuous exemplum of business repurposing and local supply chain redefinition to refurnish local medical establishments with gowns, headgears and footwears.

Moreover, insights from at least 2 advanced firms belonging to the Intellimech consortium will be reported to analyze how manufacturing companies could react to such a disruptive event modifying internal procedures, interaction with clients/suppliers and services provided.

Finally, the benefit deriving from supranational initiatives will be evaluated thanks to interviews and assessment analysis with these companies, focusing, in particular, on the employees' re/up-skill procedures and on the financial impact. Concerning the re/up-skill procedures, a virtual training demonstrator will be developed and made available to IMECH partners in order to illustrate the connected opportunities and collect feedback from industry representatives on its actual applicability.

2.1.4 GS4. Robust On-Demand Remanufacturing Networks

"GS4 is about providing support for the Manufacturing as a Service (MaaS) paradigm, leveraging capabilities of 3D printing and additive manufacturing. This scenario includes aspects of trusted supply chain as it is of paramount importance to share digital models in trusted ways (e.g., for the IP protection reasons). Since this scenario includes trusted supply chain management aspects, it can be connected to Scenario 3 i.e., it can share infrastructures and technology with the previous scenario."



Pilot #4

Pilot 4 relates to GS 4, as it is focussed on the execution of the order through an Additive Manufacturing (AM) production line where production takes place on-demand.

Three cases have been selected, where an additional element of quality assurance is present. These are chosen to represent different levels of complexity when it comes to constraints on the production. Focus is on the value gained through certified production, e.g., production adhering to ISO 13485.

Pilot #5

During the COVID-19 crisis, the rapid and evolving uncertainties have led to some key experiences such as the lack of operational capacity of healthcare intensive care units, the lack of spare parts for devices that are often produced by a very limited number of specialised companies, and the lack of standardised methods of design exchange and validation.

Additive manufacturing capability is one of the main ways to realise customised products, as well as offering the possibility to optimise complex designs. During a crisis, one of the main efforts is based on the need to match demand with suppliers' capabilities in a safe way. The Siemens Additive Manufacturing Network is a service capable of significantly covering a wide range of demands, from mass production of designs to niche replacement parts. Its role is to connect demand with the right suppliers, knowledge, expertise and technology partners needed for complex industrial scenarios, all in a secure and trusted ecosystem where enabling instant pervasive collaboration is a necessity.

Pilot #6

As millions of 3D printers get sold worldwide every year this volume is mostly driven by the low-cost printers under 500 €. During the COVID-19 pandemic individuals, maker space, schools, and small and medium size companies in possession of one of these low cost 3D printers decided to fight back the crisis by repurposing their 3D printer to produce personal protection equipment. By doing so they were the first one to be able to provide personal care equipment within a few days.

The power of the crowd was for the first time used to produce. Those low-cost 3D printers are normally used as a learning tool or a tool to make prototypes. But they can also be used as real production equipment. This GS is looking at the crowd production scenario, looking at the lessons learned during the pandemic and the fast reaction of the makers (used in the wider term here but covering the individuals, maker space, schools, and small and medium size companies).

When repurposing a hobby 3D printer, basically it could almost be considered a toy, number of considerations arise around the printed parts such as quality, tolerance, functionality. Those criteria evolve with the level of shortage of the parts. For example, certain medical establishment were happy to receive help from makers delivering personal production equipment at the beginning as there was a shortage. But then as alternatives arise, they did not want them anymore or more strict quality checks were implemented.

This GS goal is to demonstrate how this can be done by providing the right platform to makers to achieve such crowd production successfully. It should provide a method to summit 3D files to be optimized for production on low-cost 3D printers, made accessible to anyone for printing and provide metadata related to ensuring the right level of quality; preferably decentralized too, so in other words crowd quality control guidelines.

2.2 Pilot Mapping with the Reference Architecture

Figure 9 shows where the pilots are located in the reference architecture, according to their linkage with the GS described above.

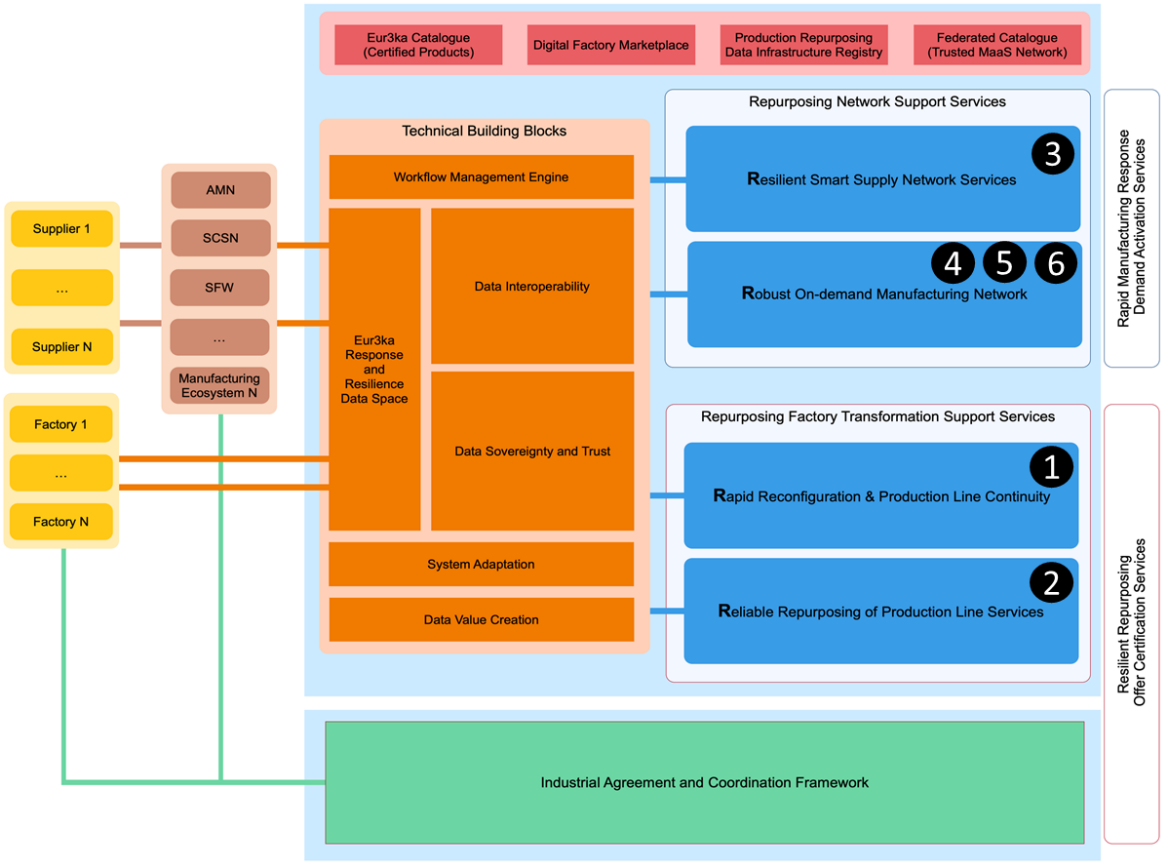


Figure 9. Pilot Mapping with the Eur3ka Reference Architecture

3 Pilot #Family1. Digital Modular Rapid Repurposing for Medical Products

This set of pilots deal with the assessment and validation of Eur3ka network increased manufacturing capacity to respond to peaks of demand with the support of production line reconfiguration, repurposing of products and smart matching in the supply chain. These use cases are based on the modernisation and digitisation for the factory transformation, creating digital workplaces that include new capabilities such as the use of Artificial Intelligence.

The first family of pilots respond to three distinct needs:

1. **Reconfiguration of production lines** for reasons such as the reduction of orders and staff, as well as the need for social distancing. The aim is to model and simulate the production lines with reduced production capacity and reduced (or null) workforce presence and maintain business continuity.
2. Manufacturing companies need to repurpose their factories to **produce different products**, and consequently their production lines, for two main reasons: high demand for products required to face the global spread of COVID-19, low demand for their original products. For this purpose, it is needed: (i) Quality Control Design Tools since medical regulations quality standards are complex; (ii) Flexible Production Line Design based on modularity, dynamic information flow, remote operations, data valorisation, up/re-skilling, flexible planning, automation and decision support; and (iii) Resiliency Maturity Assessment to facilitate the adaptation of production to respond to the changing production requirements.
3. Manufacturing supply chains can suffer unexpected disruptions and/or need to be reconfigured to respond and recover quickly to the demand, maintain operations at the desired level. **Trusted digital Supply Chain Networks** need to share production capacities to match demand with offer. The common business model is Manufacturing as a Service (MaaS) in a network of trusted companies which share data in a common/shared Data Space.

Figure 10 shows the pilots in this family addressing these needs, which are described in more detail in the following section.

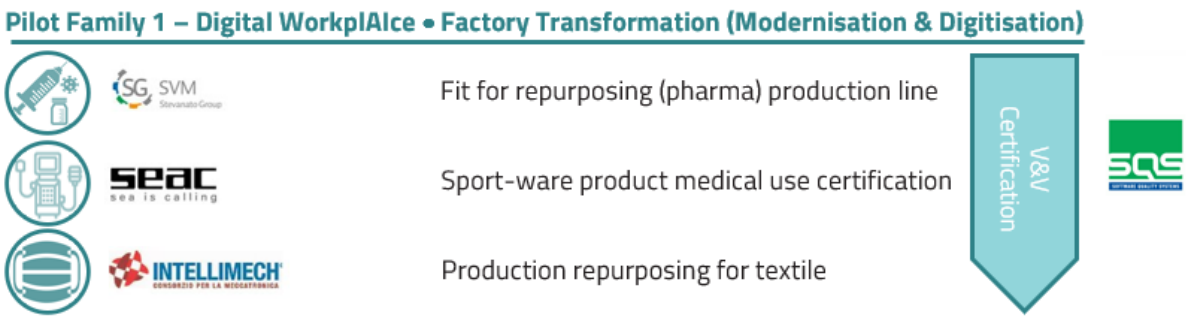


Figure 10. Pilot Family 1

3.1 Pilot #1. Fast configuration and deployment of medical and pharma lines

3.1.1 Technological Scope

3.1.1.1 Objectives

The initial objective for this pilot is to develop and implement a fast and reliable simulation library to concept and design semi-automated and fully automated lines for pharma and medical purposes.

The simulation library will facilitate to the different stakeholders the communication to make detailed designs, starting from the requirements and specifications. Concepts can be easily created to analyse production flows and costs, efficiently start the engineering process without leaving the virtual environment, and work with digital models that mirror the real equipment.

Datasets created from the requirements and specifications will be extended along the life cycle phases to be seamlessly integrated within all the processes. The simulation library is developed on top of Visual Components 4.0 (VC 4.), which will ensure the seamless integration of the engineering processes and the utilization and extension of the datasets.

Communication between the different stakeholders will be possible using 3D visualization and VR technologies. In addition, these visualization technologies will support the operators' training in parallel to the engineering phase, supporting the skills development of the operators. The digital models provide accurate system detail, even before the real system has started to be built, enhancing the design's optimization, merging knowledge from operators, designers, and integrators, and identifying errors in the early stages, avoiding costly mistakes.

Virtual commissioning technologies will be further developed within Eur3ka to validate the design in the digital twin, reducing the resources (time and material) required for commissioning and ramp-up of the line in the operational space. In addition, the virtual models will facilitate the certification process. Validation and certification methodologies will be developed to accelerate the certification process in the virtual scenario.

3.1.1.2 Participants: end user & tech provider

The participants involved in this pilot are Stevanato Group (SVM) as end-user, Visual Components (VIS), and Software Quality Systems (SQS) as technology providers, supported by the Danish Technological Institute (DTI).

End User: SVM

SVM is specialized in the design and construction of high-technology machines and systems for packaging, assembly, and serialization for pharmaceutical products. SVM develops specialized machines from the conceptual phase to production, testing, and service. Founded in 1974 in Denmark, the company joined Stevanato Group in 2016

Tech Provider: VIS

VIS is recognized as a global leader in the manufacturing simulation industry and a trusted technology partner to many of the leading brands in industrial automation. VIS develops and commercializes a 3D factory simulation and visualization suite that consists of innovative tools, which set the standard for modern simulation. The simulation suite provides an open platform for system providers, integrators, and end-users to collaborate along the entire system life cycle in the system's concept, design, commissioning, and operation. The solution extends the simulation capabilities with open standard communication interfaces to integrate with virtual commission technologies and enable the digital twin.

Tech Provider: SQS

SQS is a company specialized in carrying out verification and validation activities of critical security systems. With experience in the railway and medical equipment sectors, it has knowledge in the application of related regulations. Within the field of health, SQS has collaborated both in the realization of Verification and Validation activities (such as different kinds of medical devices, manufacturing and warehousing facilities) as well as in the definition and implementation of the development and testing strategy itself (e.g., newly created clinical hair removal equipment).

3.1.1.3 Trial present scenario (as-is)

The development and deployment of pharma and medical lines entails a high complexity as it is an area that requires high customization and the fulfilment of strict regulations. Total quality is a must in the commissioned system, accomplishing the required regulations, and documenting all the processes according to the requirements.

Testing during commissioning and ramp-up requires the use of resources, such as time and materials, that can account, depending on the case, up to 10% of the cost of the system.

3.1.1.4 Trial future scenario (to-be)

The COVID-19 crisis brought different medical and pharma industry situations which can be summarized in three scenarios. In the first scenario, the equipment is available in the facility and requires fast repurposing for the new demands. In the second scenario, the equipment available in the facility requires to be extended and repurposed for the new production requirements. The third scenario targets the case that the facility should be configured from zero. All the line has to be configured from the use cases requirements depending on the available systems or the possibility of building the systems and integrating them according to requirements and specifications.

3.1.1.5 Expected results

The simulation library developed on top of Visual Components 4.0 (VC 4.0) is a scalable solution that supports Eur3ka targets. The scalability allows defining within the simulation environment the requirements starting from the high level of the process and going into a higher level of detail. In this way, it is possible to begin the definition of the processes to be accomplished. Based on the production requirements, equipment is selected according to the availability and integration within the line. Once the equipment is set up within the virtual environment, it can be further detailed according to the specifications reaching the sensor and actuator level and specifying the I/O signals and connections.

The entire workflow from concept to operation is developed within VC 4.0, which facilitates the communication between the stakeholders, providing a realistic 3D visualization and VR support and data analytics (Figure 11). Furthermore, VR can be used in the training of operators of the lines from an early stage of the engineering design, allowing the identification of errors even before the commissioning has started. The processes workflow and the equipment signals will be used before commissioning to be validated within the virtual commissioning using the communication interface provided by VC 4.0 and the communication interfaces developed under Eur3ka.

Figure 11. Screenshot of a laboratory design example in VC 4.0, using components from the virtual library.

The utilization of the virtual models to complete certification tasks and generate related documentation is planned to be developed.

Table 3 summarizes the technology to be implemented in pilot 1.

No	Technology or Result	Technology/Result Provider	
7	Certification Support Tools	SQS	WIP
12	Manufacturing Repurposing Skills Framework	POLIMI	Linked to 13
13	Virtual Training and Remote Support	VIS	X
21	Visual Components 4.0 Platform	VIS	X

Table 3. Technologies to be implemented/developed in pilot 1.

3.1.2 PoC Results

The proof of concept targets the utilization of the simulation library in the fast deployment of an automated line for COVID-19 PCR testing.

A polymerase chain reaction (PCR) test for COVID-19 is an accurate and reliable diagnosing test for COVID-19. Since its use was authorized to detect COVID-19 in February 2020, the PCR test has been the standard for diagnosing COVID-19. It's accurate and reliable to

detect genetic material from a specific organism, such as a virus. Based on the presence of the virus at the moment of testing, the result can be positive or negative. Furthermore, the test could also detect fragments of the virus after the disease.

The polymerase chain reaction test for COVID-19 is a molecular test that analyses an upper respiratory specimen, looking for genetic material (ribonucleic acid or RNA) of SARS-CoV-2, the virus that causes COVID-19. Scientists use the PCR technology to amplify small amounts of RNA from specimens into deoxyribonucleic acid (DNA), which is replicated until SARS-CoV-2 is detectable if present.

Testing process

There are three steps to perform for a COVID-19 PCR test:

1. **Sample collection:** A healthcare provider uses a swab to collect respiratory material found in the person's nose. A swab is a soft tip on a long, flexible stick that goes into the nose. There are different nose swabs, including nasal swabs that collect a sample immediately inside your nostrils and nasopharyngeal swabs that go further into the nasal cavity for collection. Either type of swab is sufficient for collecting material for the COVID-19 PCR test. After collection, the swab is sealed in a tube and then sent to a laboratory.

2. **Extraction:** When a laboratory scientist receives the sample, they isolate (extract) genetic material from the rest of the material in the sample.

3. **PCR:** The PCR step then uses special chemicals and enzymes, and a PCR machine called a thermal cycler. Each heating and cooling cycle increases (amplifies) the amount of the targeted genetic material in the test tube. After many cycles, millions of copies of a small portion of the SARS-CoV-2 virus's genetic material are present in the test tube. One of the chemicals in the tube produces a fluorescent light if SARS-CoV-2 is present in the sample. Once amplified enough, the PCR machine can detect this signal. Scientists use special software to interpret the signal as a positive test result.

Eur3ka proof of concept

The fast advance of COVID-19 has required increasing the number of COVID-19 PCR tests to a more significant population. While the collection of samples (step 1) can be increased easily, the processing and analysis of the samples (steps 2 and 3) require time and the availability of qualified lab personnel and equipment.

Using automation solutions to process and analyse the samples (steps 2 and 3) can optimize the work of the laboratory scientists and maintain a high level of performance. In the market are available several technology providers with solutions that can be adapted to the requirements and integrated by competent systems integrators.

The simulation library, under development in Eur3ka, can be decisive in the analysis of requirements, evaluation of the market with the alternatives offered by the different providers, concept design according to the requirements and specifications and deploy a communication solution using the 3D virtual environment provided within Visual Components 4.0.

The POC is based on the requirements for deployment of the new PCR analysis system, which includes:

- The equipment will be set up in the available facilities (Figure 12)
- Will provide the functionalities to perform steps 2 and 3 of the PCR tests for COVID-19
- Minimum involvement of scientists is a must, so maximum automation is required. In addition, will be able to optimize to maintain security distance between operators.
- As testing time per sample is process locked, several configurations must be defined to have maximum efficiency
- Efficiency KPIs is determined by the cost per test
- The system should be able to process up to 30k samples/24 hours.
- Initial utilization time 24 months
- Equipment must be modular, which allows relocation to new locations if necessary.

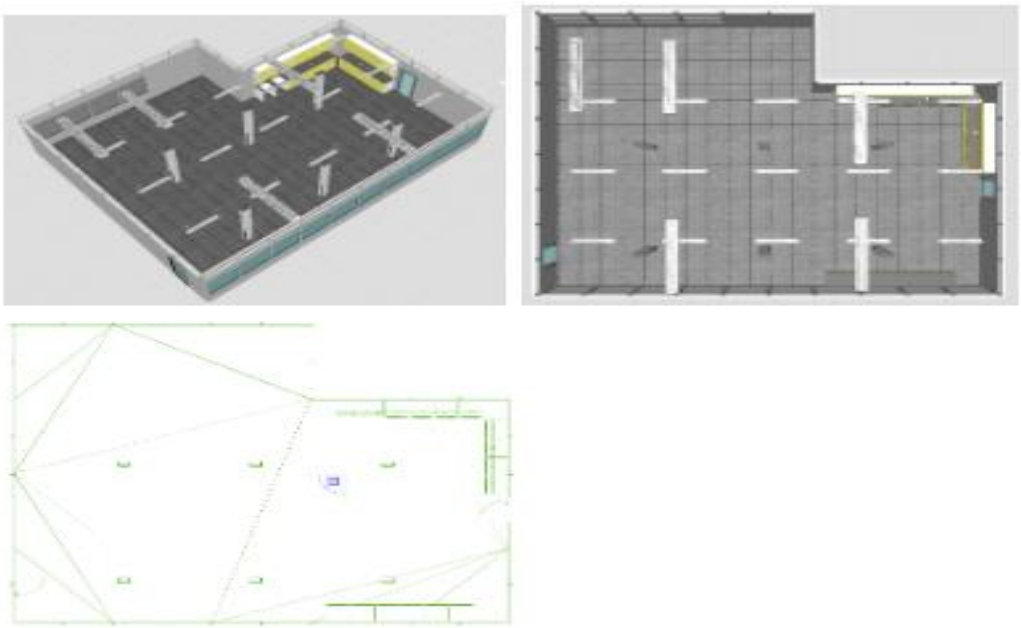


Figure 12. Detail of the available facilities

Once the initial requirements have been defined the VC 4.0 environment allows importing in the virtual space the facilities layout and the workflow starts, defining the processes and adding the equipment as shown in Figure 13.

Figure 13. Screenshot of VC 4.0 user interface while building the automatic lab cell.

Different configurations can be added during the design process, workflows and processes can be modified, redefined and the level of detail increased to be visualized and analysed. To finally proceed to validation using the virtual commissioning and the generation of the related documentation (Figure 14).

Figure 14. Final view of a completed automation laboratory design in VC 4.0

3.2 Pilot #2 Testing Facilities for PPE FF Masks

3.2.1 Technological Scope

3.2.1.1 Objectives

The need to re-configure production lines during pandemic situations is based on two main reasons: reduction of orders/personnel and need for social distancing among operators. Another important need for SEAC is readiness for a quick repurposing to produce different products, caused by the high demand of PPE and CCE, while a low demand of their original products.

The experiment's Test Bed is the repurposing of SEAC's diving FF (Full-Face) mask into a medical FF mask.

With its participation to the project, SEAC aims at the following benefits:

- Automation of the process
- Design support and optimization
- Test Results database
- Best practices towards certification

Automation of the process: the End User will exploit the tech providers' expertise to improve the as-is features of the two testing machines (CO2 residual measurement and breathing effort), in particular, to increase the level of automation of the process and decrease the needed time for tests.

Design support and optimization: SEAC aims at using the test results to optimize the design and manufacturing techniques for FF masks. To do this, SEAC needs a tech provider as an AI expert, able to develop an AI module to consume test data and put them in relation with the design parameters of the current FF mask model (e.g., the 3D geometry, materials, manufacturing methods, etc). This would be useful as a decision support tool for SEAC, to go towards an optimization of the test parameters.

Test Results database: thanks to the improvement to be done on the testing facilities, SEAC will be able to gather a database of results of tests to automatize the tracking procedure for FF masks performance. This benefit will allow SEAC to save 50% of the time when information on historical tests is needed and will open possibilities as selling data themselves to other companies interested in having a benchmark for CO2 and breathing effort testing.

Best practices towards certification: during the first COVID-19 pandemics, SEAC found the lack of legislation and regulations at the European level for anti-viral FF masks. Due to this lack, SEAC used parts of different regulations to find references for the optimal parameters in terms of CO2 residual inside the masks and breathing effort for such devices, but a unique regulation dedicated to these devices is not existing. Eur3ka project will support SEAC in processing test data to define some recommendations towards policy makers and standardization bodies, to pave the way for defining a European regulation.

3.2.1.2 Participants: end user & tech provider

End User: SEAC

SEAC, leader in the diving sector, is an Italian company and manufacturer of a wide portfolio of diving products. SEAC was founded in 1971 in San Colombano Certenoli, a small town in the province of Genoa. Currently the company is one of the main Italian providers for sea-sports equipment, leveraging a flexible supply chain and proudly delivering Made in Italy technical products.

SEAC constantly strives for improvement through its staff of professionals, engineers and designers, which in the Italian Headquarters designs, improves and perfects the smallest of details with the help of cutting-edge technological tools. The attention to technical components is accompanied by that for the aesthetics, which thanks to the work of expert hands gives each piece an unmistakable Italian touch.

Within the Eur3ka project SEAC provides one of the project manufacturing settings that will demonstrate a flexible 48-hour industrial response capability at scale, to cope with sudden spikes in demand of ventilator masks. Since the COVID-19 emergency took Europe by storm, SEAC committed to leveraging its manufacturing facilities to deliver vital medical equipment.

Tech Provider: STAM

STAM is a private engineering company with a staff of more than 35 people, based in Genoa, Italy. The main mission of the company is to provide engineering services to industries. Since its establishment in 1997, the company has been specializing in the design and manufacturing of innovative mechanical systems, based on conventional and non-conventional robotics and mechatronics.

The Company performs all stages of the product design cycle, from conception through validation with CAD and FEA tools, to component and subsystem design and specification, down to the definition of tools, and production cycles. STAM has been deeply involved in automation, robotics and new product development in several industrial fields.

In particular, STAM has deep expertise in the design and development of complex automation systems for production and testing environments, with a focus on the integration of multisensory systems and data production and exchange in real time. Control loops driven by sensor activity are one of the expertise fields of the company too.

Tech Provider: ENGINEERING

The ENGINEERING Group (ENG), Eur3ka project coordinator, is the leading Italian software and services group, with 12,000 employees and 65 sites distributed in Italy, Germany, Spain, Belgium, Republic of Serbia, South America (Brazil and Argentina) and United States, a consolidated revenue portfolio in 2019 of almost 1.27 billion Euros. Engineering has a consolidated presence on all vertical markets and operates through its 4 business units - Public Administration & Healthcare, Telco & Utilities, Industry & Services, Finance - supported by cross-business unit centres of competence and by the Research and Innovation Department which has the dual role of promoting research on software at an international level and transferring innovation to the production cycle of the business structures.

ENG has a strong experience in the ICT for manufacturing domain and is active part of digitization and innovative data-driven initiatives such as IDS, BDVA and Gaia-X. ENG, therefore, provides its management and technical expertise within the trials.

ENG is supporting the collection, preparation and finally sending transmission of data to the platform (with STAM collaboration).

Additionally, the following tech providers will participate in order to:

- **SQS:** define Best Practices towards certification
- **ETZH/BRAIN:** provide Best Practice Framework
- **INTRASOFT**: provide COVID-19 Shift Allocation Application; AI Provider for the correlation of Geometrical Features to the expected test result.

3.2.1.3 Trial present scenario (as-is)

Before being put on the market, all FF diving masks have to be tested with a CO2 residual test (according to standard EN 136:2000) and with a breathing effort test. SEAC, to do this, relies on two advanced testing machines.

The CO2 Testing Machine (Figure 3) has two different configurations. One detects the residual CO2 in FF masks and one measures the mask's watertightness. The tests consist in assembling the mask on a Sheffield head connected to the machine.

At the time being, in order to change from one configuration to the other, an operator has to detach and attach manually the corresponding pipes. Furthermore, the CO2 machine is not connected to the PC, so the result of the test is a value available only through a display.

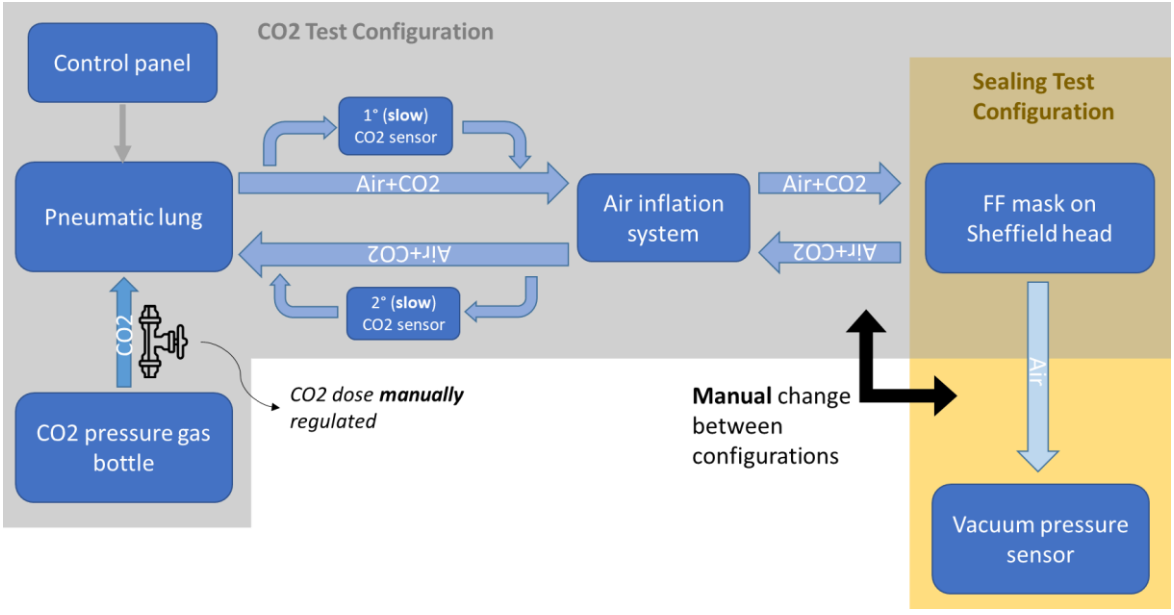


Figure 15. Flow diagram of the AS-IS CO2 testing machine

The ANSTI Testing Machine measures the breathing effort done over the course of a complete breathing cycle, providing as a result inhalation and exhalation values. These results are saved as a report printable in pdf format.

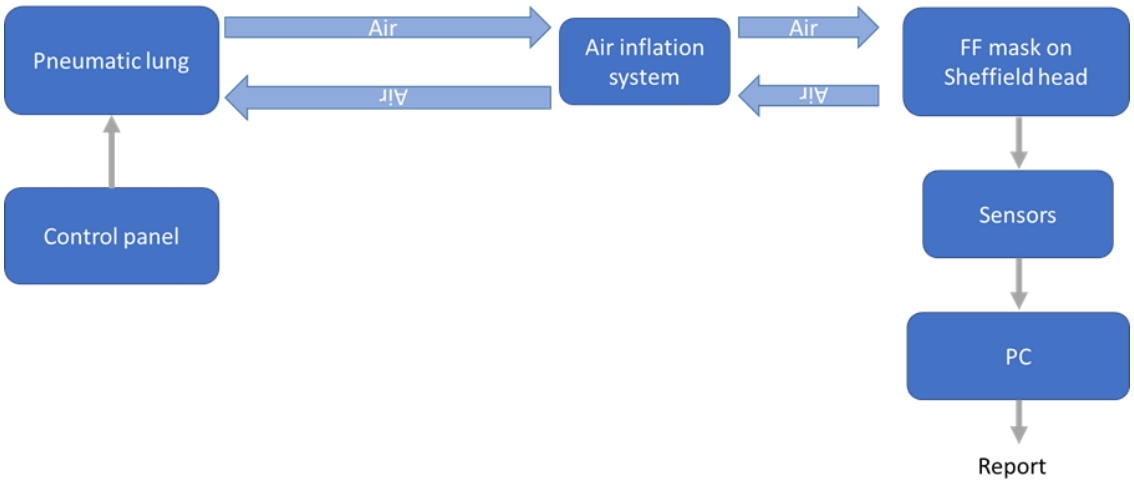


Figure 16. Flow diagram of the AS-IS ANSTI testing machine

3.2.1.4 Trial future scenario (to-be)

After the Trial, the testing processes will be automatic and faster than before.

In particular, the change between the two different configurations of the CO2 Testing Machine will be regulated by three electro valves that will close or open according to the requested configuration. Also, the regulation of the dose of CO2 entering the system will be automatic thanks to a proportional electro valve installed on the CO2 bank. Finally, the measures of residual CO2 will be faster thanks to two infrared CO2 sensors that will substitute the diffusion ones and that will allow the detected data to be saved on a PC and displayed on a new HMI panel.

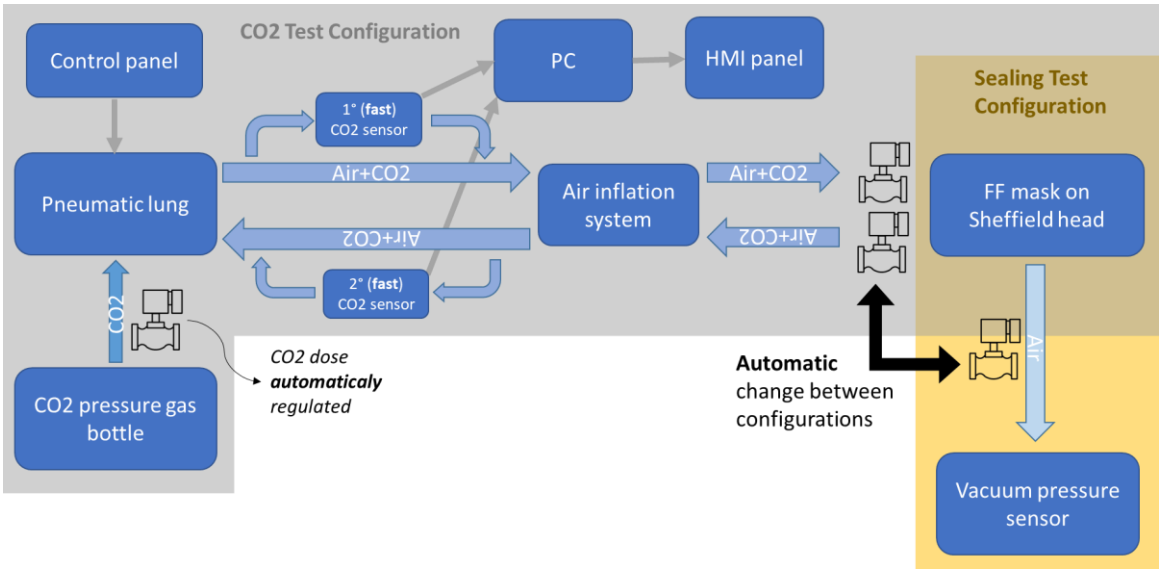


Figure 17. Flow diagram of the TO-BE CO2 testing machine

Regarding the ANSTI Testing Machine, this will generally work in the same way as it does now. The only difference will be that, thanks to software that will be installed on the machine itself, the results of each test will be saved on a PC with a standardized structure and in an easy-readable format.

Data will be represented using common (and standard) information models and transferred applying the principles of data sovereignty. Access and Usage Control mechanisms, whose principles will be defined by the data owners, will be deployed relying on IDS components as core technical building blocks of the Data Space.

3.2.1.5 Expected results

SEAC will benefit from the actions to be addressed on its pilot in a multiple manner. First of all, the company expects to achieve a working automation system on its testing machines, that will help to make all the operations quicker in the possibility of a future pandemics situation, when the company production and testing activities have to be repurposed in a rapid manner from diving to healthcare-related products. Moreover, this automation system will support not only the manufacturing line production of SEAC, but the renewed testing machines can be offered as a service by SEAC to all the other companies working in the FF masks sector. In addition, SEAC expects to find useful correlations between the FF mask features (design principles, geometries, materials, production process, etc) and the tests outcomes, referring to CO2 residual, breathing effort and sealing performance. These correlations will give SEAC some useful support to optimize the design of the next models of FF masks, which will be useful for both diving and antiviral masks. Finally, the company expects to find inside the context of Eur3ka actions support in defining some best practices linked to the certification of medical devices, with main reference to the best values of CO2 residual, breathing effort and sealing performance.

Starting from the Eur3ka Reference Architecture ENG will deploy a Data Space defining the technical building blocks in order to support the trial implementation making involved companies able to apply the data sovereignty principles and the trusted data sharing. The details will be further defined also in liaison with the pilot partner.

3.2.2 PoC Results

The scope of the pilot is repurposing 2 diving equipment testing machines into a PPE medical devices validation process to face an emergency such as COVID-19. Indeed, FF masks, after production and before commercialization, must pass different safety tests. These are primarily conducted thanks to two machines: a CO2 testing machine (figure below on the left) and an ANSTI testing machine (figure below on the right).

Figure 18 CO2 testing machine (on the left) and ANSTI testing machine(on the right)

The first mentioned machine detects the quantity (rate) of residual CO2 in FF masks (according to standard EN 136:2000) and measures the mask's watertightness. The ANSTI machine measures the breathing effort done during a breathing cycle wearing the FF mask.

Within the PoC, these machines, after being automatized, will be used to test the FF-masks. Each mask will be assembled one by one on a Sheffield head and connected to the testing machines, in order to carry out the three tests that monitor the level of residual CO2, the mask's watertightness and the breathing effort.

By the end of each test, test data (see next section for further details) are stored and integrated into a standardized format. At this point, these data, together with data about the design and the production of the mask itself, will be fed into an AI module to study how it would be possible to increase the mask performances as well as the sustainability of the production process (for example aiming to reduce waste production and/or energy consumption). In addition, test data will be processed to define Best Practices for policy makers and standardization bodies aiming at the definition of European regulation.

Data and Data sets to be used

Eur3ka Trial 2 will generate data in order to build on a set of historical information on tests done on FF masks in SEACSUB premises. In particular, the CO_2 test machine and the ANSTI test machine described in the previous section are being automatized and duly equipped with IoT devices in order to populate this kind of dataset during mask quality tests. These tests are aimed at checking new products, in particular under 3 parameters:

- Residual CO_2 inside the mask chamber after exhalation;
- Tightness of the FF mask on the user's face;
- Respiratory effort for the user.

The first and second parameters are measured by the CO_2 test machine, while the third one by the ANSTI machine. Then, for each FF mask tested by each of the machines, the following data will be bundled into a data object:

From CO_2 test machine:

- An identifier code of the FF mask tested;
- An anonymous identifier of the operator;
- The test date and hour [UTC, YYYY-DD-MM HH:MM:SS];
- The test duration [s];
- Inhaled air mixture [l];
- Breathing cycle time [s];
- CO_2 inlet level in the air mixture [%];
- CO_2 residual level [%];
- Vacuum level [bar];
- Vacuum duration [s].

NOTE: Referring to the vacuum level and vacuum duration, it would be useful having in the bundle several measures, in order to build a “tightness curve” for the mask.

From ANSTI test machine:

- An identifier code of the FF mask tested;
- An anonymous identifier of the operator;
- The test date and hour [UTC, YYYY-DD-MM HH:MM:SS];
- The test duration [s];
- Room temperature [°C];
- Water temperature [°C];
- Exhale temperature [°C];
- Breathing cycle time [s];
- Tidal volume [l];
- Breath rate [bpm];
- Ventilation rate [lpm];
- Inhale pressure [mbar];
- Inhale Pos pressure [mbar];
- Exhale pressure [mbar];
- Ext Work of breathing [J/l];
- Inhale Work [J/l];
- Pos inhale Work [J/l];
- Exhale Work [J/l].

For the sake of data openness and fully interoperability, a data format like .csv or .json will be used to bundle data into objects.

These data could be enriched by CAD models of the tested FF masks, in order to allow an AI module to correlate geometrical features to the expected test results for different models, shapes, sizes etc. of the product. Other information like manufacturing materials could be added as well.

Complementary Assets Testing and Validation

a) **Repurposing Framework – Repurposing Best Practices**
SEAC personnel will be asked to use the repurposing framework developed by ETHZ and BRAIN. Specifically, a form (e.g., like the one illustrated in the figure below) will be provided to SEAC production experts in order to solicit information about their production. The processing of this information will lead to insights about the optimal repurposing of the production. The outcomes of the process will be discussed with

SEAC. A set of telephone interviews will be used as tool for data collection and for carrying out the validation process.

	Product	External factors					Organizational factors					Product-related factor	Supply chain-related factors	
Criteria	Product	Funding from external institutes	Governmental support	Releasing emergency regulations from the governments or health administration agencies	Community effort	Pandemic accelerator	Insufficient physical facilities and infrastructure	Product design internal capabilities (know-how)	Flexibility of the production line	Dependency on external know-how	Flexibility of developing new organizational routines	Complex products (in terms of the number of components and the relationships between the components)	Market Demand	Raw material availability
Description	What is the product of focus?	To what extent did funding impact your ability to repurpose manufacture?	To what extent did the governmental support enabled your organization in manufacturing repurposing?	To what extent did emergency regulations aid in the response of manufacturing repurposing?	To what extent did community collaboration /effort impact your response to manufacturing repurposing?	To what extent did the pandemic accelerated your response for manufacturing repurposing?	To what extent did the physical facilities and equipment impact your response for manufacturing repurposing?	To what extent did your internal know-how of the product impact your response for manufacturing repurposing?	To what extent did your flexibility of production lines (modularity level of your process) impact your response for manufacturing repurposing?	To what extent did the dependence of external know-how (outside organization) impact your response of manufacturing repurposing?	To what extent did the flexibility of developing new organizational routines impact your manufacturing repurposing?	To what extent did the product complexity impact your response of manufacturing repurposing?	To what extent did the demand in the market impact your response for manufacturing repurposing?	To what extent did the raw material availability impact your response of manufacturing repurposing?
Response		Please assign 1-7 or NA												

Figure 19 Form to collect information about the production from SEAC production experts

b) COVID-19 Shifts Allocation Application

A COVID-19 Shifts allocation tool will be provided to SEAC, along with relevant usage instructions. SEAC people will use the tool based on realistic data/information from their production to generate shifts allocation (e.g., as illustrated in the following figure). SEAC users will provide relevant feedback for improving and fine tuning of the tool. A set of telephone interviews will be organized for presenting the functionalities of the tool to SEAC, collecting and using realistic data, as well as for presenting and validating the outcomes.

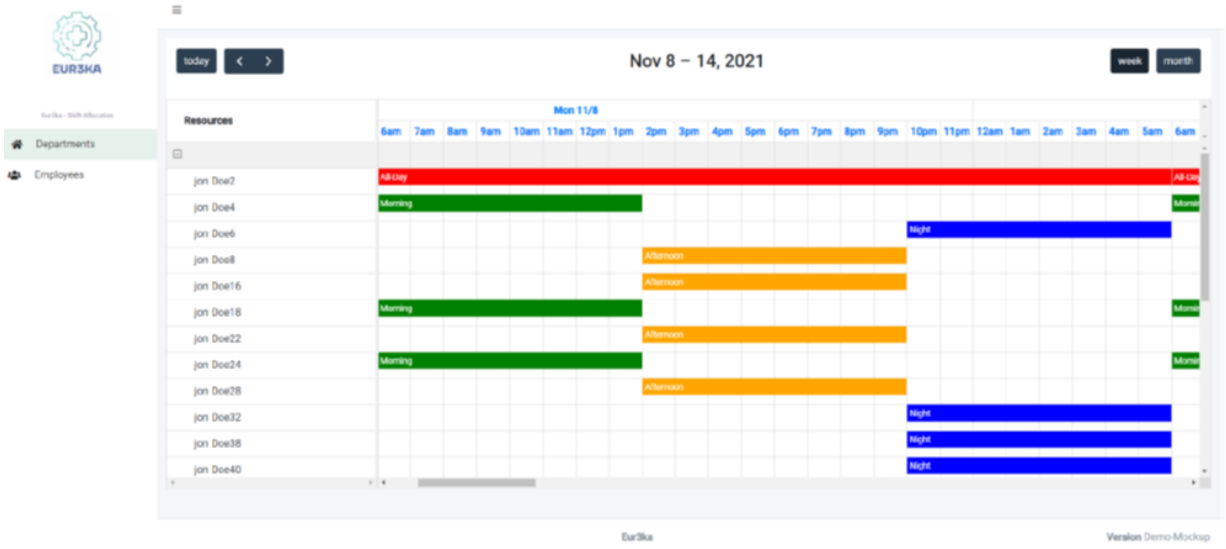


Figure 20 Shift Allocation tool

3.3 Pilot #3. Before & After COVID-19: Building a New Value Chain

3.3.1 Technological Scope

3.3.1.1 Objectives

The main objective of this pilot is to critically analyze the response of Italian enterprises to the COVID-19 pandemic. In particular, all the companies in recent years faced fluctuation in demand, rising of new market needs and new health requirements. To handle these issues, several conditions should be evaluated. In this pilot, the experiences collected from IMECH partners will be considered as case studies. Moreover, the frameworks developed by POLIMI concerning skills development and financial impact assessment will be applied for at least two different companies.

3.3.1.2 Participants: end user & tech provider

IMECH is a no-profit SME dedicated to interdisciplinary research in the mechatronics field, located in the Kilometro Rosso Scientific and Technology Park, one of the main research areas in Italy. IMECH was founded in 2006 to fill the gap between industries and research. Indeed, the Italian industrial context features a large presence of small and middle enterprises, for which it is usually hard to perform internal R&D activities, and the innovation transfer from universities and research centres is rarely effective. IMECH aims to build a collaborative network to introduce innovation opportunities to industries, connecting them with national and international stakeholders. As a consortium of 42 high-tech enterprises, IMECH can collect and compare different experiences from several industries acting in the Lombardy region.

POLIMI is one of the best scientific-technological universities in the world according to the prestigious QS World University Rankings, classified 1st in Italy and 156th worldwide (Ranking 2018-2019). In particular, the research group of Manufacturing of Department of Economics, Management and Industrial Engineering (DIG) focused its efforts on Eur3ka project especially for the development of two major frameworks to be validated and applied together with the support of IMECH. The two frameworks concern respectively, a financial impact assessment to monitor and evaluate the resilience of a certain company against drastic changes such as those caused by the COVID-19 pandemic, while the second one is reflected into a skills framework to evaluate re-skilling and up-skilling opportunities with the final aim to enhance the companies' workforce resilience.

3.3.1.3 Trial present scenario (as-is)

Thanks to the collaboration with different industrial entities, IMECH could collect several experiences concerning:

- Ensuring people health protection and contagion spread mitigation;
- Guaranteeing business continuity;
- Addressing high demand for specific equipment;
- Redefinition of future strategies and investment plans.

Some of the measures undertaken to face these challenges required significant investment. In the strategy development, generally, the following aspects have been evaluated:

- business proximity to growing markets;
- market sustainability, in both the short and long term (after the crisis);
- resources (financial resources, physical assets, workforce);
- employees' competencies and expertise (business proximity);
- supply chain and contacts with partners seeking new opportunities.

However, performing an accurate evaluation process is not trivial, and companies may significantly benefit from support tools able to guide them in this and potential future reshaping processes.

3.3.1.4 Trial future scenario (to-be)

The COVID-19 pandemic has stressed the need to speed up the industrial transformation improving the flexibility and resilience of the manufacturing system. Thus, many companies are redefining their strategies and investment plans for the future, commonly following already well-established trends that have gained prominence during the pandemic, including but not limited to:

- Digitalization and remotization;
- Improving flexibility and resilience of both production processes and supply chain;
- Introduction of innovative business models (e.g., XaaS);
- Smart predictive and planning tools to handle long term uncertainty.

Nevertheless, similar innovation plans are not free of effort. Thus, managers could draw great advantages from the provision of guidelines and best practices. Moreover, the re-skill and up-skill of employees, who will need to be kept up to date with the introduction of such innovative paradigms, will benefit from carefully designed training programmes.

3.3.1.5 Expected results

This trial will collect experience from IMECH partners. Moreover, interviews with managers from important industrial entities of the Lombardy region will be conducted. In particular, the interviews will be aimed to test the skills development framework and the financial impact assessment tools developed by POLIMI. More specifically, managers will be asked to reason on the AS-WAS scenario, AS-IS scenario (current context) and TO-BE scenario (actions to be done to improve industrial flexibility and resilience).

In conjunction, the employees' skills development issue will be investigated with the above industrial entities. In this regard, innovative technologies such as VR/AR devices to support the training process will be analysed and presented to industry representatives in order to collect feedback on the actual interest and expectations from similar tools.

Finally, the expected results of this pilot are:

- a report collecting IMECH partners' experiences (adopted measures, identified risks and lessons learned);
- survey and Interviews with at least 2 industrial entities concerning financial impact assessment;
- survey and Interviews with at least 2 industrial entities concerning the skills development framework;
- development of a Virtual Training demonstrator for training and remote support applications;
- a collection of feedback from industrial representatives on the Virtual Training potentialities.

3.3.2 PoC Results

The overall ambition of the trial is to identify useful guidelines to support industries in improving their ability to face disruptive events such as the recent pandemic. Thus, a collection of real experiences will allow managers to compare their strategies with the strategies proposed by different entities belonging to the same ecosystem. Moreover, the exploitation of support frameworks, such as the financial impact assessment and the skills development framework, will represent significant support in redesigning future innovation plans. Finally, the investigation on advanced technologies, including the development of the AR/VR demonstrator, will allow industries to directly experience innovative tools and tangibly feel the connected potentialities.

4 Pilots #Family2. On-Demand Additive Manufacturing of Medical Supplies and Components

The second set of pilots deals with the assessment and validation of the flexibility of the Eur3ka network to respond to peaks in demand supported by additive manufacturing and 3D printing capabilities.

These pilots are focused on the execution of the order (usually a "one-of-a-kind" product) through an Additive Manufacturing production line (on-demand). On-demand production networks should share transparent descriptions 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".

Figure 21 shows an overview of the pilots considered in the second family.

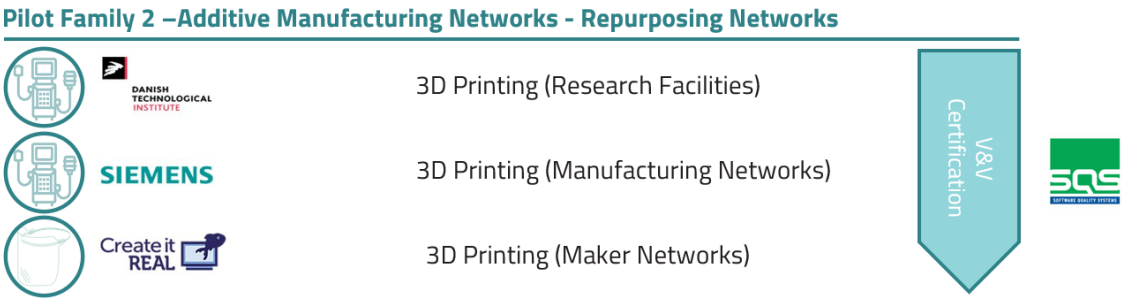


Figure 21. Pilot Family 2

4.1 Pilot #4. Additive Manufacturing at Danish Technological Institute

4.1.1 Technological Scope

4.1.1.1 Objectives

The objective of pilot 4 is to demonstrate how to rapidly transition from running an industrial Additive Manufacturing production facility fulfilling the requirements of ISO9001 and transforming this to fulfilling the requirements of ISO13485. This will be used as a demonstration case to be disseminated to a broad audience of European industries to aid in clarifying what requirements should be kept in mind when going through this transformation in a crisis situation. The demonstration will utilize and evaluate the Eur3ka MedTech production line certification developed by SQS for enabling the transition in general across manufacturing industries, where rapid transition in quality management systems is needed for urgent manufacturing demands within the society.

However, ISO13485 is agnostic to the technique used to manufacture a device. The recently developed ISO52920:2021 standard specifies the requirements for part manufacturers using additive manufacturing techniques. This standard also specifies criteria for additive manufacturing processes as well as quality-relevant characteristics and factors along the process chain and defines activities and sequences within an additive manufacturing production site.

The approach will be to use ISO52920:2021 to provide specific AM-content to the ISO13485:2016 compliant QMS.

Additionally, other standards will also be used as reference as considered applicable and relevant. This is the case of ISO52926, ISO52935 and ISO52937 for personnel Qualification; ISO52904 and 52930 for specific verification/validation steps or ISO14971 for Risk Management.

At this point in the project, it is not possible to identify the complete set of reference standards required to complete a successful qualification and validation of DTI production line. In addition, it is not even clear whether existing standards are sufficient to cover the technical challenges. Therefore, both standards and approaches will be specified during the project phases.

In relation to the manufactured parts, three are the products that will be used to assess compliance of DT manufacturing process to MedTech requirements. They belong to the same family type.

- A part for a ventilator assist device (Podovo)
- A Robot gripper (Pharma manufacturing)
- A metal implant (AUH)

A preliminary gap analysis has been done as a first step to elaborate the migration plan from ISO9001:2015 to ISO13485:2016.

4.1.1.2 Participants: end user & tech provider

The Danish technological institute (DTI) is one of the biggest RTOs of Denmark. The additive manufacturing centre at DTI consists of 20 employees and has as forerunners within the industry in Denmark been working with a high number of AM technologies for the past 30 years. The focus area for the centre includes aiding companies in optimising their production through the benefits of AM production. Both through research, production facilities and knowledge transfer.

The production line is running as a ISO9001 certified facility; however, DTI is experiencing increased interest from Danish companies and hospitals for being able to manufacture components for medical applications according to the ISO13485 quality management system.

DTI is experienced in producing medical equipment of less complex classes and will be bringing several of these productions into pilot 4 of Eur3ka, these will in the following be presented as the cases of the pilot.

4.1.1.3 Trial present scenario (as-is)

Currently manufacturing follows the procedures, as descried in the flow chart below (Figure 13).

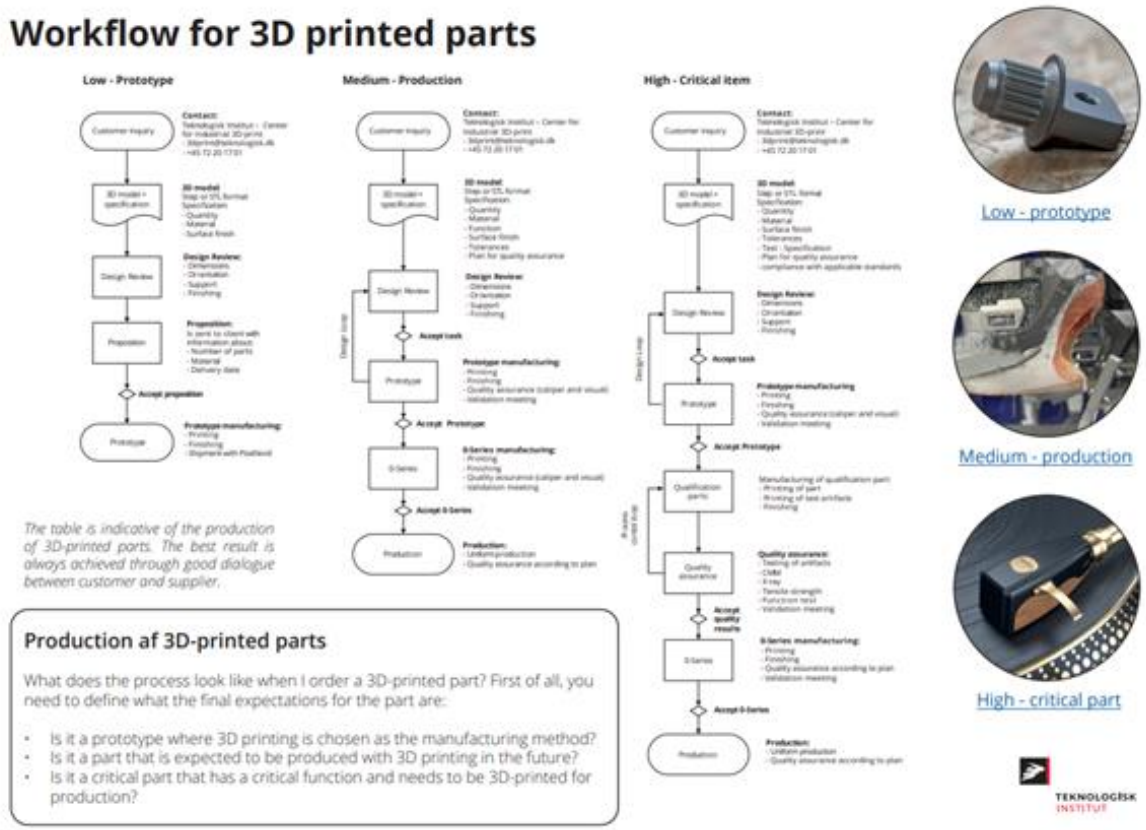


Figure 22. DTI workflow for 3D printed parts

On the data side, automatic data acquisition is currently being gathered on machine performance (sensors, events etc.), analysed on a cloud solution providing both a dashboard for easily tracking KPI's on machine performance, as well as automatically sending quality control reports to operators for assessing the quality and possible actions on machine non-conformity.

Three specific customer cases are discussed in relation to increasing/adding QMS from 9001 to 13485, two manufactured on the setup as is, while another, metal implants, is requested by the Danish hospitals,

- **Case** 1: A manifold manufactured at DTI in AlSi10 using L-PBF technology for respiratory aid (cough stimulant). The costumer is JW Industries in association with Podovo (2 Danish SME's).
- **Case 2:** Robot gripper manufactured at DTI in TiAl6V4 for use in a sterile environment. The costumer is a Danish SME.
- **Case 3:** Titanium implants to be manufactured at DTI at extremely low lead times. (Currently DTI only manufacture components for animal studies etc) The costumer is generally the Danish hospitals.

4.1.1.4 Trial future scenario (to-be)

During the pilot work, a new process flow will be developed related to the process flows described in section 4.1.1.3. This will describe the process to be used with all medical components produced at the facility in the future. DTI will be able to supply the demand for urgent and critical components needing ISO 13485 certified manufacturing capabilities within additive manufacturing.

4.1.1.5 Expected results

The trial will prepare an ISO 13485 column in Quality-flowchart and facilitate knowledge-sharing of the processes behind. This will result in added value on specific business cases described and used for demonstration case. Furthermore, it will allow for a broader accessibility of ISO 13485 certified manufacturing capabilities across Europe, increasing the manufacturing line repurposing ability in case of urgent needs as well as the general competitiveness of European manufacturing.

Through the trial, Eur3ka will showcase what it takes to go from ISO 9001 to ISO 13485 (in case of a crisis) in the case of AM and what is the added value. By disseminating this Eur3ka will facilitate easier access to producing medical equipment at a wide range of European production facilities.

4.1.2 PoC Results

The overall ambition of the trial is to make it easier to transition a manufacturing facility from one quality management system to another with higher demands for quality and control. This has proven in the COVID-19-crisis to be an overall bottleneck for manufacturing.

The initial result will be on the DTI site, demonstrating the transition in this case, and secondly how to generalise these results. The first step will be to test the gap analysis tool to determine how quickly this transition can be performed, enabling other manufacturing sites to perform the transition and disseminate results in general and when it makes sense, in precise terms.

The gap analysis has been carried out by SQS.

ISO9001:2015, ISO13485:2016 and ISO52920

The emphasis of ISO 9001 is on continuous improvement and customer satisfaction in the manufacturing and service industries with minimal regulatory compliance focus. ISO 9001 specifies the guidelines to organize a Quality Management System (QMS) and its effective implementation. It was designed to sufficiently meet all the mandatory needs and demands of the customer and set the expectation for constant quality improvement. It is used by a wide variety of non-regulated industries.

However, regulatory compliance is the first and highest priority of ISO 13485 in developing and manufacturing medical devices toward mitigating human safety. That is why the ISO 13485 system was developed. ISO 9001 was used as a starting point, but ISO 13485 was specifically developed for medical device related industries and their quality management systems (QMS). It focuses on the development and manufacturing of a medical device, as

well as on the management of the device's whole lifecycle and traceability. ISO 13485 was developed to ensure reliability, quality, trust and a strong commitment to human safety.

It has to be mentioned that the evolution of both standards (ISO9001:2015 and ISO13485:2016) has not been fully aligned. This has ended up in standards with different structures, scope and content. However, both standards maintain similarities in essential aspects such as: risk based and process approach; customer focus; infrastructure identification; employee competence and role management. The differences between ISO9001 and ISO13485 clauses are shown in Table 4 in Annex I.

The additional requirements demanded by ISO13485 in comparison to ISO 9001 are also in Table 5 in Annex I. As it can be seen, there are some clauses not covered in ISO9001 and some of them insufficiently covered that should be further developed.

The comparison indicates stronger evidence is required in review, verification and validation activities that are to be carried out during the design and development phases of a medical device. Besides evidence of appropriate control and management activities during the whole life-cycle (from design to service provision and post-delivery) is required.

In addition, and at a minimum, additional technical documentation should be provided for each medical device type (Clause 4.2.3):

- A device description and specification section. This should also have your unique device identification (UDI) number.
- Labelling and instructions for use.
- Detailed information on design and manufacturing. It is recommended to use flow charts to clearly show processes and relationships. The manufacturing process, suppliers, and materials used are to be detailed.
  Installation Qualification, Operational Qualification and Performance Qualification, or IQ/OQ/PQ, are the ISO 13485 basis by which you prove that the manufacturing equipment and systems for your medical device will perform as intended.
- Detailed risk management information in compliance with ISO 14971.
- General Safety and Performance Requirements (GSPR), formerly known as essential requirements. It identifies all the things you must do for your device type. From a design control perspective, the contents of your traceability matrix will assist you with addressing the criteria of GSPR.
- Verification and validation information. In terms of verification and validation, the European Commission places a heavy emphasis on clinical data - not just during design and development, but post-market, too. CERs (Clinical Evaluation Reports) should provide a comprehensive overview of the device's design and composition, as well its intended applications and any relevant literature reviews.
- Post-market surveillance (PMS) information, including PMS plan, post-market clinical follow-up (PMCF) plan, and periodic safety update report (PSUR).

ISO 52920

This standard has got three parts:

- **Part 1: Qualification of the additive system operations.**

  It provides precise information on the requirements to be taken into account to define quality-assured processes in additive manufacturing.

It also provides an approach to perform the qualification of the process (PQ) to confirm that it can operate reproducibly with defined, part-related indicators.

This part of the standard can be used as a reference to define the manufacturing process as well as to plan the PQ process. This chapter can be used to implement Chapter of ISO13485 and provide technical documentation of the Medical File.

- **Part 2: Quality Assurance**

The individual elements of the quality assurance to be considered by the part manufacturer are detailed. These elements comprise personnel, documentation, infrastructure and quality controls.

This Part helps implement clauses in chapters 4, 6 and 8 of ISO13485.

- **Part 3: Verification of the part Requirements**

This section provides guidelines to address the manufacturing feasibility assessment of the part requirements and to elaborate and implement the validation plan during manufacturing.

This Part helps generate the Verification and Validation information required by the Medical Device File.

4.2 Pilot #5. Open 3D Printing Catalogue for Professional Additive Manufacturing Network

4.2.1 Technological Scope

4.2.1.1 Objectives

Pilot 5 aims to demonstrate an extended chain of functionalities, where various potential roles in a medical crisis (e.g., hospital admin, medical design expert, medical manufacturing expert) are able to deploy their model from a safe data space to a catalog of certified parts, find and generate orders and benefit from a fitted match making of design with supplier's match.

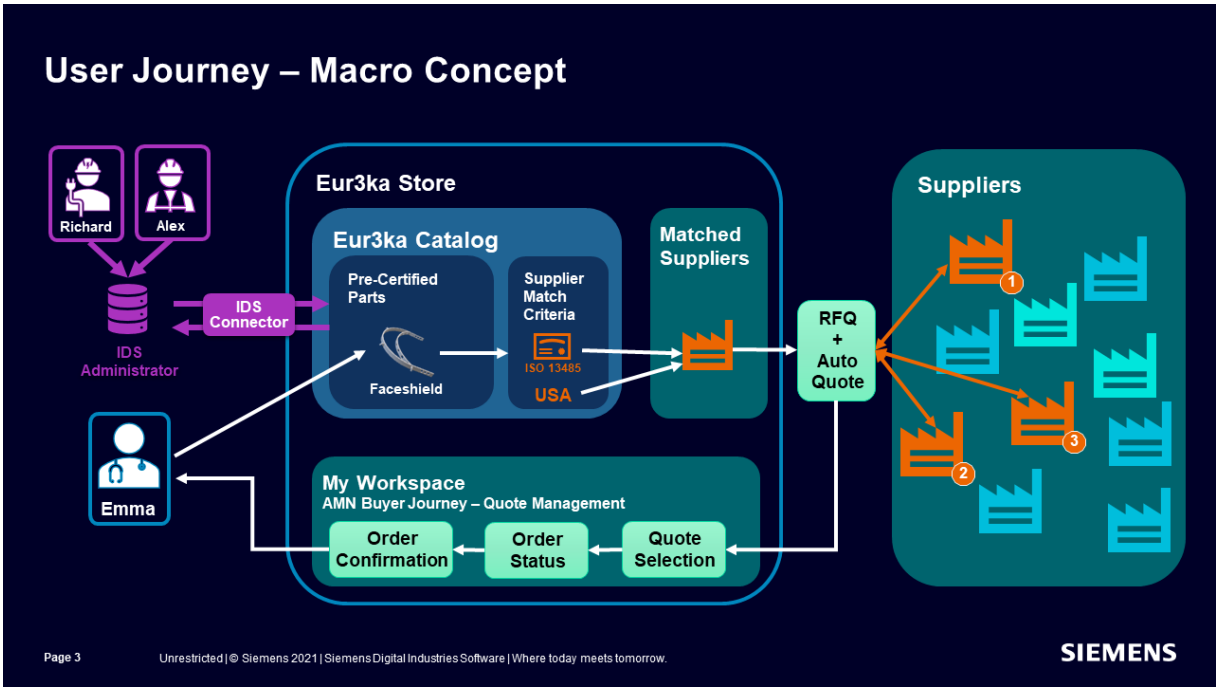


Figure 23. Eur3ka Catalogue & Additive Manufacturing Network

4.2.1.2 Participants: end user & tech provider

The participants involved in this pilot are Siemens (SIERO) as end-user, and Intrasoft (INTRA) and Fraunhofer IOSB (FhG) as technology providers.

4.2.1.3 Trial present scenario (as-is)

COVID-19 crisis showed many similarities with several scenarios where costs, availability of fitted suppliers and speed of production are making the difference. Speed and evolution of uncertainties lead to a few key experiences like lack of operational capacity of critical care health units, lack of spare parts for devices usually produced by a very limited number of specialized companies and lack of standardized design sharing and validation methods.

Additive manufacturing capabilities are considered one of the key relevant ways to realize customized products, and printing technologies are optimized to realize complex designs. A key issue, especially for a crisis situation is to bridge demand with supplier capabilities in a safe way. The safety and trustworthiness of the relationship between demand and supply are complementary to the ability to execute certified and validated designs on certified printing facilities. Siemens Additive Manufacturing Network is a service capable of meaningful bridge a wide range of demands ranging from mass production of designs up to niche spare parts. Its role is to connect demand with the right suppliers, knowledge, expertise and technology partners needed for complex industrial scenarios, all those in a safe and trusted ecosystem where enablement of instant generalized collaboration proves to be a must.

4.2.1.4 Trial future scenario (to-be)

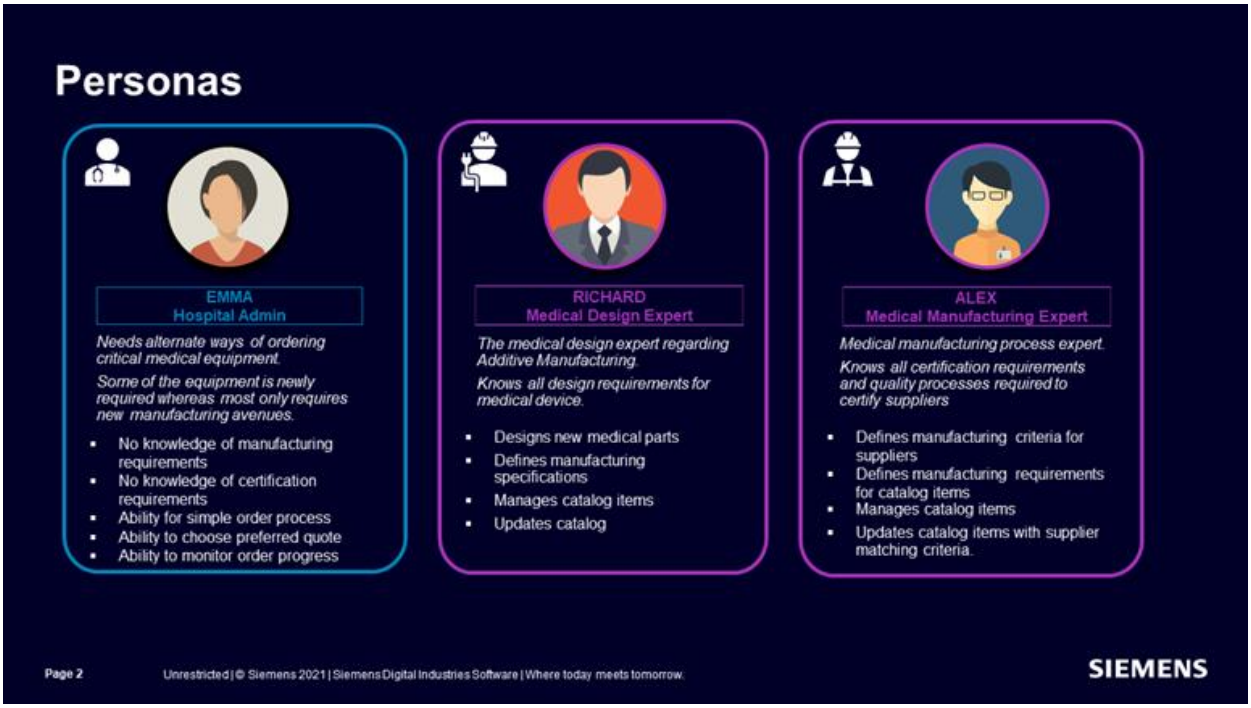
In order to demonstrate such features Siemens AMN developed as a side component of main platform a catalog component accessible to various personas identified in the potential process. Below are observable the roles identified acting in a crisis context. All those roles

are related to the generation, identification and ordering of certified parts via Siemens AMN catalog. Of course, each role is generic for identified crisis context and it serves only to demonstrate key features implemented.

Relevant processes identified involve some generic personas, each of them covering various steps in the life cycle of a 3D printed product, namely:

- A hospital admin, entitled to select for a catalog spare part needed and to execute ordering and acquisition process
- A medical design expert, capable to design and push towards the catalog a design capable to satisfy medical equipment needs
- A medical manufacturing expert, focusing on the validation of the designs against manufacturing processes, able to enrich parts descriptions with supplier specific criteria to be fulfilled along with selection and quotation processes

Each individual role has associated key capabilities for a crisis situation and is designed to fulfil necessary steps in the functional combination between a catalog of certified medical parts and Siemens AMN.



4.2.1.5 Expected results

Trial exercise aims to show fast and safe assembly of an ordering solution, linking certified designs produces, medical equipment validators and beneficiaries.

4.2.2 PoC Results

Trial tasks: Before 2022 (proof of concept)

Demonstrate the solution of a catalogue of parts capable to integrate with Siemens AMN and perform an ordering process

Trial tasks during 2022

- Integrate full API features of Siemens AMN within the catalogue – Siemens Q1 2022
- Design and implement Trusted+ connector – Siemens Q2 2022
- Demonstrate matchmaking mechanism - Siemens Q3-Q4 2022

4.3 Pilot #6. Crowd Production and Validation

4.3.1 Technological Scope

4.3.1.1 Objectives

As millions of 3D printers get sold worldwide every year this volume is mostly driven by the low cost printers under 500 €. During the covid 19 pandemic individuals, maker space, schools, and small and medium size companies in possession of one of this low cost 3D printer decided to fight back the crisis by repurposing their 3D printer to produce personal protection equipment. By doing so they were the first one to be able to provide personal care equipment within few days. The power of the crowd was for the first time used to produce. Those low-cost 3D printers are normally used as a learning tool or a tool to make prototypes. But they can also have the capability to be used as real production equipment.

The general benefit is to success recipe for a quick reaction from the maker community.

1. Demonstrate the action needed for successful decentralized production (crowd production)
2. Demonstrate possible validation process in a decentralized setup (crowd quality control)
3. Accessibility of relevant crisis specific 3D objects
4. The online slicer provides the technology to achieve optimized results for best production results (3D printing in this case), transforming a toy 3D printer into a real tool.
5. The validation of an item produced decentralized needs to be harmonized and therefore a protocol for validation needs to be insured for example video instruction can be shared.

4.3.1.2 Participants: end user & tech provider

End User: Create it REAL

Based in Aalborg, the old Danish "Silicon Valley", the Create it REAL international team is made up of 15 experts in 3D printing core technologies (Software, Electronics, 3D graphics and Mechanics for 3D printing). We are professionals with a very good understanding of opportunities around the additive manufacturing technology. We have experience in high technology product development, and we are well aware of the need for flexible and easy to use solutions. Our team works like an R&D center, using its unique collection of 3D printing “LEGO” bricks to quickly release customized 3D printing solutions with a focus on productivity.

Our core technology is state of the art and feature unique advanced features such as High-speed printing (up to 5 times faster or improvement of print quality) and Secure printing (enabling decentralized production with respect to the intellectual property of the different parties involved and creation of new business models).

Our library of technology bricks allows quick integration of the technology into new products and considerably reduces the time to market. We allow our clients to focus on what they already know best: production and introducing product to market, while we focus on what we know best: 3D printing technology & flexible production. Our technology covers the whole 3D printing process: the slicer engine (Software), the electronics with our world first Real-time processor for 3D printing (Hardware) and our Secure printing solution (Software+ Hardware). Those elements are available under different forms: desktop slicer, online slicer, slicer API, Server base slicer, different versions of electronics (from price optimized to mid-range industrial grade).

The role in the project will be to demonstrate the feasibility for makers to transform a 3D printer toy into a production tool, and to organize quickly to be the first in line producer of validated life protection design.

Tech Provider: DTI

DTI has experience with the individual production of 3d printed items on high end 3D additive manufacturing machines. They also have the processes that ensure the validation of the produced items to the highest possible standard. The experience in this field will be used as inspiration for similar processes for validation.

The Danish technological institute (DTI) is one of the biggest RTOs of Denmark. The additive manufacturing centre at DTI consists of 20 employees and has as forerunners within the industry in Denmark been working with a high number of AM technologies for the past 30 years. The focus area for the section includes aiding companies in optimising their production through the benefits of AM production.

The section has a proven track record of participating in and coordinating research projects both at the national and European level, as for example in the domains of expanding the use of AM production within the industry (12M EUR, funded by the Danish innovation fund) materials (“Nanomaster”: Graphene-based Thermoplastic Masterbatches for Conventional & Additive Manufacturing Processes, funded by FP7), thematic (FoF.NMP.2011-6: Manufacturing chains for nano-phased components and coatings), Material reuse (E!13547 VARETIT Multiple Valorisation of Recycled Titanium alloys for metal industry), and part optimisation for energy efficiency (EASY-E, 3M EUR from 2020-2024, funded by the Danish energy agency).

DTI has experience in producing medical equipment of less complex classes and will be bringing several of these productions into pilot 4 of Eur3ka, these will in the following be presented as the cases of the pilot.

4.3.1.3 Trial present scenario (as-is)

Current scenarios are 3D printers used by hobbyist to print fun figurines or other 3D objects found online. The printers are used as a toy or a way to learn how to design low fidelity prototypes.

4.3.1.4 Trial future scenario (to-be)

Repurposing challenges will be addressed in order to improve the current scenario. By using professional additive manufacturing software to improve print time and print quality. Strategy to help automation or reduce user interaction will be investigated. Showcase on validation of the printed part will also be looked into. The scenario will be a simplification of scenarios used by professional prototyping houses (such as technology institute, see workflow below)

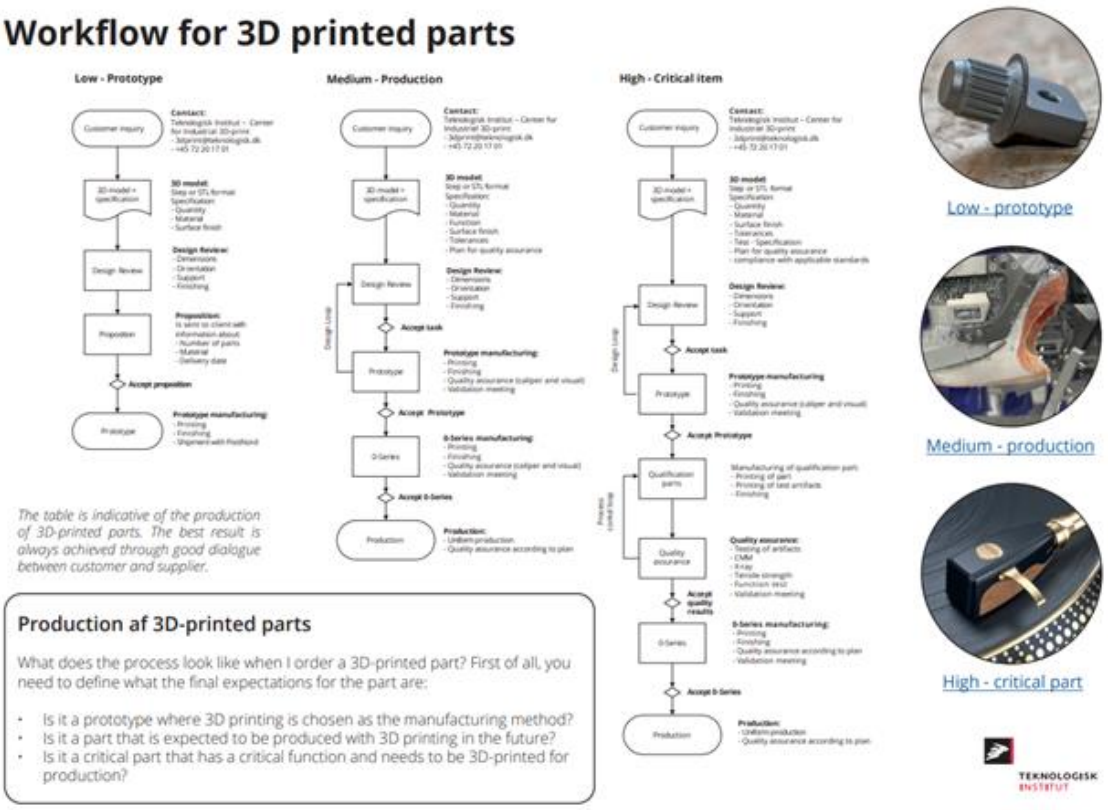


Figure 24 Workflow for 3D printed Parts – Technology Institute

Of course, those principles might not be fully applicable for the crowd production setup, but ideally the concepts even though simplified should be recognizable.

4.3.1.5 Expected results

The goal is to enable the repurposing of low cost 3D printers into a decentralized crowd production setup by providing the right platform to makers to achieve such crowd production successfully.

It should provide a method to summit 3D files to be optimized for production on low cost 3D printers, made accessible to anyone for printing and provide metadata related to ensuring the right level of quality; preferably decentralized too, so in other words, crowd quality control guidelines. This implies providing the combination of a Market place, an Online slicer and a Validation (Instructions for successful quality insurance of part 3D printing).

4.3.2 PoC Results

Trial tasks 2021 Proof Of concept

The different technology bricks to ensure the feasibility of the 3D printer journey are all available to CIR for full implementation of both a Marketplace and online slicing with certification information can be provided.

Small experiment was run on CIR online slicer freemium service to display popular products to prints:

Figure 25 Pilot 6 – Popular products to print

The content was chosen based on the popularity of pre-existing marketplace and user profile. Parts were optimized for print quality and time and made easily accessible through a personalized dashboard.

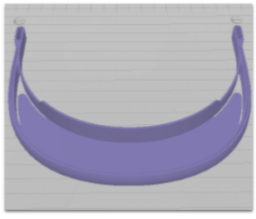
Slicing API was modified to add the capability to add metadata to print files (Gcode) to embed the quality control and assurance information is part of the same file. This is important as this information is material and machine specific.

Trials tasks 2022

Tasks for 2022 are :

- Custom generation of tracking number added on the part
- Auto extraction of parts
- Quality Control procedure (Tolerance, Strength test…)
- Quality Control report
- Production report

certified



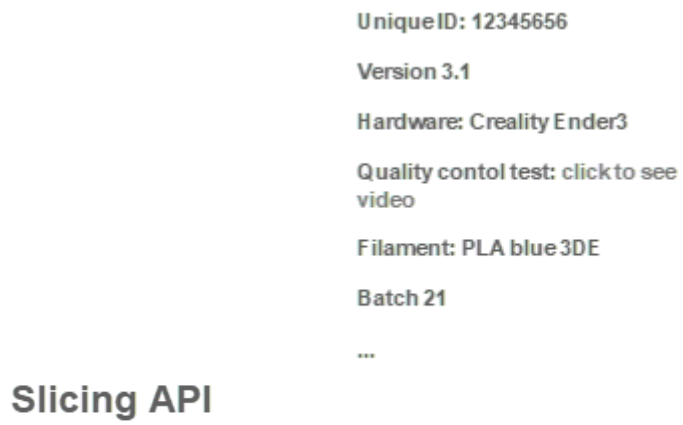


Figure 26 Pilot 6 - Tasks 2022

This capability will be made available to any owner of low cost 3D printer to enable the crowd production and validation of parts.

5 Certification Framework

5.1 Strategy for Verification and Validation of the Components

Within the Eur3ka certification framework, a validation and verification (V&V) programme has been designed to address the specific manufacturing repurposing assessment for security, safety, sovereignty, interoperability and performance of repurposed modular manufacturing lines addressed in the pilots. In relation to this, D3.2 shows more detail on the certification framework, especially regarding the regulations and mandatory and optional standards focused on medical devices and products, as well as the main requirements from regulations and standards to perform the certification process.

SQS has developed a web-based platform (Q-Med Tech) to provide certification and validation services to ensure the quality and compliance of standards of the processes and products offered by technology providers, in order to ensure that customers can make any purchase with confidence. In this context, Eur3ka pilots will allow the early deployment of the platform to verify and validate their processes and products.

The following section 5.2 describes the standard roadmap for the certification of medical devices, and section 5.3 the description of the developed Q-Med Tech platform, some aspects of which are described in detail in deliverable D3.2.

5.2 Certification Roadmap

Medical device manufacturers are aware of the complexity of the regulatory requirements landscape, as there is a wide range of national and international regulations and certification standards for medical equipment. These regulatory requirements are complex and vary from region to region, which can make it challenging to obtain medical approval for the targeted market.

This section provides an overview of the general demands that are to be met by new or upgraded medical devices, which may have multiple different components including software hardware and medical components. Figure 27 presents the 5-step roadmap of the documents and processes to be implemented by medical devices manufacturers.

- **Phase I – Create QMS and Risk Assessment**. Initiation of the development of the device followed by the opportunity and risk analysis.
- **Phase II – Establish Management Process.** It is critical for analysing the financial feasibility, prototype and concept formulation.
- **Phase III – Elaborate Technical Documentation**. For the validation and verification of the design developed to meet the regulatory requirements. The designed product should be planned for trials in an appropriate environment.
- **Phase IV- Perform Verification and Validation**. For the validation of the device before it is launched, which has to be tested and approved by a competent authority.
- **Phase V – Post Market**. Involves product launch and post launch assessment.

Figure 27. Preliminary Roadmap

The type of product or device determines the complexity of the certification scheme, depending on the standards and regulations to be met. For instance, low-risk devices (e.g., oxygen masks or surgical tools) are subjected to general controls on good manufacturing practices and standards, registration and general record keeping requirements. However, more complex devices require special control on the product labelling, some mandatory standards and testing requirements.

This has been taken into consideration within Eur3ka certification framework. As mentioned before, the complexity and/or coverage of the process varies based on the classification of the device, as explained in D3.2. For instance, companies manufacturing medium-risk (Class II) or high-risk (Class III) devices will require a different QMS implementation than companies manufacturing low-risk, non-sterile, non-measuring, non-reusable surgical instrument devices (Class I).

There are lot of reference standards supporting the implementation of these roadmaps. The next figure (Figure 28) shows major process reference standards.

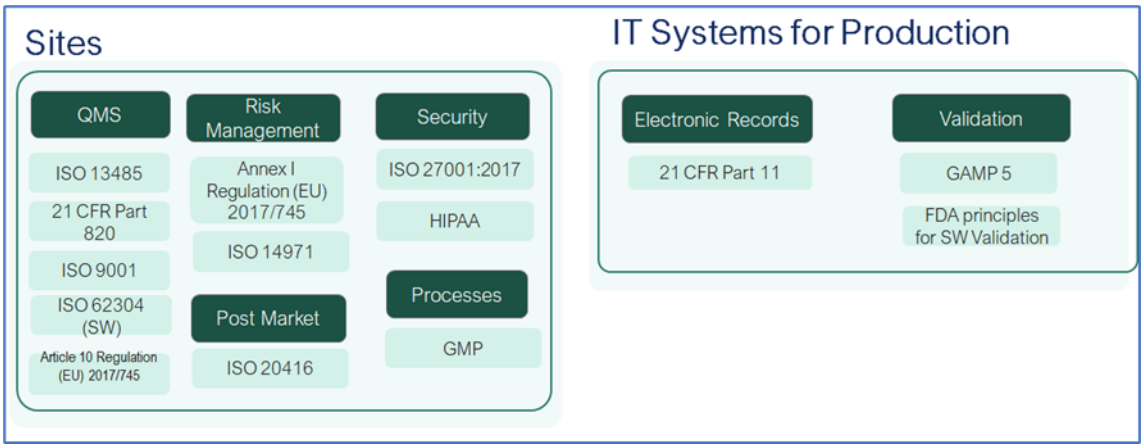


Figure 28. Overall Reference Standards

5.3 Q-MedTech Platform

Q-Med Tech is a web platform, based on Mango Apps, created by SQS. It is designed to support the provision of certification services as well as the marketing of certified products and services within the medical device community.

This platform is designed for three types of users, whose role is described in more detail in deliverable D3.2:

- Certification providers: offer customised certification services
- Tech providers: providers of solutions and production capacity, who register their products and processes according to the established certification criterion
- Consumers: have access to the Marketplace of certified products and processes, and can negotiate with the providers

Registration is mandatory for both certification providers and technology providers. For customers, certification is not mandatory, but some functions are not available until registration has been formally completed.

The platform has two major components:

- **Market Place**, where Consumer users can register in order to purchase already certified and validated products and/or processes. Also, Consumers can check several technical repositories:
    - Catalogue of Providers, contains a list with all the technology providers (from now on Tech Providers) conforming Q-MedTech, already registered in the platform.
    - Catalogue of Certified Solutions, accessing here, consumers can find ever technical solutions (processes and products) in the platform. These solutions were previously registered by Tech Providers.
    - Certifications: Technical Information, where consumers find a repository with all the information required (documentation, forms, etc) in the roadmap plan to certify a product, technology or medical device.

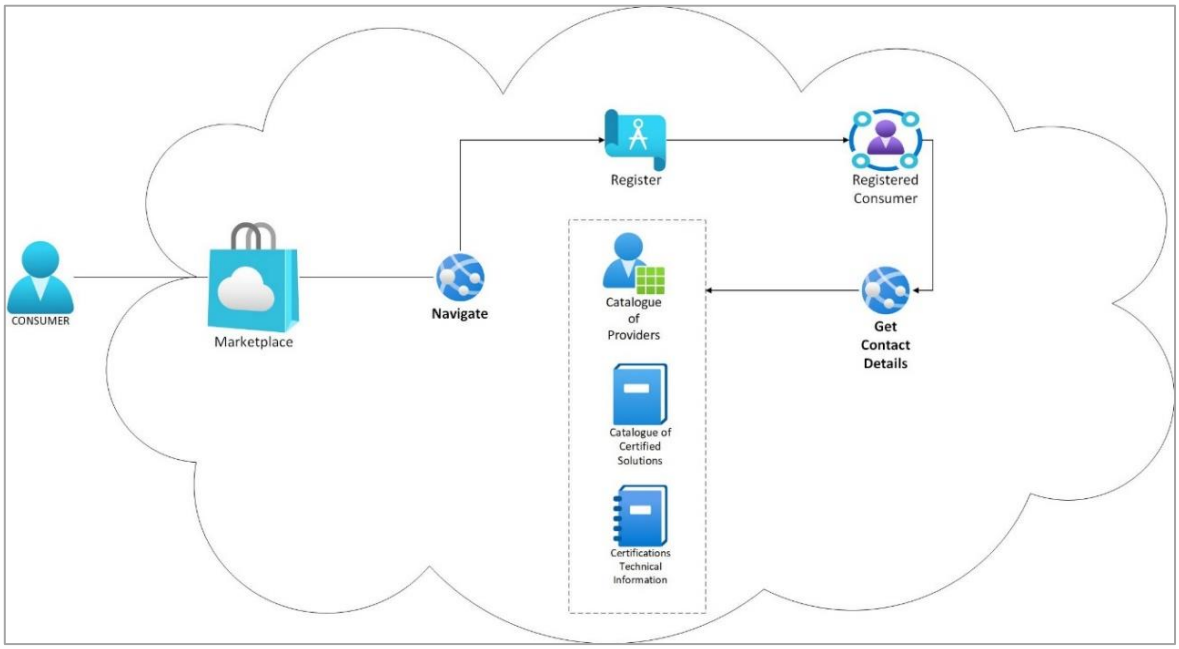


Figure 29. Q-Med Tech platform Marketplace

- **Certification Site**, where Technical Providers can request for the Certification or Registration of a medical device, technology and/or capability, and where Certification providers can design and develop the corresponding certification plans.

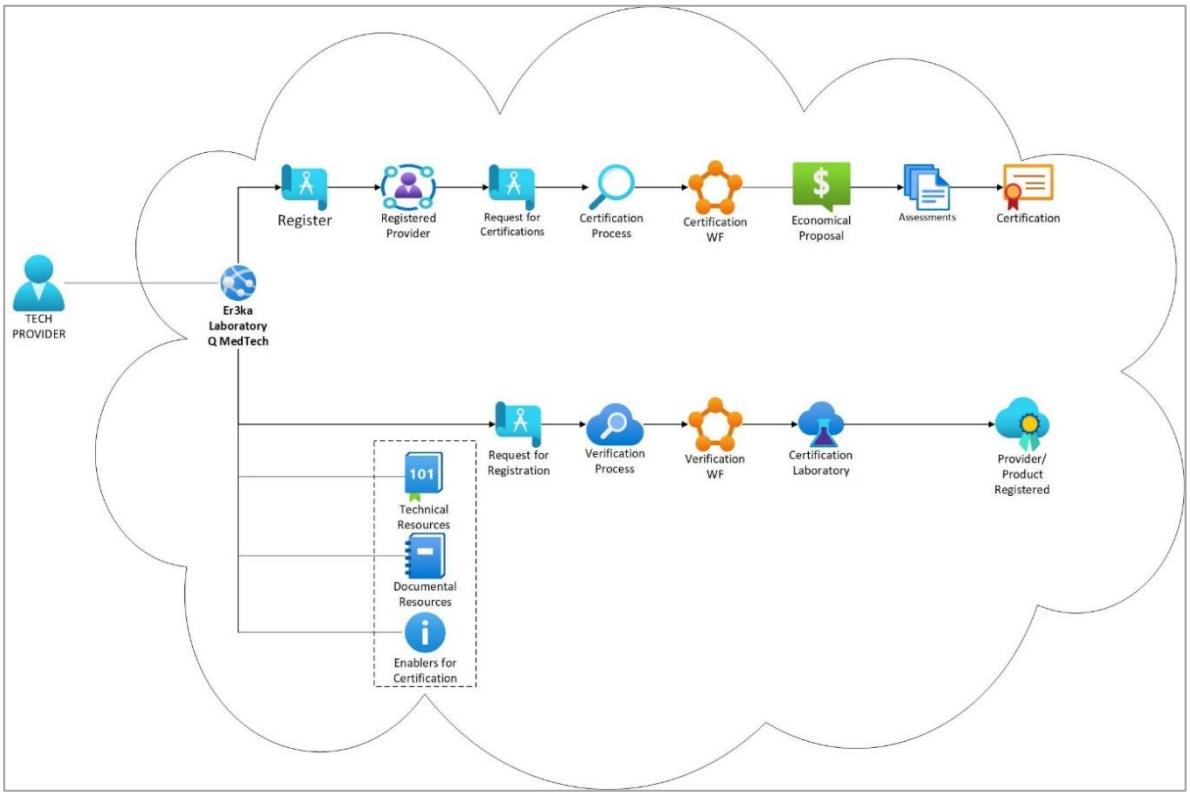


Figure 30. Q-Med Tech platform Certification Site

5.3.1 Front End of Q-Med Tech platform

The **Front End** gives access to the (i) Marketplace, to (ii) the Certification and (iii) to Registration Services.

The Marketplace is composed of a **catalogue** of certified products and processes ready to be integrated into a medical device manufacturing supply chain. Full details of the characteristics of the product/process, pricing model and of the certification scope are included. Search utilities facilitate a fast and effective navigation process.

Negotiation utilities are not covered by the platform. Access to the corresponding Tech Provider contact details is given to Consumer after registration, and then, both parts should negotiate the business relationship.

Certification services are provided to both product and process providers:

- Process providers.
  - Providers of **production capacity**.
- Product providers.
  - Providers of **technology**.
  - Providers of intermediate/final **medical devices**.

Figure 31. Front end of Q-Med Tech platform

The workflows for the interaction with the platform of the different users are described in deliverable D3.2.

5.3.2 Back End of Q-Med Tech platform (Certification Site & Access to the laboratory)

This site is only accessible for Registered Certification Providers. This site offers a complete set of tools to design and execute a Certification Roadmap adapted to the characteristics of the system to be certified.

It also offers communication and data sharing tools between Certification Providers and the Customers, following some tools are detailed:

Technical Resources

The platform includes several software resources to make a pre-testing for the products and/or services for the certification and validation process.

Using these resources, providers can perform a previous verification process, to execute a similar validation and certification roadmaps, making easy and faster the workflow for the Team in charge of it.

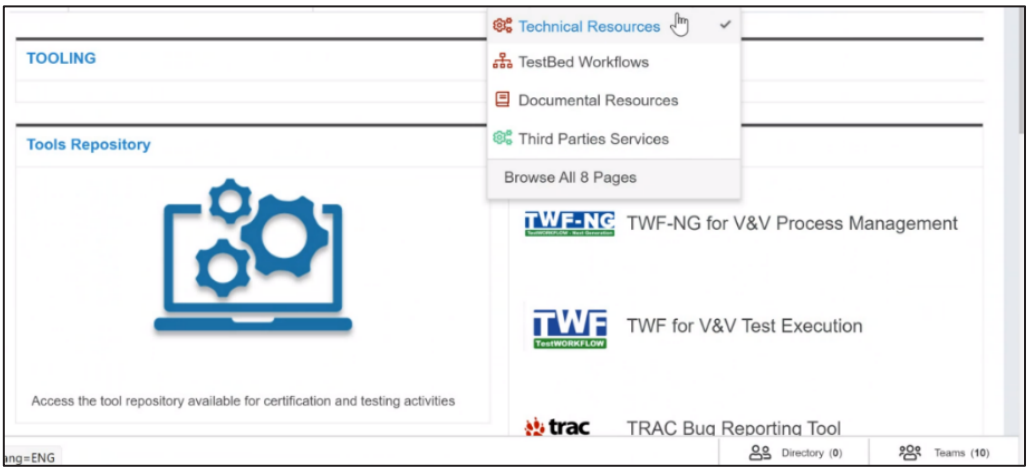


Figure 32. Technical Resources of the platform

Documental Resources

In this repository, providers will find all the documents related with the certifications for the products and services.

With them, they can pre check all the requirements needed to ensure that the certification and/or validation workflow will be executed successfully.

Also, they can access all the resources related to the several certifications (ISO, FDA, etc) providers supported by the platform.

Enablers for certification

In addition to services, Tech Providers and Certification Providers are given access to a complete set of resources, identified as “certification enablers”. These assets are offered to help understand the scope of the certification and to fasten its adoption. The following assets are provided:

- Certification Support Tools.
- Technical Documentation.

6 Conclusions and Future Outlook

Eur3ka aims to enhance the agility and flexibility of the manufacturing chains for any kind of unforeseen event. To this end, during the first phase of WP5, the six pilots have defined their PoC, in order to respond to the main Grand Scenarios that emerged during the COVID-19 outbreak, addressing the challenges for building resilient and reliable manufacturing networks for re-use by addressing the modernisation and digitisation of factories.

The present deliverable has provided an outline of the early deployment of the Eur3ka services, covered among the defined two families of pilots:

- Resilient Smart Supply Networks Services
- Robust On-demand Manufacturing Networks
- Rapid Reconfiguration & Production Line Continuity
- Reliable Repurposing of Production Line Services

This phase has also defined the certification framework to address the verification and validation of the pilots' repurposing actions in the context of Eur3ka project.

From now on, the pilots will focus their efforts on aligning their main services and enablers with Eur3ka services, deploying the necessary components and technologies suggested in WP3 and WP4, and aligned with the blocks of the WP2 Reference Architecture, in order to address the challenges of repurposing. In this phase, the certification framework will also be refined according to emerging needs.

Finally, during the last phase of the project, the effort will be dedicated to the integration of the test services into the Manufacturing Global Response Initiative (MGRI) Plug&Response platform of the Digital Factory Alliance (DFA), just after testing and approving in the framework of Eur3ka. The ultimate goal of the project is to provide both a coordination and manufacturing reuse management platform for Plug&Respond (P&R) in order to provide a rapid response to disruptions and outbreaks in the global value chain. The pilots will thus demonstrate that Eur3ka offers a unique and trusted capability to collectively connect and respond to sudden demand in a coordinated and efficient manner in the event of a crisis, such as the COVID-19 health crisis.

Annex I

Equivalence between ISO13485:2016 and ISO9001:2015 Clauses	
Clause in ISO 13485:2016	**Clause in ISO 9001:2015**
1 Scope	1 Scope
4.1.1 (no title)	4.3 Determining the scope of the quality management system
4 Quality management system	4 Context of the organization
	4.1 Understanding the organization and its context
	4.2 Understanding the needs and expectations of interested parties
	4.4 Quality management system and its processes
4.1 General requirements	4.4 Quality management system and its processes
	8.4 Control of externally provided processes, products and services
4.2 Documentation requirements	7.5 Documented information
4.2.1 General	7.5.1 General
4.2.2 Quality manual	4.3 Determining the scope of the quality management system
	4.4 Quality management system and its processes
	7.5.1 General
4.2.3 Medical device file	*No equivalent clause*
4.2.4 Control of documents	7.5.2 Creating and updating
	7.5.3 Control of documented information
4.2.5 Control of records	7.5.2 Creating and updating
	7.5.3 Control of documented information
5 Management responsibility	5 Leadership
5.1 Management commitment	5.1 Leadership and commitment
	5.1.1 General
5.2 Customer focus	5.1.2 Customer focus
5.3 Quality policy	5.2 Policy
	5.2.1 Establishing the quality policy
	5.2.2 Communicating the quality policy
5.4 Planning	6 Planning
5.4.1 Quality objectives	6.2 Quality objectives and planning to achieve them
5.4.2 Quality management system planning	6 Planning
	6.1 Actions to address risks and opportunities
	6.3 Planning of changes
5.5 Responsibility, authority and communication	5 Leadership
5.5.1 Responsibility and authority	5.3 Organizational roles, responsibilities and authorities

5.5.2 Management representative	5.3 Organizational roles, responsibilities and authorities
5.5.3 Internal communication	7.4 Communication
5.6 Management review	9.3 Management review
5.6.1 General	9.3.1 General
5.6.2 Review input	9.3.2 Management review inputs
5.6.3 Review output	9.3.3 Management review outputs
6 Resource management	7.1 Resources
6.1 Provision of resources	7.1.1 General
	7.1.2 People
6.2 Human resources	7.2 Competence
	7.3 Awareness
6.3 Infrastructure	7.1.3 Infrastructure
6.4 Work environment and contamination control	7.1.4 Environment for the operation of processes
7 Product realization	8 Operation
7.1 Planning of product realization	8.1 Operational planning and control
7.2 Customer-related processes	8.2 Requirements for products and services
7.2.1 Determination of requirements related to product	8.2.2 Determining the requirements for products and services
7.2.2 Review of requirements related to product	8.2.3 Review of the requirements for products and services
	8.2.4 Changes to requirements for products and services
7.2.3 Communication	8.2.1 Customer communication
7.3 Design and development	8.3 Design and development of products and services
7.3.1 General	8.3.1 General
7.3.2 Design and development planning	8.3.2 Design and development planning
7.3.3 Design and development inputs	8.3.3 Design and development inputs
7.3.4 Design and development outputs	8.3.5 Design and development outputs
7.3.5 Design and development review	8.3.4 Design and development controls
7.3.6 Design and development verification	8.3.4 Design and development controls
7.3.7 Design and development validation	8.3.4 Design and development controls
7.3.8 Design and development transfer	8.3.4 Design and development controls
7.3.9 Control of design and development changes	8.3.6 Design and development changes
	8.5.6 Control of changes
7.3.10 Design and development files	7.5.3 Control of documented information
7.4 Purchasing	8.4 Control of externally provided processes, products and services
7.4.1 Purchasing process	8.4 Control of externally provided processes, products and services
	8.4.1 General

	8.4.2 Type and extent of control
7.4.2 Purchasing information	8.4.3 Information for external providers
7.4.3 Verification of purchased product	8.4.2 Type and extent of control
	8.4.3 Information for external providers
	8.6 Release of products and services
7.5 Production and service provision	8.5 Production and service provision
7.5.1 Control of production and service provision	8.5.1 Control of production and service provision
7.5.2 Cleanliness of product	*No equivalent clause*
7.5.3 Installation activities	*No equivalent clause*
7.5.4 Servicing activities	*No equivalent clause*
7.5.5 Particular requirements for sterile medical devices	*No equivalent clause*
7.5.6 Validation of processes for production and service provision	8.5.1 Control of production and service provision
7.5.7 Particular requirements for validation of processes for sterilization and sterile barrier system	*No equivalent clause*
7.5.8 Identification	8.5.2 Identification and traceability
7.5.9 Traceability	8.5.2 Identification and traceability
7.5.10 Customer property	8.5.3 Property belonging to customers or external providers
7.5.11 Preservation of product	8.5.4 Preservation
7.6 Control of monitoring and measuring equipment	7.1.5 Monitoring and measuring resources
8 Measurement, analysis and improvement	9 Performance evaluation
	9.1 Monitoring, measurement, analysis and evaluation
8.1 General	9.1.1 General
8.2 Monitoring and measurement	9.1 Monitoring, measurement, analysis and evaluation
8.2.1 Feedback	8.5.5 Post-delivery activities
	9.1.2 Customer satisfaction
8.2.2 Complaint handling	9.1.2 Customer satisfaction
8.2.3 Reporting to regulatory authorities	8.5.5 Post-delivery activities
8.2.4 Internal audit	9.2 Internal audit
8.2.5 Monitoring and measurement of processes	9.1.1 General
8.2.6 Monitoring and measurement of product	8.6 Release of products and services
8.3 Control of nonconforming product	8.7 Control of nonconforming outputs
8.3.1 General	10.2 Nonconformity and corrective action
8.3.2 Actions in response to nonconforming product detected before delivery	8.7 Control of nonconforming outputs

8.3.3 Actions in response to nonconforming product detected after delivery	8.7 Control of nonconforming outputs
8.4 Analysis of data	9.1.3 Analysis and evaluation
8.5 Improvement	10 Improvement
8.5.1 General	10.1 General
	10.3 Continual improvement
8.5.2 Corrective action	10.2 Nonconformity and corrective action
8.5.3 Preventive action	0.3.3 Risk-based thinking
	6.1 Actions to address risks and opportunities
	10.1 General
	10.3 Continual improvement

Table 4. Equivalence between ISO13485:2016 and ISO9001:2015 Clauses

ISO9001: 2015 compared with ISO13485:2016 additional Requirements	
ISO9001: 2015	**ISO13485:2016**
7.1.4 Environment for the operation of processes	6.4 Work Environment and contamination Control
7.5.3 Control of documented information	4.2.3 Medical Device File 4.2.4 Control of Documents 4.2.5 Control of Records 7.3.10 Design and Development files
8.3.4 Design and Development Controls	7.3.5 Design and Development Review 7.3.6 Design and Development Verification 7.3.7 Design and Development Validation 7.3.8 Design and Development Transfer
8.5.5 Post-delivery Activities	7.5.1 Control of production and service provision 7.5.3 Installation activities 7.5.4 Service Activities 8.2.2 Complaint handling 8.2.3 Report to regulatory authorities 8.3.3 Actions in response to non-conforming product after delivery
9.1.2 Customer Satisfaction	7.2.3 Communication 8.2.1 Feedback 8.2.2 Complaint handling
10.2 Non-Conformity and Corrective actions	8.3 Control of non-conforming product 8.5.2 Corrective action
No equivalent Clause	7.5.2 Cleanliness of product 7.5.5 Particular requirements for sterile products 7.5.7 Particular requirements for validation of processes for sterilization and sterile barrier system

Table 5. ISO9001: 2015 compared with ISO13485:2016 additional Requirements

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