D5.2

Second Integration PlugFest & Validation

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Internal review	2022-12-21	DTI	Few smaller corrections using track changes and one comment for SQS which needs answer
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Disclaimer

Executive Summary

This document provides an update on the status of all Eur3ka project pilots, in terms of service alignment and integration beyond the initial proof of concept described in D5.1. The document covers the integration of the various services and platforms provided by the various partners as enablers for the implementation of the repurposing services and applications.

The document presents the validation framework that would be used to certify the products before they are incorporated into the P&R catalogue as well as the processes involved (Section 4). The pilots incorporate WP4 tools and services and have allowed the validation of the 4 grand scenarios defined in the Project (see Section 2). As shown below:

- **Grand Scenario 1 (Rapid reconfiguration and continuity of production line operation):**
  - Production Line Reconfiguration
  - 3D Printing /Additive Manufacturing
  - Digital Simulations and Digital Twins
  - Business Continuity Framework
- **Grand Scenario 2 (Reliable repurposing of production processes):**
  - Production Line Reconfiguration (Optional)
  - Digital Quality Management
  - Digital Simulations and Digital Twins
  - Regulatory Compliance and Certification
  - Trusted Information Sharing Industrial Data Space
  - Business Continuity Framework (Optional)
- **Grand Scenario 3 (Resilient smart supply networks):**
  - Digital Simulations and Digital Twins
  - Smart Match Making in Supply Chain
  - Trusted Information Sharing Industrial Data Space
  - Business Continuity Framework (Optional)
- **Grand Scenario 4 (Robust on-demand):**
  - 3D Printing /Additive Manufacturing
  - Regulatory Compliance and Certification (Optional)
  - Trusted Information Sharing Industrial Data Space (Optional)
  - Business Continuity Framework (Optional)

The document describes the status of the implementation of the 6 pilots (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 (4). Additive Manufacturing at Danish Technological Institute (5.) Open 3D Printing Catalogue for Professional Additive Manufacturing Network (6). Crowd Production and Validation. These pilots cover the 2 families of trials (1*) Digital Modular Rapid Repurposing for Medical Products* (2) *On-demand additive Manufacturing of Medical Supplies and Components*.

The document illustrates the final implementations and IT infrastructures supporting the repurposing functionalities and the rapid response manufacturing approach. (Section 3)

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1 Introduction

1.1 Scope and Purpose

The COVID-19 crisis has put the spotlight on the globalisation trend. Companies were locating manufacturing sites in areas far away from their main customer base, making China, among others, one of the largest manufacturers. The resulting complex supply chains have become susceptible to being disrupted more easily than expected. The COVID-19 sanitary crisis led to the closure of borders in many countries as well as the implementation of isolation, which coupled with high demands for certain products, has condemned many supply chains to disruptions. In addition to COVID-19, other problems such as the Suez Canal blockage have raised questions about the reliability of such globalised supply chains.

For this reason, the Eur3ka project is committed to helping supply chains to not cease to function when facing similar events. The solution proposed by Eur3ka involves the support of local manufacturing capabilities of small and medium-sized enterprises. The idea is that, if needed, local factories could be repurposed to manufacture new products or increase their production in less than 48 hours.

The main products Eur3ka is focused on are those related to the COVID-19 health crisis. For the manufacture of these products Eur3ka will rely on common manufacturing capabilities, but also on 3D printing networks. 3D printing has been going from strength to strength in recent years, and it can play a critical role in the production of both, simple products (e.g., masks) speeding up the processes, and much more complicated products (e.g., ventilator) where the set-up of a production line is not trivial. Moreover, in a shortage scenario, time is always precious, therefore, Eur3ka´s plan by reducing set-up and ramp-up times and achieving zero-defect manufacturing provides the manufacturing system with the necessary resilience.

Effective repurposing of local factories requires coordination among the participants, where not only the repurposing of a factory is necessary, but also the support of a whole supply chain to ensure the viability of the new production processes. The Eur3ka project will demonstrate that it is possible to establish a coordination strategy to make Europe's medical suppliers become more resilient, filling gaps in their supply chains when demand spikes or transport routes are disrupted.

On the other hand, during these pandemic years, we have seen how very few factories have been able to convert to manufacture medical products, while the majority have fallen by the wayside. The truth is that establishing manufacturing processes that fulfil the regulations imposed by the medical sector and that at the same time are an economically attractive incentive for the factories involved is non-trivial. The Eur3ka project considers this scenario and proposes to enable a global Plug & Response (P&R) manufacturing repurposing coordination framework for **certified** production processes of PPE & CCE products.

The technologies and tools that enable the achievement of these Eur3ka´s objectives (described in detail in the D3.2) have been developed in previous work packages (WP2, WP3, WP4). All these many capabilities offered by the Eur3ka project should be able to be validated at scale in real-life productions, as well as ensuring wider use among manufacturers through international dissemination, global cooperation and business

exploitation. Therefore, in order to test their performance, 6 pilots have been designed and implemented in this work package (WP5) to demonstrate the integration of these technologies and tools, as well as their usefulness in accordance with the 4 Grand Scenarios (described in D3.2) stablished from the objectives. Specifically, within the 7 WPs into which the project is divided, WP5 (Large-Scale Validation of Rapid Repurposed Manufacturing Processes) is the one in charge of: the set-up of the technical validation, experimentation and on-site trials, the performance of the last systems improvements based on evaluation conclusions, and the consolidation and generalization of particular pilot findings into the general Eur3ka impact evaluation framework.

In addition to proving the integration and usefulness of the developed tools and technologies, we must ensure that the resulting products and processes are going to be quickly certified for their use. Therefore, in order to achieve this, it is first necessary that the tools and technologies developed in Eur3ka are certified prior to utilisation. Consistently, the pilots have used these certified capabilities in their deployment. The second is to create a certification framework to ensure that the production processes and products obtained by using these capabilities can be certified. The method for certification is described in section 4 of this document, Certification Framework. Thanks to the former, the process of the latter is much faster and more agile. This non-trivial certification framework is indeed part of the scope of this deliverable.

For the sake of consistency between deliverables, this document *"Second Integration PlugFest & Validation*" is an updated and extended version of deliverable D5.1 "*First PlugFest & Validation".*

1.2 Methodological Approach

The scope of work package 5 has been divided into 3 waves, not to be confused with waves of COVID-19 infection as reported in the media during the pandemic, but as a project phases, as we can see in Figure 1. The effective duration and scope of each wave has been defined iteratively, with Figure 1 being the last update agreed between the partners.

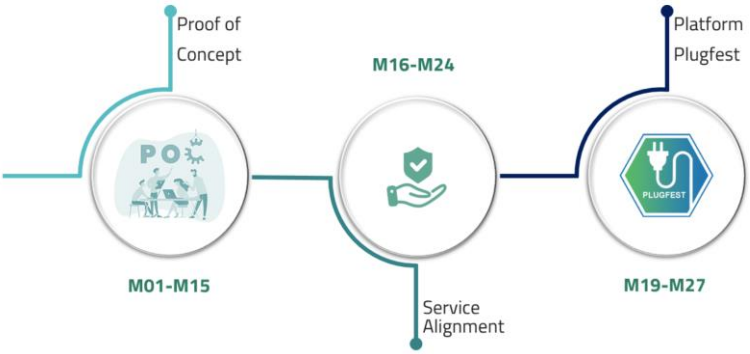


Figure 1. Integration PlugFest and Validation Timeline, 3 waves or project phases are defined

Six different pilots were created, corresponding to 2 pilot families.

- Pilot family 1 (Digital Modular Rapid Repurposing for Medical Products): pilots 1, 2 and 3
- Pilot family 2 (On-Demand Additive Manufacturing of Medical Supplies and Components): pilots 4, 5 and 6.

Further details on these pilots will be provided in the following sections of the document.

The methodology used for the organisation of pilot information is the Trial Handbook (TH). The Trial Handbook is a guidance tool developed to achieve uniformity among pilots to ensure that the collection of technical and business information is clear. An agreed table of contents for the TH has been used by each pilot to define the process followed in detail, ensuring that all pilots reach a similar level of implementation and have a similar documentation structure.

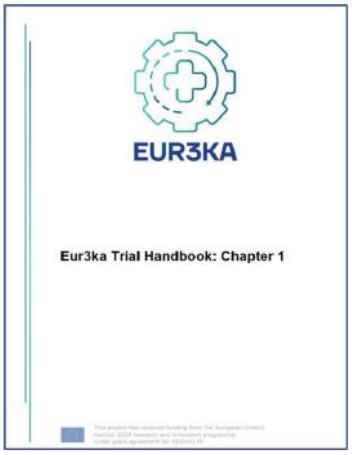


Figure 2. Eur3ka Trial Handbook

While implementing the pilots, each demonstrator has 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 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

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.

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.

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 pilots, 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 waves progress, more chapters can be created, depending on the needs of both the demonstrators and the technical work packages 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.

1.2.1 First wave – Proof of Concept Development (M01-M15)

During the first wave, the table of contents of Chapters 1 (scenario definition and objectives) and 2 (requirements needed) of the TH were agreed between partners.

Table of Contents

Figure 3. Table of Contents of the Chapter 1 (TH)

Table of Contents

Figure 4. Table of Contents of the Chapter 2 (TH)

Thanks to this guidance, the pilot demonstrators were able to carry out The Proof of Concept (PoC). 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 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. During this wave, the certification framework to address the verification and validation of the pilots' repurposing actions in the context of Eur3ka project has also been addressed. For instance, the resulting information from the PoC was captured in deliverable D5.1.

1.2.2 Second wave - Alignment with Eur3ka services (M16-M24)

The second wave has allowed service alignment, moving from The Proof of Concept to a real implementation of the technologies/services developed in previous work packages. Specifically, this wave was designed for the deployment of the necessary components and technologies suggested in WP3 and WP4, aligned with the WP2 Reference Architecture blocks, in order to face the repurposing challenges. In this phase, the certification framework has also been refined in line with emerging needs.

The Table of Contents of another chapter (Chapter 3) of the Trial Handbook has been settled during this wave, thanks to the partners' collaboration.

Table of Contents

Figure 5. Table of Contents of the Chapter 3 (TH)

In this alignment process, and following the reviews' recommendations, we have agreed on the use of a common frame of reference to designate specific profiles for the actors involved during the pilots. We are deepening a common characterisation, allowing a homogeneity between the development of the pilots, as well as a better understanding of their services. We believe that the development of these profiles is important both for the pilots and for the integration of the services in the DFA.

It has been concluded that the characterised users involved in the DFA are the following:

Personalities

Emma: Hospital Administrator

Richard: Medical Design Expert

Alex: Medical Manufacturing Expert

Juan: owner of a 3D low-cost printer

Authorities

Notified Bodies

Enterprises

DINE 3D: additive manufacturing enterprise

- Charles: Operator
- Jake: Customer Project Manager
- Marcos: Mechanical Designer
- Louisa: Sales Engineering
- Sarah: Software Programmer

XCreative: develops a tool (software) that can be included in the DFA Marketplace

SUMA MEDICAL DEVICES: an enterprise that manufactures masks and is willing to enter to the P&R platform.

1.2.3 Third wave - PlugFest (M19-M27)

The third and final wave is being 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 6, 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.

Figure 6. MGRI Plug & Respond MaaS Network

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.

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.

The development of this integration as well as the results of the KPIs of the pilots are not part of the scope of this deliverable, and will therefore be reported in other deliverables.

Specifically, the results of the KPIs will be covered in deliverable D5.4 and the integration in deliverable D2.3.

The content of a fourth chapter of the TH is under development in an iterative approach. As a nutshell, the relationships to date between deliverables and chapters of the TH are shown in Figure 7.

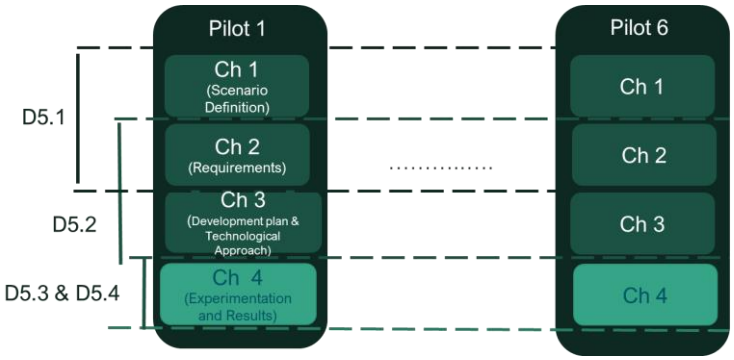


Figure 7. Possible linkage between the deliverables and chapters of the Trial Handbook

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 a crisis affecting the manufacturing process and supply chains.

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

1.3 Linkage with other Deliverables

The first stages of WP5 aimed 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".* The whole PoC total was thus collected in deliverable D5.1 *"First Integration PlugFest & Validation".*

Afterwards, the pilots have been 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". This alignment has been compiled in this deliverable. The results of the KPIs derived from the pilot trials will be covered in deliverable D5.4. Finally, the integration of the trial's services into the Plug & Response platform of the DFA has to be addressed. Further details will be explained in deliverable D2.3.

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 deployment of the pilots is shown in order to achieve the alignment of Eur3ka services.
- Section 5 is devoted to the Verification and Validation (V&V) scheme, which has been developed as an efficient and flexible Certification Scheme in the framework of Eur3ka.

2 Coverage Strategy

2.1 Mapping of Grand Scenarios with Main Services

During the Eur3ka project, 4 Grand Scenarios (Figure 8) have been considered to allow a clearer organisation of the objectives pursued. These scenarios were defined in deliverable D5.3. The scenarios envisaged involve different layers of intervention: internal factory layer, production network layer, supply chain layer and legislative layer. All of which are necessary to cover Eur3ka's services.

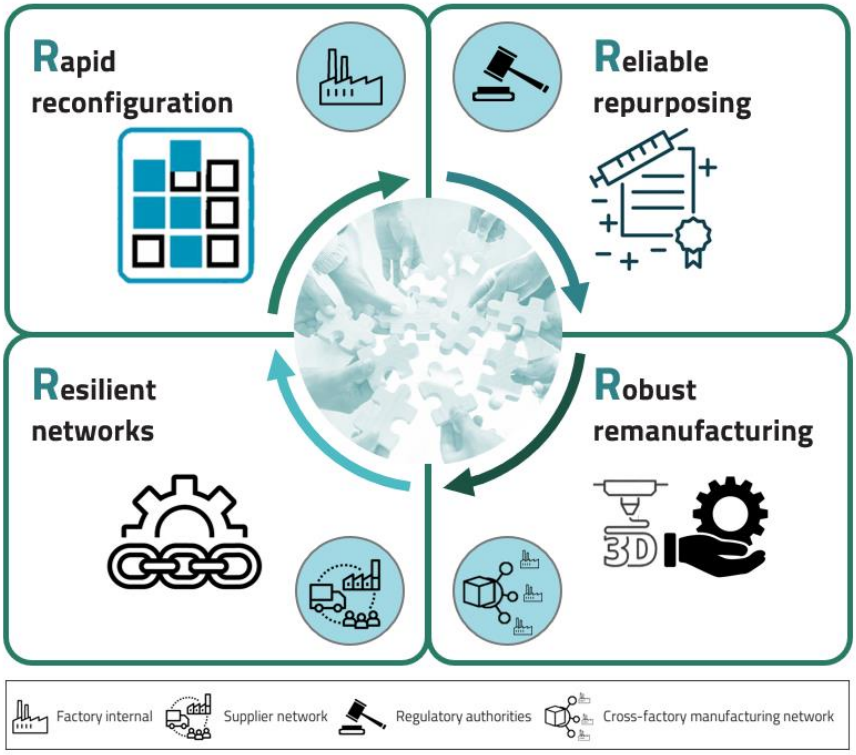


Figure 8. Eur3ka´s Grand Scenarios

These grand scenarios can only be present if certain services are fulfilled. During the Eur3ka project these services have been identified, and it has been noted that several of these services coexist between different scenarios. In accordance with deliverable D3.2, the main services identified in each scenario are as follows:

- **Grand Scenario 1 (Rapid reconfiguration and continuity of production line operation):**
  - Production Line Reconfiguration
  - 3D Printing /Additive Manufacturing
  - Digital Simulations and Digital Twins
  - Business Continuity Framework
- **Grand Scenario 2 (Reliable repurposing of production processes):**

- Production Line Reconfiguration (Optional)
- Digital Quality Management
- Digital Simulations and Digital Twins
- Regulatory Compliance and Certification
- Trusted Information Sharing Industrial Data Space
- Business Continuity Framework (Optional)

- **Grand Scenario 3 (Resilient smart supply networks):**
  - Digital Simulations and Digital Twins
  - Smart Match Making in Supply Chain
  - Trusted Information Sharing Industrial Data Space
  - Business Continuity Framework (Optional)
- **Grand Scenario 4 (Robust on-demand):**
  - 3D Printing /Additive Manufacturing
  - Regulatory Compliance and Certification (Optional)
  - Trusted Information Sharing Industrial Data Space (Optional)
  - Business Continuity Framework (Optional)

The fact that certain services are repeated between scenarios suggests that the tools that have been created for the P&R will be used to cover more than one scenario. This makes sense since the applicants for the participation in the network will each have a different situation and pursue different short-term objectives. The tools created allow different services to be covered, and the union of all of them with their different interdependencies allows the 4 Grand Scenarios described above to be addressed.

On the other hand, it is noteworthy to mention that Eur3ka has focused on the manufacture of medical products, in particular products of complexity 1, 2 and 3 (according to WHO classification). Depending on the product to be manufactured, a different repurposing process will be required, as well as a varying level of intervention. As can be seen in Figure 9, products of complexity 1 will need less time to reach commercialisation than those of complexity 2. In addition, complexity 1 products do not generally present regulatory problems. The Plug & Response platform takes into account the requirements of the manufactured product. Thus, both the time and the tools needed to manufacture these products are invested without wasting capabilities, only using what is necessary, efficiently and effectively. More details on the WHO classification can be found in the Figure 10.

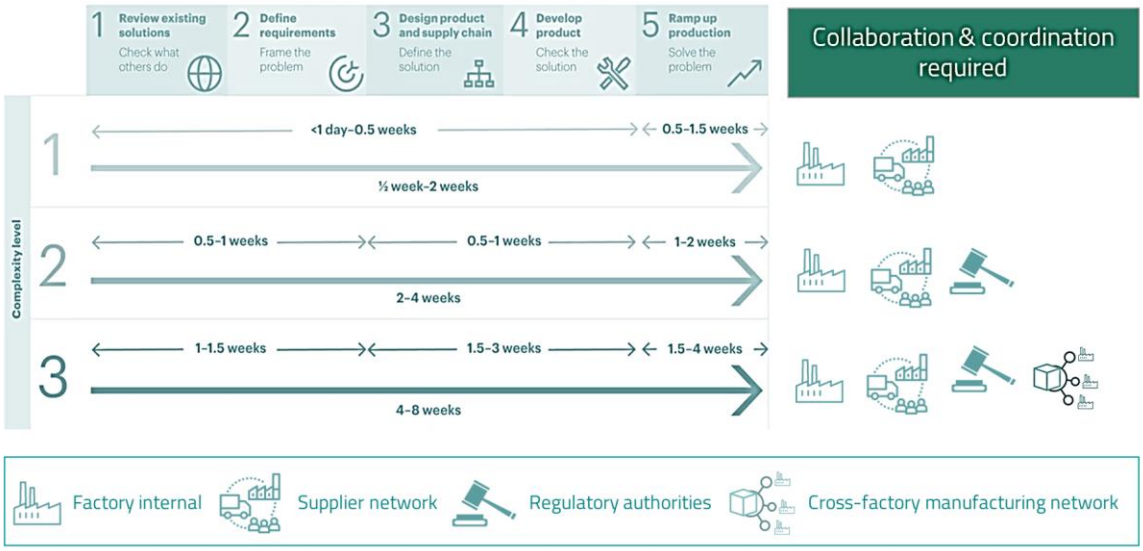


Figure 9. Repurposing process according to the complexity level of the products

Category	Critical items identified by WHO
Protective personal equipment (PPE)	• Gloves, examination • Gloves, surgical • Goggles, protective • Gown, protective • Face shield • Mask, particulate respirator • Mask, surgical
Diagnostic equipment	• Lab screening test kit • Lab confirmation test kit • RT-PCR kit • Extraction kit • Cartridges for RT-PCR automatic systems • Swab and viral transport medium
Clinical care equipment	• Pulse oximeter • Concentrator O2, 10L, 230V, 50 Hz + acc. • Nasal oxygen cannula, with prongs, • Ventilator patient, for adult, pediatric. • CPAP with tubing and patient interfaces for adult and pediatric. • Suction pump, mechanical • High-flow nasal cannula (HFNC)

Figure 10. Medical Products categories following the World Health Organisation (WHO)

In work package 5 it has been decided to test the usefulness of the tools developed in the alignment with the Grand Scenarios to be achieved. It was decided to create at least one use case to test each scenario. Finally, the arrangement was to conduct 6 pilots using some of the tools already created for the platform. Specifically, pilot 1 covers scenario 1, pilot 2 covers scenario 2, pilot 3 covers scenario 3, and pilots 4, 5 and 6 cover scenario 4. An overview of the relationship between pilots and scenarios can be seen in Figure 11.

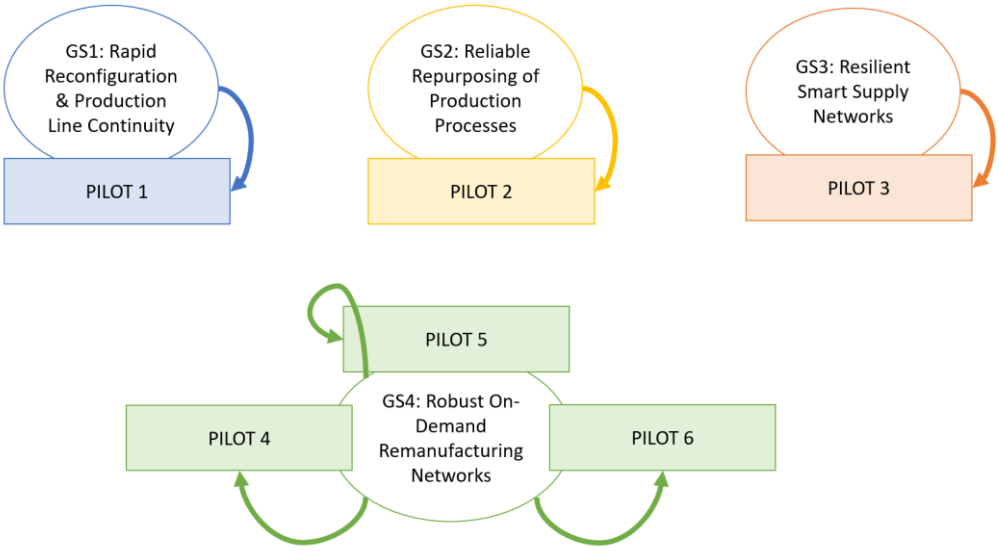


Figure 11. Grand Scenarios mapped with pilots

More precisely, the pilots cover the services shown in the table below (Table 1).

	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
Pilot 1	X			X		X		X
Pilot 2	X	X				X	X	
Pilot 3				X				X
Pilot 4			X			X		
Pilot 5			X					
Pilot 6			X			X		

Table 1. Mapping of the pilots with the main services

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 how 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 (Fast configuration and deployment of medical and pharma lines) is related to GS1 and focuses on the pharma and medical supply industry. 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.

The project partner 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 project partner 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 project partner 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.

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.

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 was created based on this scenario. The project partner SEAC needed to be capable of a rapid and reliable repurposing action in order to respond properly to a sudden high demand for personal protective equipment.

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.

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

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 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 46 high-tech enterprises, the project partner IMECH collected and compared different experiences from several industries acting in the Lombardy region. This pilot has provided an overview of the adopted measures, identified risks and lessons learned. More specifically, one use case has been 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 IMECH consortium have been reported to analyse how manufacturing companies could react to such a disruptive event modifying internal procedures, interaction with clients/suppliers and services provided.

Furthermore, the benefit deriving from supranational initiatives has been 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 has been developed and made available to IMECH partners in order to illustrate the connected opportunities and collect feedback from industry representatives on its actual applicability. Finally, the virtual training technology has been applied to a real industrial applicative scenario collecting feedback from the company's managers and operators.

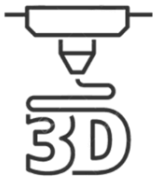
2.1.4 GS4. Robust On-Demand Remanufacturing Networks

"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 GS4, as it is focussed on the transition to a certified production facility in additive manufacturing, enabling a trusted supply chain.

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 has utilized and evaluated 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.



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

- A part for a ventilator assists device
- A Robot gripper (Pharma manufacturing)
- A metal implant

Pilot #5

Pilot 5 relates to GS4, as it is focussed on the sharing of digital information in trusted ways in order to cover different demands and offers (matching).

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 pilot 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 pilot 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

Two different architectures have been developed, one that supports the operation of the P&R platform, and another that allows the integration of the tools available in the P&R with the internal systems of each company that intends to use a tool.

P&R architecture

As seen in Figure 12, there are 4 main blocks supporting all the pilots and addressing the 4 Grand Scenarios. A deeper overview of the architecture can be seen in Figure 13, where the assets and tools of the P&R as well as the services offered are reflected.

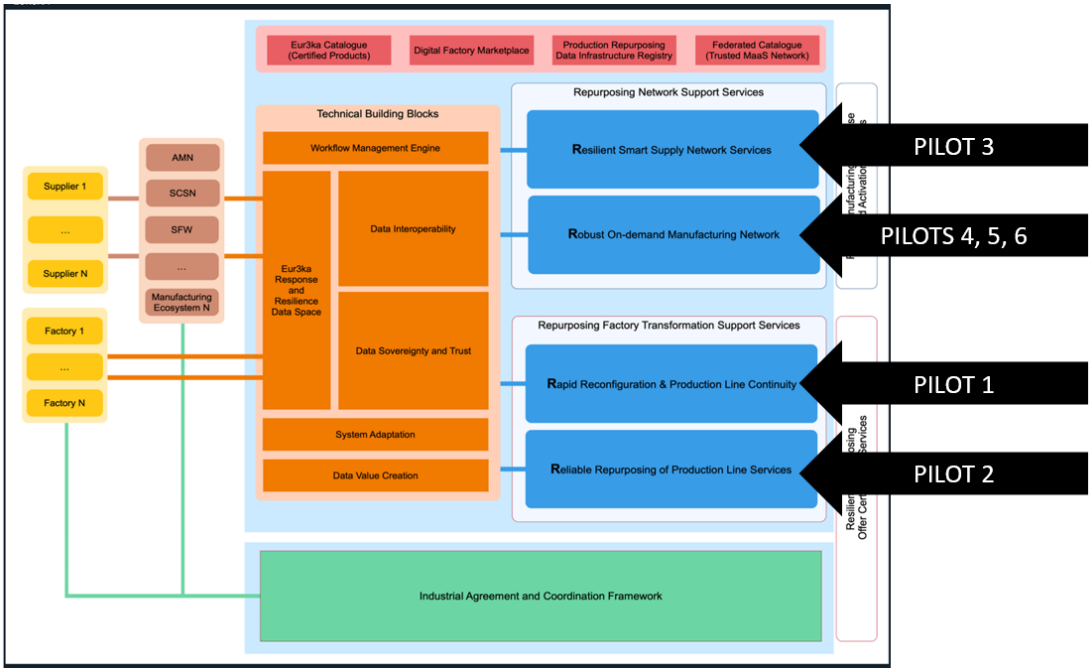


Figure 12. Manufacturing as a Service Network for Fast Pandemic Reaction Reference Architecture (overview)

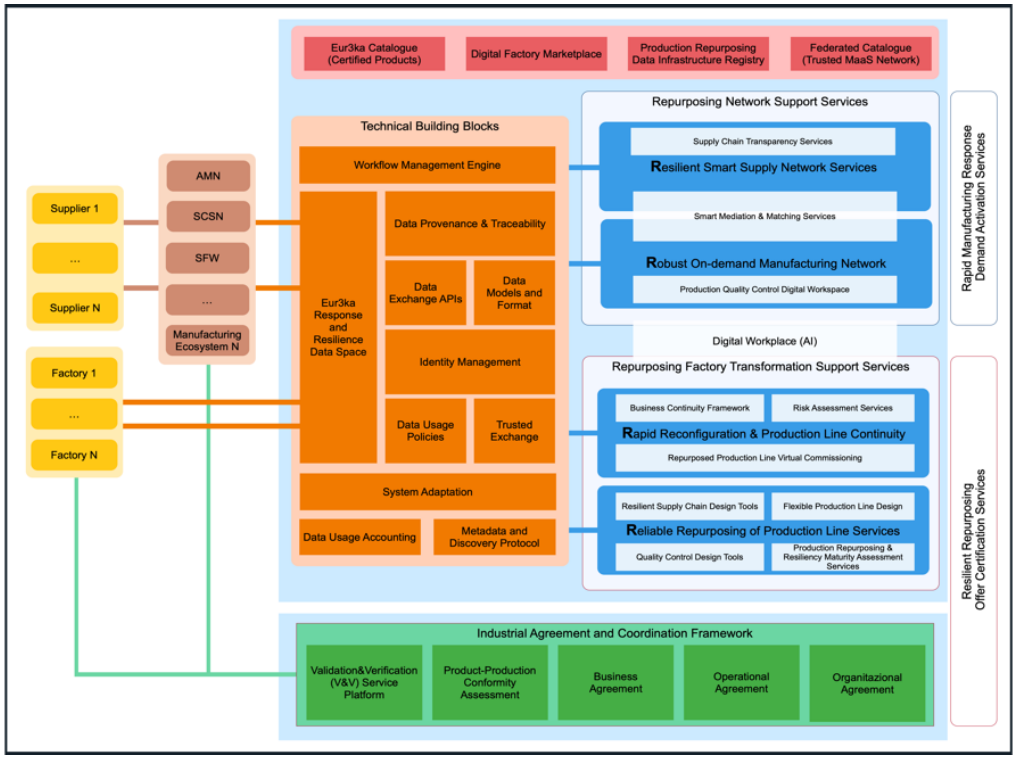


Figure 13. Manufacturing as a Service Network for Fast Pandemic Reaction Reference Architecture (in detail)

Integration architecture

Eur3ka uses the Digital Factory Alliance Reference Architecture (DFA RA) for Industry 4.0. It is composed of three main pillars, as depicted in Figure 14:

- Digital Service Engineering: This pillar provides the capability in the architecture to support collaborative model-based service enterprise approaches to digital service engineering of (autonomous) data-driven processes with a focus on supporting smart digital engineering and smart digital planning and commissioning solutions to the digital factory. The pillar is mainly concerned with the harmonization of digital models and vocabularies. It is this pillar that should develop interoperability assurance layer capabilities with a focus on mature digital factory standards adoption and evolution towards an “industry commons” approach for acceleration of big data integration, processing and management.
- Digital Manufacturing Platforms (DMPs) and Service Operations: This pillar supports the deployment of services and DMPs across the different layers of the digital factory to enact data-driven smart digital workplaces, smart connected production and smart service and maintenance manufacturing processes.
- Sovereign Digital Service Infrastructures: The operation of advanced digital engineering and digital manufacturing platforms relies on the availability of suitable digital infrastructures and the ability to effectively develop a digital thread within and across the digital factory value chain. This pillar is responsible for capturing the different digital computing infrastructures that need to be resiliently networked and orchestrated to support the development of different levels and types of intelligence across the digital factory.

The DFA RA is aligned with ISO 20547 Big Data Reference Architecture.

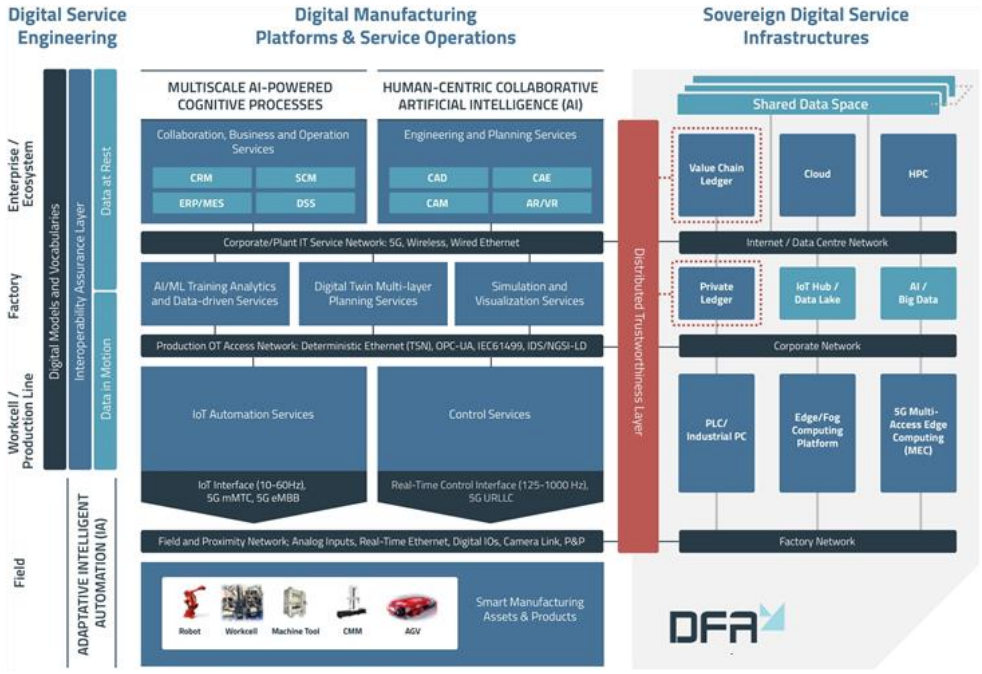


Figure 14. Digital Factory Alliance Reference Architecture (DFA RA)

3 Pilots Deployment

The structure of this section is as follows. In the first place, the technical information of each pilot is discussed in the following order: tools developed in Eur3ka that have been implemented so far, current IT structure, data sets used or generated so far and standards applied. Secondly, information regarding their deployment is presented.

3.1 Family 1. Digital Modular Rapid Repurposing for Medical Products

3.1.1 Pilot #1 Fast configuration and deployment of medical and pharma lines

3.1.1.1 Technical Information

Visual Components 4.0 (currently commercially available under release 4.6). Flexible 3D simulation and visualization suite, that supports the development of the digital twin of the pharma and healthcare systems. The suite incorporates all the modelling tools to start from the initial simulations of the system during the concept phase based on the end-user requirements to the development of the digital twin that will support the deployment of the system in an operational environment. The suite supports standardized communication interfaces, combined with open interfaces that have been de based for the Eur3ka core developments in digital twin.

Certification Support Tools. The pilot is analysing the viability of the use of the digital twin to accelerate the validation and certification of the system for accelerating the commissioning and ramp up of the production at the end-user site.

Virtual Training and Remote support (commercially available as Visual Components Experience release 1.6.0). Visual Components experience is a VR add-on that interfaces with Visual Components 4.0 to provide the fully VR immersive experience. By using the add-on, the users of the VR system will be able to navigate into the 3D environment and interact with the equipment even before the system has been started to be built. This facilitates the communication along the system lifecycle between all the stakeholders. Meanwhile the concept and design phases the VR advantage focus on getting more accurate designs, the engineering phases can initiate the training of the end-users into the use of the new machinery and processes. In addition, the processes can be evaluated and optimized in a realistic environment. The digital models available in the VR, can support different grades of granularity, making them suitable for remote support, allowing technical teams to be in communication in the same equipment even they are in different locations. This support is suitable for design, commissioning, operation and maintenance tasks.

Manufacturing Repurposing Skills framework. Linked to the virtual training supported by the VR functionality, the up-skilling requirements for end-user's employees can be easily tailored within the virtual scenario to instruct the users of the systems in the new operation tasks in the manufacturing system. First cases have been identified and tested in demo machines.

The current components of the IT infrastructure are the following:

ID			BC-<Partner short name>-<Ascending id> SVM-01- Pen Assembly Line
Responsible partner			SVM
Tool name			Pen Assembly line
Overall Description			The system developed for the SVM pilot is a production line for insulin pen assembly. The line is based on the SVM modular platform BasiQX XTV. The system provides and efficient solution reducing CAPEX investment
Details	Functionalities offered		1. Modular platform flexible to be adapted to end-user requirements 2. Adaptable to future requirements and changing market demands 3. Modular design facilitate scalability, adapting to future market demands, adjusting to devices and markets 4. Incorporate standardized technologies, marked tested and validated 5. Equipment customizable to fit any medical device 6. Scalable capacity and supports different automation levels to support customer requirements and specifications 7. Line capacity up to 200 units per minute 8. Easy to operate, access and clean 9. Operator friendly and ergonomical
	Inputs	Description	• Subproducts to be
		Format	End-user specific
		Standard adopted	End-user specific
	Output	Description	Fully assembled Pen
		Format	Customer Specific

		Standard adopted	Customer Specific
	Integration requirements		According to customer requirements and specifications
	Current execution environment		The assembly line is deployed as a product, incorporating: • Tray Infeed (3) • Tray outfeed (1) • Inspection module • Cartridge infeed • Height inspection • Assembly dial • Final inspection • Delta robotics

ID	BC-<Partner short name>-<Ascending id> VIS-01
Responsible partner	VIS
Tool name	SVM pilot simulation library
Overall Description	The simulation library developed for SVM pilot extends the functionality developed for the project based on process modeling feature targeting the SVM pilot. The library is for being using in Visual Components 4.0 (currently working on the release 4.6 until the end of the project, Feb-23). The library has been developed from the digital twin perspective introducing the communication interfaces to the control systems (virtual and real), robotics, automation, and HMI. Simulation capabilities have been added during the pilot development extending the use of the library to the entire lifecycle of the system.

			The library is fully integrated within Visual Components 4.6 providing all the capabilities available and interfaces, including and no limited to communication, VR integration and signal processing.
Details	Functionalities offered		1. Modular Simulation library for the SVM pilot. 2. Supports plug-and-play for easy use during the quotation and design concept phase. 3. Open interfaces to easily configure to end-user requirements and specifications 4. Fully integrated to be used with other visualization tools available within the Visual Components 4.0 ecosystem, such as Visual Components Experience (VR and 3D visualization), 3D pdf, BOM and Video (mp4,
	Data input(s)	Description	• Sensor data from robots • Production data • Etc.
		Format	CAD primary step (.stp, .step), but the library can integrate practically all the commercial step formats. Communication, XML, json, I/O Data sets: csv, XML, json
		Standard adopted	OPC UA, MQTT
	Data output(s)	Description	Visualization
		Format	Data sets: XML, json, I/O
		Standard adopted	OPC UA, XML
	Integration requirements		Open APIs integrated on Visual Components 4.0, etc.

3.1.1.2 Deployment

Despite the modularity of the solutions provided by SVM, it is necessary to remark the high customization of the final system to match each end-user requirements to produce its unique products and keeping the higher levels of performance and quality.

The recent COVID-19 pandemic has demonstrated the necessity to further develop and integrate technologies and digital enablers to accelerate the design and deployment of systems to support the production of pharma and healthcare products.
If the modularity of the solutions developed by SVM is a very effective and faster way to design and commissioning systems, technologies such as the digital twin provided with Visual Components 4.0, accelerates the development and commissioning of the new system. The digital twin, enhances the digital continuity, enabling the introduction of other technologies further developed within Eur3ka such as the virtual training and remote support, supports the training and up-skilling of the operators.

The digital twin integrates within the virtual space the physical shape of the of the different subsystems (machines and equipment), together with the behaviour of the different subsystems (PLC code, robot code, control systems, etc). (Figure 15)

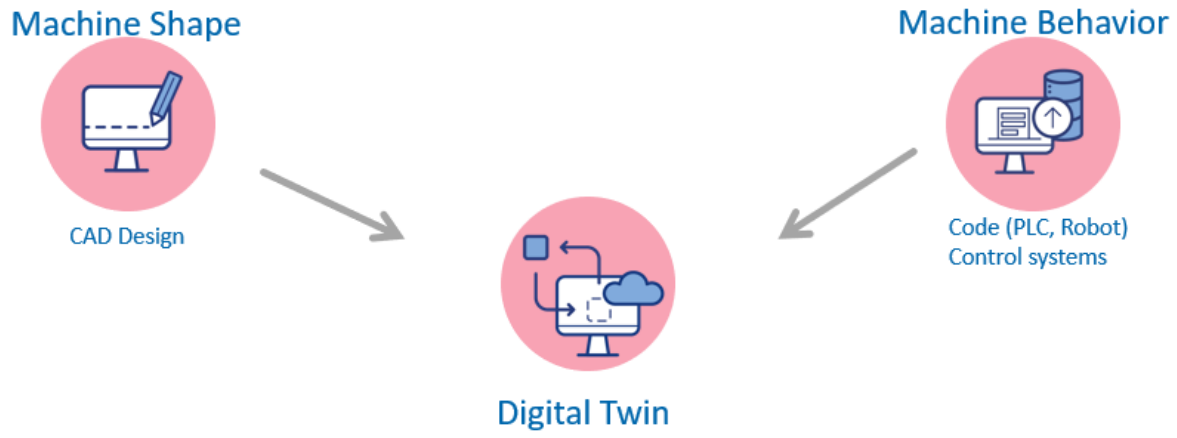


Figure 15. Detail of the integration of the digital twin within the virtual space

The development of the digital twin goes through different stages, along the system lifecycle. When an end-user requests from a machine provider such as SVM, the development of a new system, the process depicted in (Figure 16) starts. The lifecycle starts with the quotation of the new system.

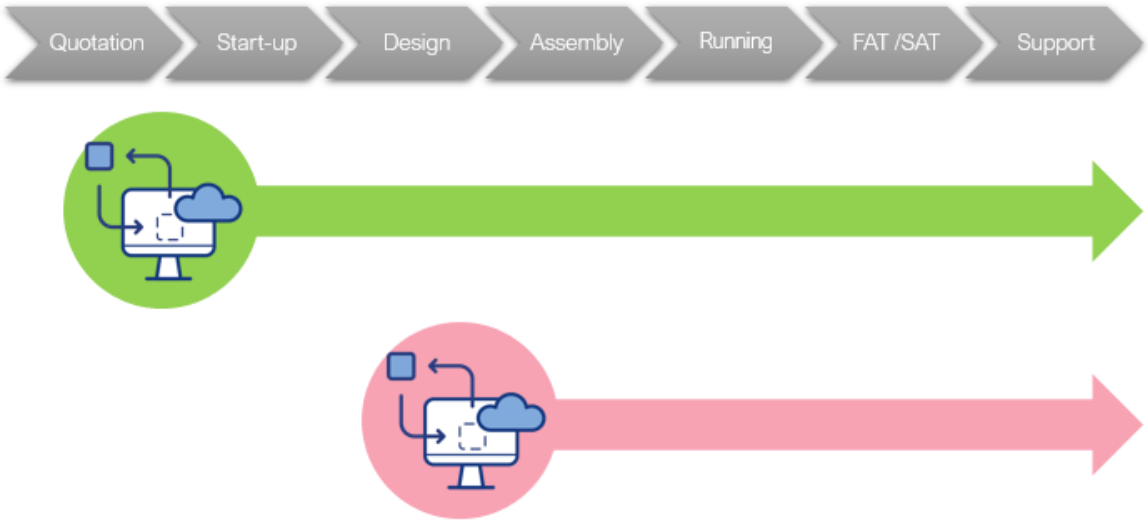


Figure 16. Description of system lifecycle, describing the phases where simulation (green) is available and the digital twin (pink)

During the quotation, the end-user requirements are analysed, and the first CAD designs are created. During this phase the modularity is crucial to accelerate the creation of the first concepts based on the analysis and evaluation of the end-user requirements. Digital models available from previous projects can be reused to develop more accurate concepts and provide better financial evaluation, that will guide to the acceptance of the project by the customer (end-user). Simulation is used during this phase, allowing to devise the required behaviours to be performed by the system and sub-systems.

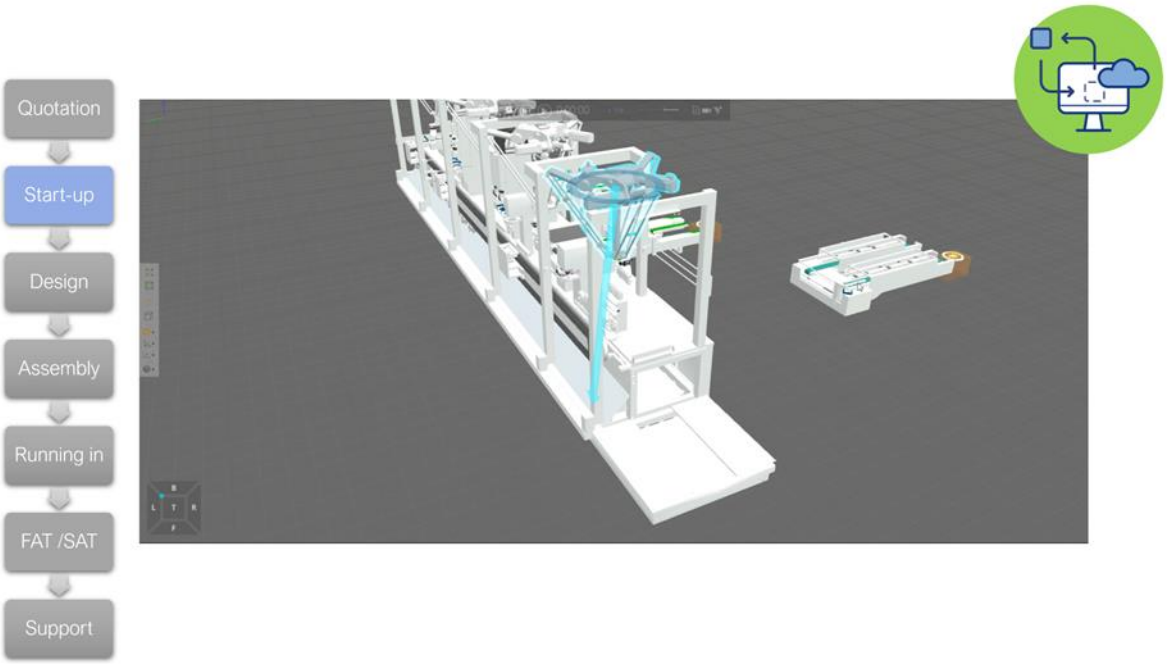
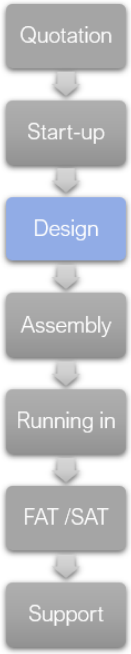


Figure 17. Start-up phase



Step	Condition	Action	Time [ms]
1	PPU in waiting pos. (M1 and M2). Carton support disengaged (M3). Fixtures in pos. (EM03).	PPU to start bend pos. (-Y and +Z axis) (M1 and M2). Carton support engage (+Y axis) (M3).	200
2	PPU in start bend pos. (M1 and M2). Carton support engaged (M3).	PPU bend front locking flaps (-Y and +Z axis) (M1 and M2).	200
3	PPU bend front locking flaps done (M1 and M2).	PPU return to wait pos. (+Y and -Z axis) (M1 and M2). Carton support disengaged (-Y axis) (M3).	200
4	PPU in wait pos. (M1 and M2). Carton support disengaged (M3).	Move 3 pcs. fixtures (+X axis) (EM03)	500
6	Total		1100

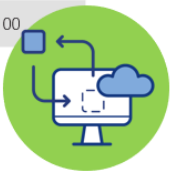


Figure 18. Design phase

While the project is progressing, the simulations are getting more accurate and the development of the initial control systems, automation code (plc and robot) as well as the availability of control systems (virtual and real) allows the integration of the first systems within the virtual environment to enable the digital twin.

Figure 19. FAT/SAT phase

3.1.2 Pilot #2 Testing Facilities for PPE FF Masks

3.1.2.1 Technical Information

The technologies involved are the following: Manufacturing Repurposing Guidelines from ETHZ, COVID-19 Aware Shifts Scheduling from INTRA, Context-Awareness Dashboard from ENG + Asset monitoring and automation FROM STEAM. The Certification Support Tools from SQS are also planned to be deployed.

The current components of the IT infrastructure are the following:

ID			BC-SEAC-1
Responsible partner			SEAC
Tool name			Testing Machine CO_2
Overall Description			Machine to measure CO_2 residual in the FF mask and sealing on the user's face
Details	Functionalities offered		1. Quality inspection 2. Data generation 3. Data presentation 4. Automatization of data collection
	Data input(s)	Description	• CO_2 level (Input and output) • Configuration for the machine
		Format	4-20 mA signal
	Data output(s)	Description	• Residual CO_2 level • Inlet CO_2 value • Sealing potential through pressure sensor • Proportional valve position
		Format	JSON
	Integration requirements		Output data to be collected on a cloud environment to be consumed by tech providers
	Current execution environment		Currently, data obtained from CO_2 sensor, Pressure sensor can be collected on a local PC

ID	BC-SEAC-2
Responsible partner	SEAC

Tool name			ANSTI Machine
Overall Description			Machine to measure breathing effort needed while wearing FF mask
Details	Functionalities offered		1. Quality inspection 2. Data generation 3. Data presentation 4. Data collection on a local PC
	Data input(s)	Description	• Tidal Volume • BPM
	Data output(s)	Description	• Breathing cycle (3145 data points ca) • Inhale Pressure (mbar) • Inhale Pos Pressure (mbar) • Exhale Pressure (mbar) • Ext Work of Breathing (J/l) • Ext Inhale Work (J/l)
		Format	CSV, Dat, Res
	Integration requirements		Output data to be collected on a cloud environment to be consumed by tech providers
	Current execution environment		No communication is provided at the time being for this machine. The system is closed.

ID			BC-SEAC-3
Responsible partner			ENG
Tool name			Data Connectors
Overall Description			Collected Data are harmonized making them ready for the data sharing (through IDS).
Details	Functionalities offered		1. Data Collection 2. Data Harmonization 3. Data Sharing (IDS)
	Data input(s)	Description	• Residual CO2 level • Sealing potential • Breathing cycle
		Description	Harmonized Input Data

	Data output(s)	Format	Json

ID			BC-SEAC-4
Responsible partner			INTRA
Tool name			Shifts Scheduling Service
Overall Description			Shifts Allocation Service that accounts for COVID19 Infections. Enables Dynamic Rescheduling of Shifts (Per Department & Sector) in case of Healthcare Infections.
Details	Functionalities offered		1. Employee management 2. Department management 3. Shift managent 4. Shift scheduling optimization
	Data input(s)	Description	Department data for shift scheduling and optimization
		Format	• JSON (thru exposed API) • TEXT (thru the offered UI)
	Data output(s)	Description	Optimized Shift scheduling
		Format	• JSON (thru exposed API) • TEXT (thru the offered UI)
	Integration requirements		The system is provided as standalone service and currently is not integrated with other components
	Current execution environment		The shift scheduling is delivered as a service and can be hosted in any cloud provider as it consists of multiple components that can be deployed independently using docker-compose scripts. The installation process is automated using the Gitlab CI/CD pipelines building the software directly from version control, publishing images and making the deployments to the cloud provider virtual machines. The shift allocation solution consists of multiple software components that are developed under different technologies and

		frameworks and are separated into 3 layers which implement the frontend the backend and the algorithm respectively: • Frontend: The frontend software component is developed under Angular framework and implements the logic that is presented in the previous section. • Backend: The backend software component is developed under spring boot framework and is responsible for providing data to the frontend and by exposing the following Rest APIS • Algorithm: The algorithm software component is developed in Python programming language and is implementing the formulation and execution of the shift allocation problem.

The current DataSets employed are the following:

Dataset name			CO_2 test Data
Type			Quality Test Data
	Data	Description	1. Set of CO_2 measurements 2. Set of design features of FF masks
		Format	.csv CAD
		Data set size	As needed by the AI experts
		Date to make the dataset available to the Consortium	The automation system installation on testing machine is almost completed

		Mechanisms to make the dataset available to the Consortium	CO_2 testing machine will be connected to the external world by a microcontroller where data will be generated. They can be pushed on a cloud platform or any other repository as needed by the AI experts (TBD)
		Availability to derive an open dataset from it	Open within Eur3ka consortium, after a preliminary check on data quality

Dataset name			ANSTI test Data
Type			Quality Test Data
	Data	Description	3. Set of breathing effort measurements 4. Set of design features of FF masks
		Format	.csv CAD
		Data set size	As needed by the AI experts (TBD)
		Date to make the dataset available to the Consortium	Depending on the capacity of sample testing after the automation system installation on testing machine
		Mechanisms to make the dataset available to the Consortium	ANSTI machine will be connected to the external world by a microcontroller where data will be generated. They can be pushed on a cloud platform or any other repository as needed by the AI experts (TBD)
		Availability to derive an open dataset from	Open within Eur3ka consortium, after a preliminary check on data quality

3.1.2.2 Deployment

The ultimate goal of SEAC is the possibility to store test data from their testing machines and use them within Eur3ka platform. SEAC in collaboration with its partners has adopted the following roadmap:

1. Automatize the machines to extract the output data in a standardized way. The data extracted from the machines will be integrated in a single standardized format from an application developed by STAM, a json file. The data extracted will be: breathing effort data and percentage of C02 residual.
2. Integrate both data streams and fed them to the cloud (Eur3ka). ENG will help SEAC to complete the task.
3. Optimization of the full-face mask design to reach better results in terms of performance (breathing effort and CO2 residual). An AI expert (INTRA) will help develop an AI module that will allow optimization.
4. Receive assistance from SQS to address the lack of specific EU regulation and to reach the compliance with European regulations as medical device.

SEAC has already defined the functional requirements for the automation of the testing machines:

- CO2 testing machine:
    - CO2 sensors: short reading time (< 1 sec), capacity to detect at least 1% and 5% of CO2;
    - Pressure sensor: capacity to detect a pressure of 0,01 bar, accuracy of 0,001 bar;
    - Automatic valves for rapid reconfiguration of the air pipeline set up: 62 lpm flow rate;
    - Proportional valve to control CO2 input level inside the circuit: 5% of CO2;
    - Access to data in digital format.
- ANSTI test machine:
    - Access to data in digital format.

To improve the machines new hardware elements have been bought (CO2 sensors, pressure sensor, automatic valves, proportional valve) with a new pneumatic scheme adopted. New screens have also been installed close to the machines. Furthermore, a new digital interface for SEAC users has been implemented for the ANSTI Machine output (with the help of STAM).

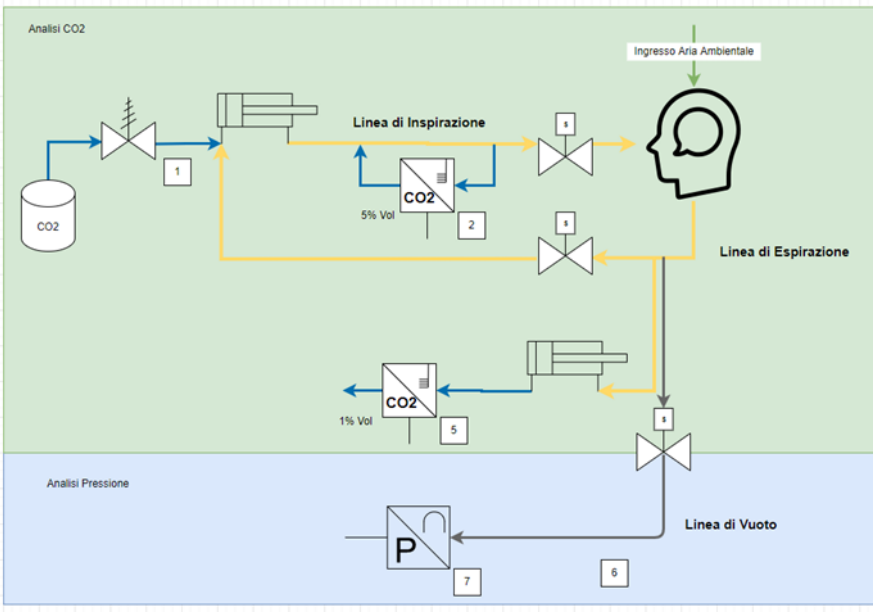


Figure 20. New pneumatic scheme

Specifically, STAM implemented “Asset monitoring and automation” for the SEAC needs.

Here, STAM is applying its expertise in the monitoring and automation field on SEAC pilot plants, where two test machines for full-face anti-viral masks will be integrated together to register digital data and send them to an on-cloud platform, for their visualization and analysis. Moreover, STAM is developing an operator local interface for the CO_2 machine, through which the operator can supervise all new devices installed (CO_2 sensors, pressure probe, Automatic Valves, Proportional valves) and then control the different configurations of the machines and monitor output data with graphics such as the one presented in the images below.

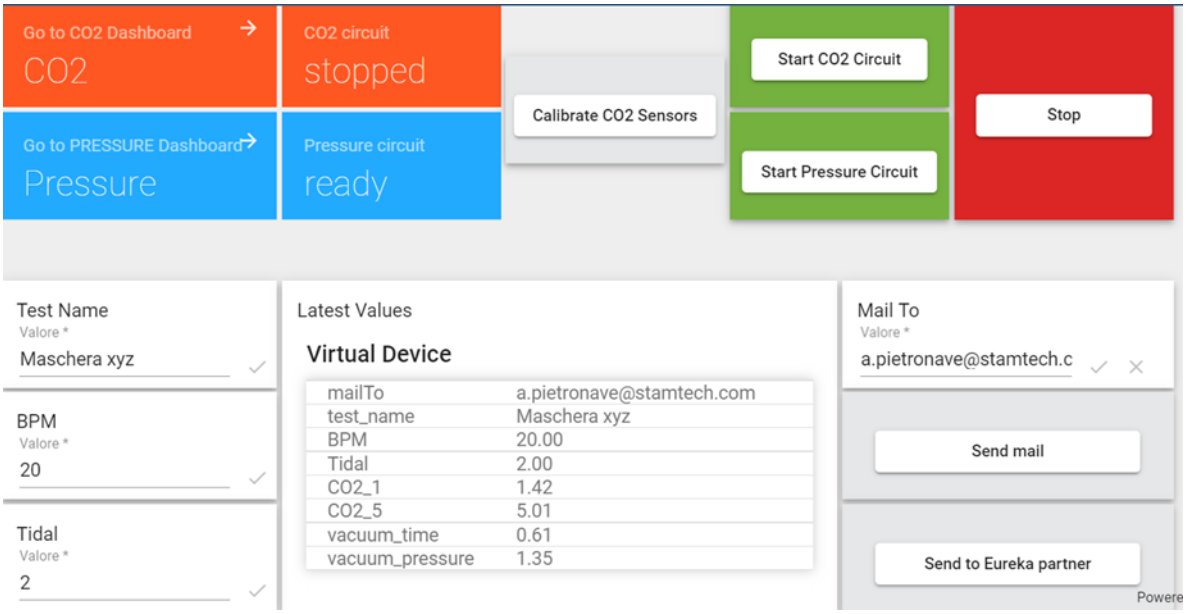


Figure 21. HMI Graphical user interface

For both the machines, another tool has to be installed respectively in the local ANSTI computer and the HMI interface, from Engineering that allows the tests data to be collected and presented on a Eur3ka cloud platform.

SEAC, the end-user of STAM services, is able to benefit from novel functionalities of its assets. In fact, SEAC in the Eur3ka project will have a renewed testing environment, with the possibility of both having a more efficient test, both timing and technically, of its own products and hiring its testing machines to its competitors. Data can represent one more asset for SEAC, to be analysed and/or to be used to create best practices related to the design and manufacturing of such products.

Figure 22. CO2 data dashboard

The set-up of the software logic of the newly installed components has been carried out, then the system has been calibrated and tested by STAM. SEAC employees have also validated these changes. Further corrections can be made to make the system as simple as possible from the point of view of the graphic interface and of the functionalities/ configurations to let a full-face mask test as fast as possible.

The AI module is currently being developed. The goals are to:

1. Verify compliance with standards
2. Optimize the FF masks performance.

In Figure 23 you can see a very preliminary structure of the AI module. As input, it will take several different information, like test data, info about the design of the mask, about the production process and others. As output, it will give feedback about the compliance with standards and suggestions to achieve compliance with standard and/or to optimize mask performance at both design and production level. This objective is still on discussing, some data have been sent to INTRASOFT but they were not enough to establish a proper model. A discussion on correlations between data and formula is ongoing.

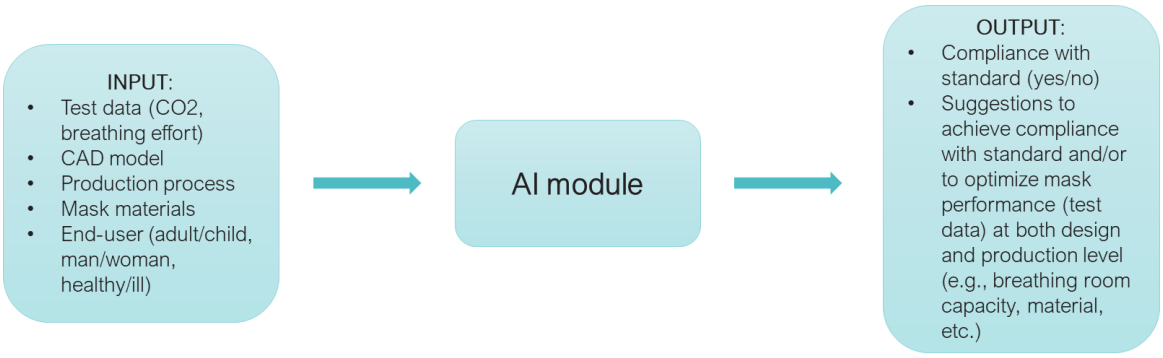


Figure 23. AI module

Specifically, a tool developed by ENG during the Eur3ka project was used: Context-Awareness Dashboard. The impact is: online data collection, AI use on data to optimize geometry, data persistence to a database and historical analysis.

The main functionalities are:

- Secure endpoint to receive batch data in JSON format (Eur3ka System Adaptation)
- MySQL DB to collect data received from the plant
- Historical analysis
- Possibility to run processing on the datasets in order to apply logic and AI on them

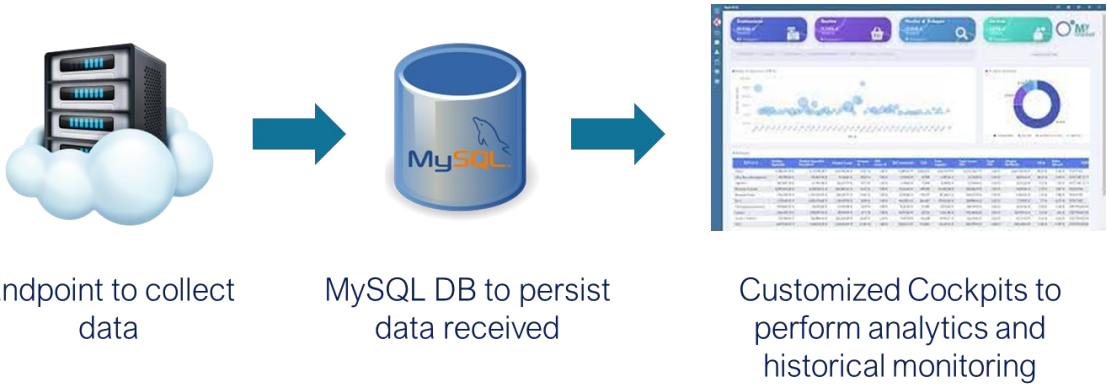


Figure 24. Situation Awareness Service in action

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

3.1.3.1 Technical Information

The technologies participating in the pilot are: Financial Impact Analysis & S-ROI (POLIMI), Manufacturing Repurposing Guidelines (ETHZ), Manufacturing Repurposing Skills framework (POLIMI, VIS), a Virtual Training and Remote Support tool created during this pilot.

The pilot will be focused on the business processes outlined below.

Repurposing

The rapid evolution of the COVID-19 and the related uncertainties make it very difficult for companies to define efficient strategies. Thus, repurposing processes have been defined without a standard framework on which rely, with following inefficiency and incurring in avoidable errors. A structured collection of best practices could provide significant benefits to companies facing disruptive events. Thus, the Eur3ka tool “Manufacturing Repurposing Guidelines” could be applied a posteriori to the IMECH partners’ experience and validated through the comparison between what happened and what could have been improved.

Business continuity and strategy definition

Moreover, the COVID-19 pandemic has stressed the need to speed up the industrial transformation improving the flexibility and resilience of the manufacturing system. Digitalization and interconnection are 2 of the main trends that gained evidence in this period, aiming at the creation of an industry in which company production resources (assets, people and information) are interconnected and cooperate to ensure real-time optimization of production processes in terms of quality, flexibility and costs. Nevertheless, a solid financial impact assessment based on standard methodology was missing. Thus, the Eur3ka tool “Financial Impact Analysis & S-ROI” could be exploited to provide a clearer understanding of the current situation, the main development objectives and the financial impact of such investments.

Re/Up-skill

Generally, the measures undertaken to avoid the spread of the contagion have been all addressed to the social distancing promotion, for example through the minimization of the number of entrants. This measure has required the industrial and manufacturing layout and schedule modification, and the following redistribution of working tasks and reskilling of the employees to ensure the core business continuity in restrictive conditions. Moreover, reskilling may be required also in the repurposing process, where it gains greater prominence since the employees are demanded to apply their knowledge in fields that may be completely different from what they are used to. Thus, the Eur3ka tool “Manufacturing Repurposing Skills framework” could represent a valuable support to identify the crucial roles and skills, the current gaps and the path to fill these gaps.

The current components of the IT infrastructure are the following:

ID			BC-IMECH-1
Responsible partner			IMECH
Tool name			Pacelab WEAVR
Overall Description			tool built on top of Unity and designed for industrial enterprises to create, manage, and play XR content experiences.
Details	Functionalities offered		1. WEAVR Creator which provides a WYSIWYG development environment allowing non IT-experts creating the AR application and procedures without doing coding activities. 2. WEAVR Player which runs the procedures generated by the creator and is available for all major headsets. 3. WEAVR Manager which provides functionalities to manage users, procedures and connectors.
	Data inputs	Description	• Line and environment 3D model • Training procedure description
		Format	3D FBX model Textual and graphical information
		Standard adopted	3D CAD file format: STEP (Standard for the Exchange of Product Data) and FBX (Filmbox)
	Data output	Description	Immersive training tool
		Format	Unity standalone executable
	Integration requirements		VR headset Next step: connectors for manufacturing enterprise IT systems to ensure future exploitability

	Current execution environment	VR headset: Oculus Rift 2

The DataSets are not applicable in this trial.

3.1.3.2 Deployment

The main objectives of this pilot are:

1. To support companies, mainly manufacturing SMEs, in the assessment of their position with respect to the competitors and in the identification of the main areas of improvement. The tool should provide clear indications to identify the company maturity level following a list of indicators and a comparison method to evaluate the current and the expected situation;
2. To identify roles and relevant skills to support digitization and flexibility improvement. The as-is situation should be evaluated through surveys so as to analyse gaps related to the defined skills and provide roadmap and best practices to fill these gaps;
3. To collect feedback from industrial companies concerning the assessment tool and the skills framework. In this view, at least two industrial entities will be involved in interviews in which they will define their current situation, analyse the identified gaps and evaluate the proposed development paths considering the related advantages, disadvantages, feasibility and alignment with the internal strategy;
4. To develop a Virtual Training demonstrator. Indeed, this technology addresses the above-mentioned driving factors allowing the company to provide continuous training activities to employees in a flexible, more efficient and less expensive way than traditional training. These tools enable employees to experience critical situations in a safe environment ensuring business continuity since they do not require to stop production for training on the physical assets. Moreover, the configurability of this technology allows the operator to interact with modular, flexible and constantly evolving processes representing a step towards the digitization and remotization of internal processes;
5. To apply the Virtual Training concept in at least one real industrial application. This applicative use case will provide evidence of the benefits connected with this technology. To this purpose, feedbacks will be collected from both managers and operators of the involved company.

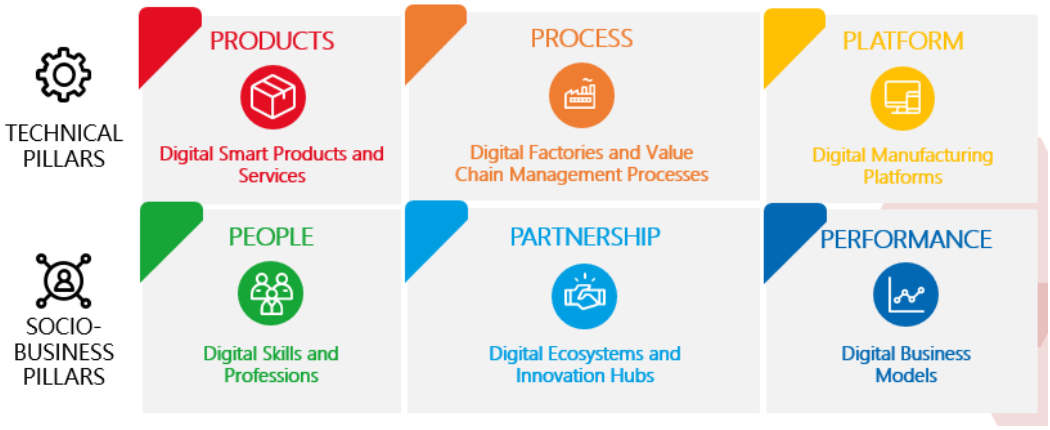


Figure 25. 6P Methodology Framework

The Financial Impact Assessment tool is extracted from the 6Ps methodology.

PERFORMANCE DIMENSION

In the 6P Methodology Framework, the pilot has focus firstly on the performance dimension:

The main objective is to investigate the relevant performance dimensions to be kept under control to monitor the resilience of a company. In this way, it is expected to be able to evaluate the capacity of a company to react against unexpected events and crises. In this regard the objective is to design and develop a structured methodology able to assess the current level of resilience maturity to be able to design a specific action plan to fill the gaps identified.

The main activities to be done were:

- #1 Identify the key performances to be monitored and introduce the related needed KPIs to be kept under control across the key performance identified as fundamental
- #2 Design and development of a structured methodology (surveys based) able to assess the current level of resilience maturity of companies and organizations
- #3 Collect the needed feedback from the partners in the development stage of the project
- #4 Identify new KPIs to improve the current balance score card

Activity 1

Activity #1 has already been addressed. 6P's Performance dimension aims at investigating what the role that Industry 4.0 technologies have in the definition, monitoring and interpretation of KPIs of the manufacturing SMEs. The dimension is divided into 6 areas, namely: Operational/Technical, Economic, Environmental, Social, Product-Service Lifecycle and Supply Chain. Each area has 5 levels (from 1 to 5) each one corresponding to a certain maturity level. The firm will score each area both for the current situation (as is) and for the expected one (to be).

	LEVEL-1 INITIAL	LEVEL-2 MANAGED	LEVEL-3 DEFINED	LEVEL-4 INTEGRATED	LEVEL-5 EXPLOITED
OPERATIONAL/ TECHNICAL	Operational performance is often not measured or understood	Descriptive Performance - Measurement and analysis of business KPIs are largely retrospective	Diagnostic Performance - Measurement of KPIs is clear. Attempt to understand the causes that affects events and behaviours	Predictive Performance - Measurement of KPIs is prospective. Statistical models and forecasts techniques to understand the future KPIs	Prescriptive Performance – future-oriented. Optimization and simulation to find the best course of action and operational KPIs measurement
ECONOMIC	Economic performance is often not measured or understood	Descriptive – Measurement of economic KPIs is largely retrospective	Diagnostic - Measurement of economic KPIs is clear. Attempt to understand the causes of events and behaviours	Predictive - Measurement of economic KPIs is prospective. Statistical models and forecasts techniques to understand the future	Prescriptive – future-oriented. Optimization and simulation to find the best course of action and economic KPIs measurement
ENVIRONMENTAL	Environmental performance is often not measured or understood	Descriptive – Measurement of environmental KPIs is largely retrospective	Diagnostic - Measurement of environmental KPIs is clear. Attempt to understand the causes of events and behaviours	Predictive - Measurement of environmental KPIs is prospective. Statistical models and forecasts techniques to understand the future	Prescriptive – future-oriented. Optimization and simulation to find the best course of action and environmental KPIs measurement
SOCIAL	Social performance is often not measured or understood	Descriptive - Measurement of social KPIs is largely retrospective	Diagnostic - Measurement of social KPIs is clear. Attempt to understand the causes of events and behaviours	Predictive - Measurement of social KPIs is prospective. Statistical models and forecasts techniques to understand the future	Prescriptive – future-oriented. Optimization and simulation to find the best course of action and social KPIs measurement
PRODUCT-SERVICE LIFECYCLE	No product life cycle assessment	A few life-cycle aspects are included in some KPIs but occasionally	Life Cycle Costing (LCC) towards recycling, de-re-manufacturing KPIs	Life Cycle Costing + Environmental LCA towards Circular Economy	Life Cycle Costing + Environmental LCA + Social LCA towards Sustainability and Green Deal
SUPPLY CHAIN	Performance is often not measured or understood	Only the most important physical performance of suppliers (e.g. punctuality, quality, operational flexibility)	Physical and Economical performance (purchase price, non-quality costs, delivery delays, lack of flexibility, etc.).	Physical, economical, sustainability performance for almost all the suppliers.	Physical, economical, sustainability and integration with other external sources (e.g., social media, weather)

Figure 26. Areas involved in the performance dimension

Activity 2

Activity #2 has already been done with the following outputs:

1. Performance Analysis (survey)
    a. Objective: To assess the current situation (As-Is) of the project experiments and also their future expectations (To-Be) in relation to the introduced KPIs
    b. Target group. Experimenters "one answer of each" -Tech providers and Users
    c. **Link**

Activity 3

Activity #3 has also already been executed. With the following outputs:

Figure 27. First iteration of the survey

Activity 4

Activity #4 is on-going, as well as the second iteration of the methodology. The goal is to compare the previous answers about AS-IS and desired TO-Be with the current AS-IS to evaluate structured improvement paths in case the desired TO-BE in the past has not yet become the current AS –IS. Moreover, it is asked the set of KPIs introduced to extend the current platform.

1. Performance (Survey)
    a. Link

PEOPLE DIMENSION

On the other hand, this pilot has also addressed the People Dimension (from 6P Methodology). The main scope is to consider People dimension affected by digitalization and the occurrence of unexpected events and crises within the industrial and other.

In this regard the objective is to design and develop a structured methodology able to assess the current level of digital maturity and resilience that these latter aim at achieving and design a specific action plan to allow the transition needed to fill the gaps identified.

The main activities considered were:

- #1 Identify and Introduce new job profiles and relevant skills
- #2 Design and development of a structured methodology (surveys based) able to assess the current level of digital maturity and resilience of companies and organizations
- #3 Collect the needed feedback from the partners in the development stage of the project
- #4 Identify resources related to training courses to adapt new skills and improve existing ones

Activity 1

Activity #1 has already been realise, as presented in the following schema:

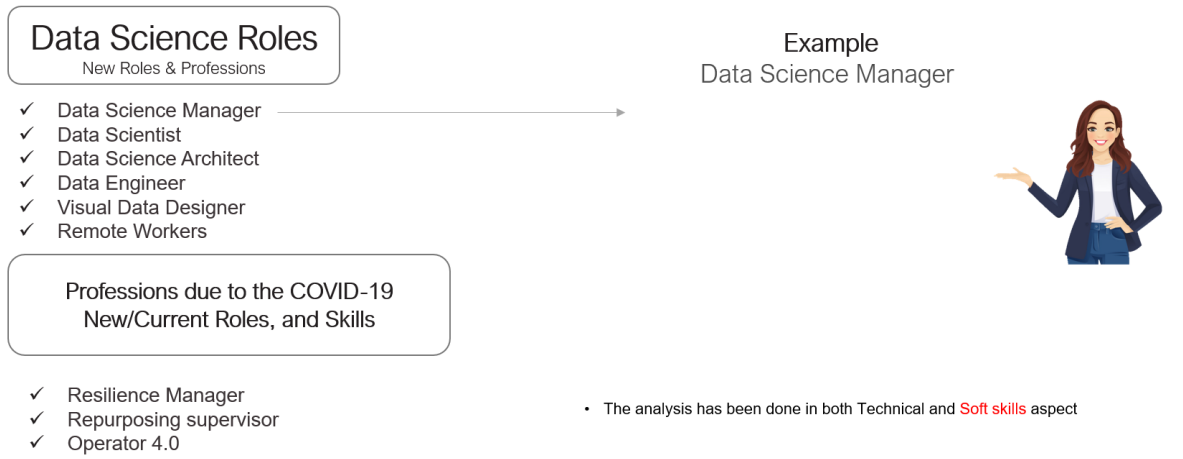


Figure 28. New job profiles

Activity 2

Activity #2 has also been executed. As presented below:

1. Voting and prioritizing skills (Survey)
    a. Objective: Prioritize skills related to each profile based on Project Partner's opinions
    b. Target group: All individuals – Internal – Project Partners
    c. **Link**
2. Possessed and Needed (Survey + Interview)
    a. Objective: To assess the current situation (As-Is) of the project experiments and also their future expectations (To-Be) in relation to the introduced job profiles
    b. Target group: Experimenters "one answer of each" -Tech providers and Users
    c. **Link**

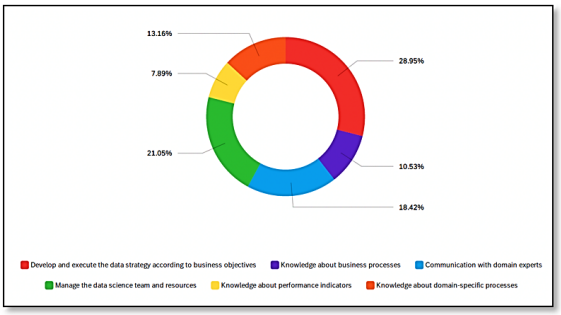
Activity 3

Activity #3 has already been implemented (as a first iteration), as presented in Figure 29.

Voting and prioritizing skills (Survey)

Ex. Data Science Manager

Possessed and Needed (Survey + Interview)



#	Field	N/A	1	2	3	4	5	Total
1	A: Develop and execute the data strategy according to business objectives	0.00%	0.00%	0.00%	25.00%	25.00%	50.00%	4
2	B: Knowledge about business processes	0.00%	0.00%	0.00%	0.00%	50.00%	50.00%	4
3	C: Communication with domain experts	0.00%	0.00%	0.00%	0.00%	25.00%	75.00%	4
4	D: Manage the data science team and resources	0.00%	25.00%	0.00%	0.00%	25.00%	50.00%	4
5	E: Knowledge about performance indicators	0.00%	0.00%	0.00%	50.00%	25.00%	25.00%	4
6	F: Knowledge about domain-specific processes	0.00%	0.00%	0.00%	50.00%	25.00%	25.00%	4

1- Basic, 2- lower intemediate, 3- Intermediate, 4- Upperintermediate, 5- Expert

Figure 29. Example of feedback

Activity 4

Activity #4 is on-going, as well as the second iteration of the methodology. The existing outputs are:

Matrix: relation between courses and Roles *1 - Awareness* *2 - Foundations* *3 - Extended Know-How*		*Provider*	HMS	PoliTecnico di Milano	PoliTecnico di Milano	HMS
		Course name	AI Opportunities for SMEs	Artificial Intelligence - An Overview	Artificial Intelligence and legal issues	Assessing HPC readiness for SMEs
DATA Science Management New Roles & Professions	**Data Science Manager**					
	Knowledge about domain specific processes		1	1		
	Knowledge about business processes		2		1	2
	Communication with domain experts					
	Manage the data science team and resources			1		
	Knowledge about performance indicators				1	1
	Develop and execute the data strategy according to business objectives		1	1	1	
	Data Science Architect					
	Ability to integrate data universe			1		
	Select software platforms for big data (Hadoop, Data Lake)			1		
	Knowledge about big data architectural standards				1	
	Select hardware platforms for big data (performances...)			3		
	Data Scientist					
	Identify and interpret relevant data sources			1		
	Use a programming language (R, Python)					
	Communicate with domain experts					
	Mathematical and statistical models' knowledge			3		
	Knowledge about domain-specific processes			1		
	Use of machine learning, Bayes classifier, Deep Learning techniques and OR methods		3			
	Use of optimization algorithms		1	1		

Figure 30. Relation between courses and roles

1. Voting and prioritizing skills (Survey)
    a. Link
2. Possessed and Needed (Survey)
    a. Link

As a summary, the pilots next steps are: complete the second iteration of the methodology, complete the DataBase and execute a Workshop in collaboration with IMECH and AFIL.

In addition to the 6P Methodology, a tool for Virtual Training has been developed. The activities planned were: the development of a demonstrator for an automated assembly line in the SMILE Laboratory and the presentation to industrial stakeholders (done 28/1/2022).

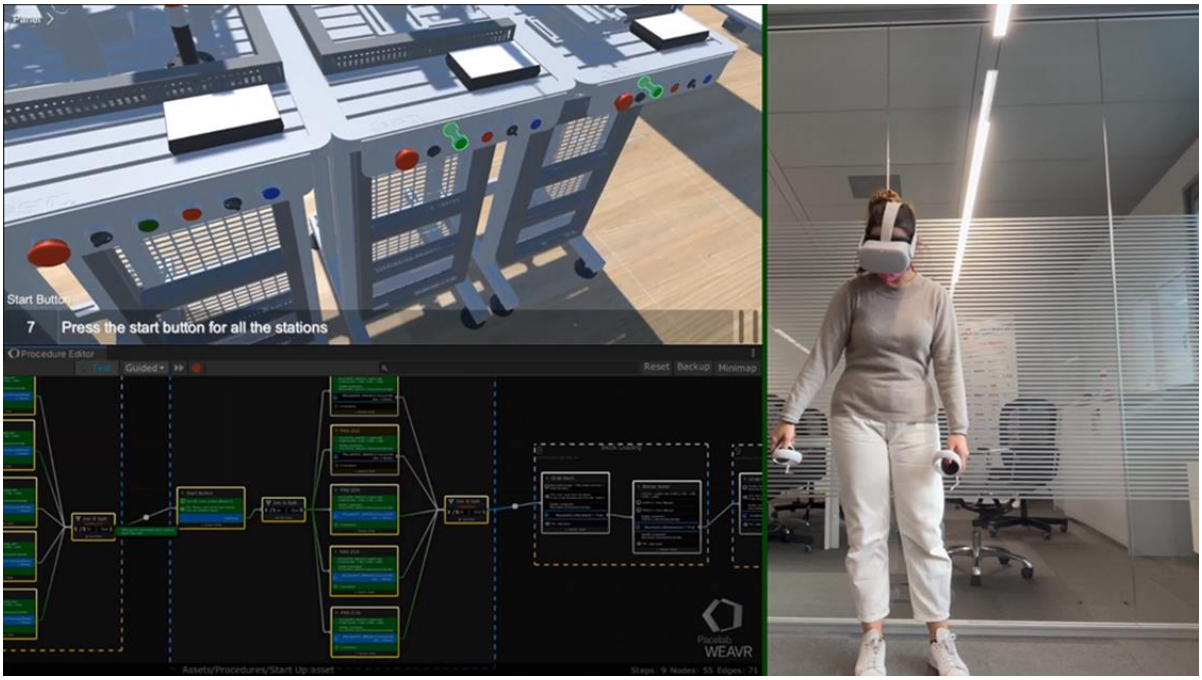


Figure 31. Virtual Training Tool demonstrator at the SMILE laboratory

Figure 32. Virtual Training presentation to industrial stakeholders

Furthermore, the Virtual Training had to have a successful industrial application, therefore, some activities were planned: development of the industrial application (done), interviews with operators (on going) and performance re-evaluation (on-going). In collaboration with SIAD this final phase it is being deployed.

SIAD currently has an area dedicated to training, with assets used by the new resources to learn about the compressor's main components and assemblies, as well as assembly/disassembly operations useful for carrying out service activities. Replacing it with a VT tool would allow:

- Reduction of fixed assets
- Improved scalability
- Ease of extension to different locations

3.2 Family 2. On-Demand Additive Manufacturing of Medical Supplies and Components

3.2.1 Pilot #4. Additive Manufacturing at Danish Technological Institute

3.2.1.1 Technical Information

This trial is utilizing the Process and Product Conformity Assessment tool developed in collaboration with SQS, which is part of the Certification Support Tools (From Q-MED Tech Platform).

The current components of the IT infrastructure are the following:

ID			BC-SQS-1
Responsible partner			SQS
Tool name			Process and product assessment toolset
Overall Description			Toolset conceived to deliver an automatic gap analysis to comply with ISO13485 standard. This is a semiautomatic tool.
Details	Functionalities offered		Module 1: Data capture Module 2: Automatic assessment Module 3: Generation of implementation plan
	Data input(s)	Description	Information provided by manufacturers. Configuration data for the assessment.
		Format	Manual data Database – MySQL
	Data output(s)	Description	Assessment and implementation report Raw data of information provided
		Format	CSV, pdf
	Current execution environment		SW application.

ID	BC-SQS-2

Responsible partner			SQS
Tool name			Implementation support toolset
Overall Description			Toolset conceived to help manufacturers perform the qualification process.
Details	Functionalities offered		Module 1: Data capture Module 2: Automatic assessment Module 3: Repository of documentation
	Data input(s)	Description	Assessment and implementation report • Raw data of information provided
		Format	CSV, pdf
	Data output(s)	Description	Assessment and implementation report Raw data of information provided
		Format	CSV, pdf
	Current execution environment		SW application.

ID			BC-SQS-2
Responsible partner			SQS
Tool name			Implementation support toolset
Overall Description			Toolset conceived to help manufacturers perform the qualification process.
Details	Functionalities offered		Module 1: Data capture Module 2: Automatic assessment Module 3: Repository of documentation
	Data input(s)	Description	Assessment and implementation report • Raw data of information provided
		Format	CSV, pdf
	Data output(s)	Description	Assessment and implementation report Raw data of information provided
		Format	CSV, pdf

	Current execution environment	SW application.

The current DataSets employed are the following:

Dataset name			Answers DTI ISO
Type			Text
	Data	Description	5. Answers to the questionnaire in module 1 from above, supplied by DTI relevant for making an implementation plan of ISO 13485.
		Format	CSV/excel data sheet
		Data set size	<1Gb
		Date to make the dataset available to the Consortium	Data will only be available to SQS during the project
		Availability to derive an open dataset from it	Yes after anonymization

The standards used for this pilot are mainly ISO 13485 and ISO 9001 for the quality management systems, ISO 14971 for the risk evaluation and ISO 52920 for the AM specific standard manufacturing of critical component such as MedTech class 2-3.

3.2.1.2 Deployment

The Danish Technological Institute, DTI, already has ISO 9001 and are able to control and validate processes for food contact within Additive Manufacturing. This pilot´s objectives were: guidance on the transformation from ISO 9001 to ISO 13485, guidance on the implementation of risk management ISO 14971 and the elaboration of a plan to implement ISO 13485.

SQS had to elaborate an implementation plan for the ISO 13485 and for the ISO 52920, in collaboration with the end user (DTI). In addition, SQS´s software was validated via this pilot's results.

One the tools that SQS has developed for Eur3ka (belonging to the group of Certification Support Tools from Q-MED Tech) is the Process and Product Assessment Tool.

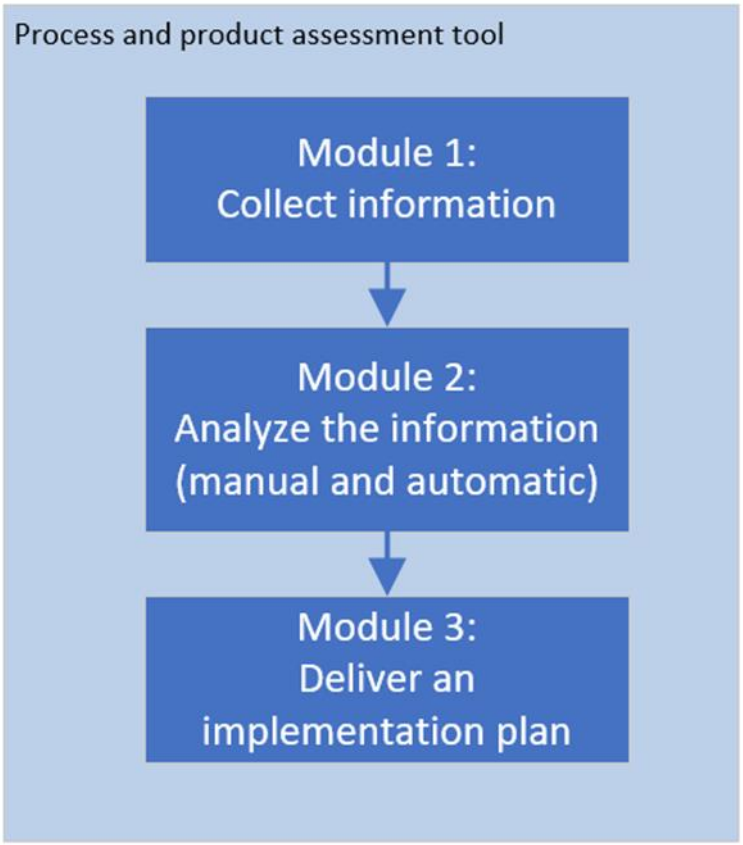


Figure 33. Process and Product Assessment Tool

Module 1 contains the following components:

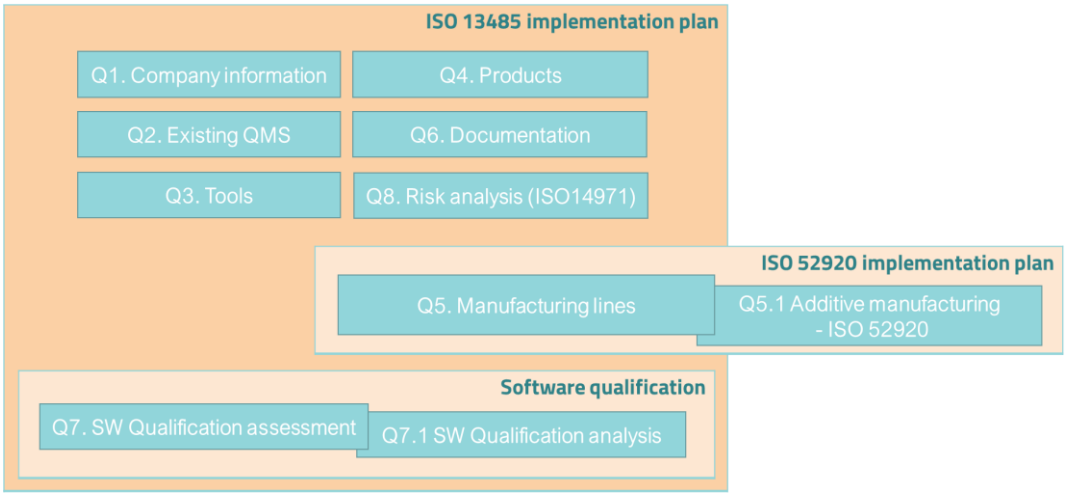


Figure 34. Components from Module 1

Module 2 works based on the following structure:

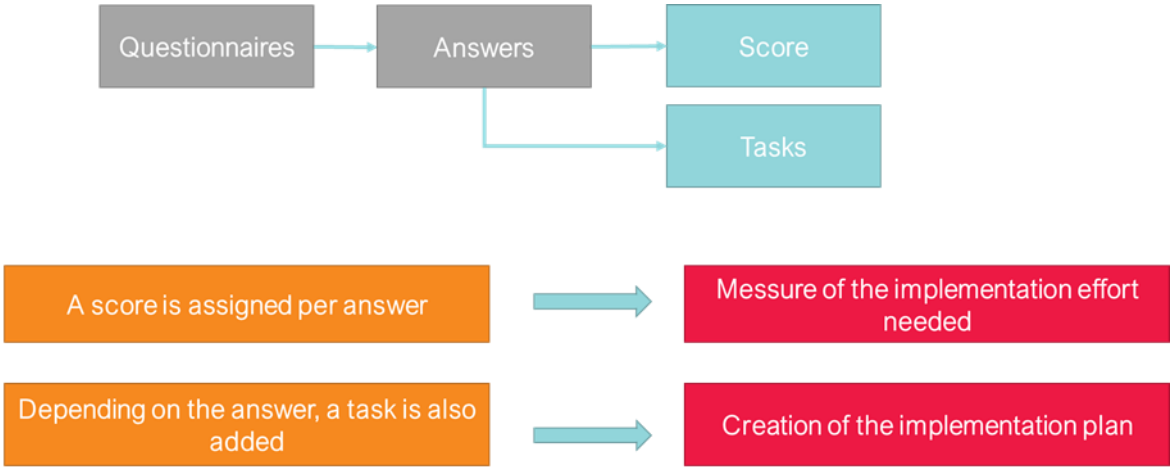


Figure 35. Components from Module 2

As an example, the company information questionnaire results in the following analysis and associated implementation task as shown below

Q1. Company information

Question ID	Question	Possible answers	Automatic score criteria	Task associated
Q1-7	Is there a quality department in the company? How many people work on it?	1. 0 people	100 points	Hire a quality manager
		2. 1 person	50 points	NA
		3. 2 people	20 points	NA
		4. A department of more than 3 people	0 points	NA

Figure 36. Questionnaire analysis (1)

Q2. Existing quality management system (QMS)

Question ID	Question	Possible answers	Automatic score criteria	Manual score criteria (Evidences evaluation)
Q2-1	Select the option best describe the organization in the intended scope of ISO13485. Upload evidences.	1. The organization has the certification of ISO 9001. 2. The organization has an existing quality management system (QMS) but it is not certificated. 3. The organization doesn't have a QMS but the processes are documented. 4. The organization doesn't have a QMS and processes are not documented.	1. 0 points 2. 50 points 3. 80 points 4. 100 points	0: Process fully documented and implemented -> ISO 9001 certificate as evidence 50: Implemented 100: Partially defined

Figure 37. Questionnaire analysis (2)

In the end, the implementation plan will be based on these results following the schematic below:

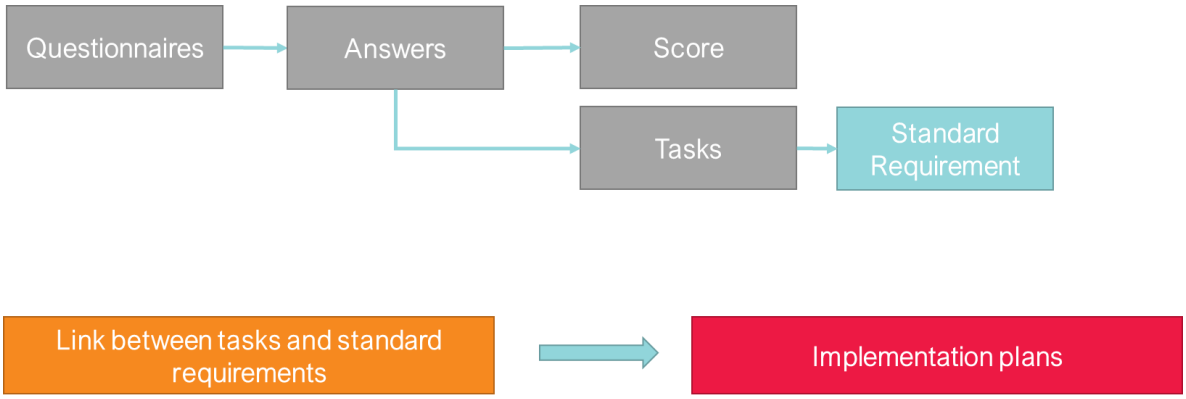
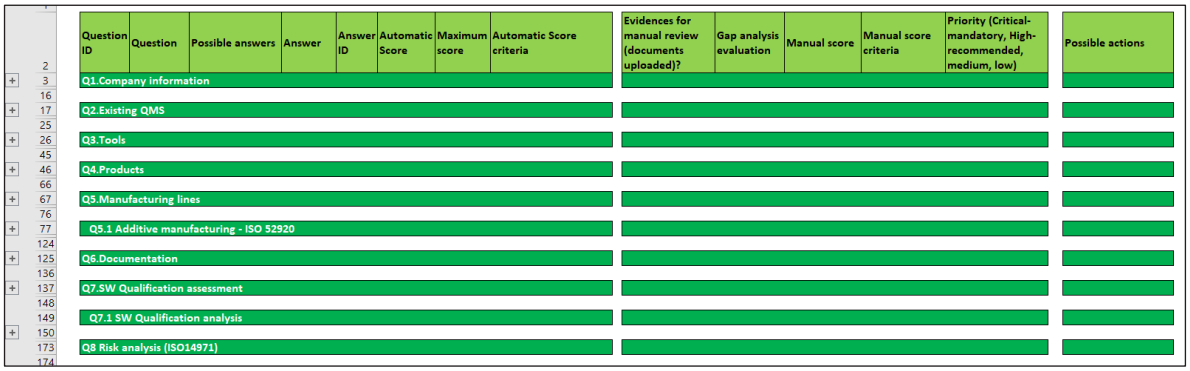


Figure 38. Implementation Plan

Currently a gap analysis tool from SQS has been utilized for finding the holes in ISO 9001 relative to ISO 13485 and the missing areas have been highlighted.

In the pilot information was collected via excel (example screen shot, not for reading text):



	Question ID	Question	Possible answers	Answer	Answer ID	Automatic Score	Maximum score	Automatic Score criteria	Evidences for manual review (documents uploaded)?	Gap analysis evaluation	Manual score	Manual score criteria	Priority (Critical-mandatory, High-recommended, medium, low)	Possible actions
2														
3	Q1.Company information													
16														
17	Q2.Existing QMS													
25														
26	Q3.Tools													
45														
46	Q4.Products													
66														
67	Q5.Manufacturing lines													
76														
77	Q5.1 Additive manufacturing - ISO 52920													
124														
125	Q6.Documentation													
136														
137	Q7.SW Qualification assessment													
148														
149	Q7.1 SW Qualification analysis													
150														
173	Q8 Risk analysis (ISO14971)													
174														

Figure 39. Information collection

The results are presented below (example screenshot, not for reading text):.

	Question ID	Question	Possible answers	Answer	Answer ID	Automatic Score	Maximum score	Automatic Score criteria	Evidences for manual review (documents uploaded)?	Gap analysis evaluation	Manual score	Manual score criteria	Priority (Critical-mandatory, High-recommended, medium, low)	Possible actions
	Q1.Company information													
INPUTS	Q1-1	Company name	Free text	Danish Technological In	NA	NA	NA	NA	No	NA	No	NA		NA
	Q1-2	Company description	Free text	Research, development and validation, RTO	NA	NA	NA	NA	No	NA	No			NA
	Q1-3	Is the company a startup? How old is the company?	1. Less than 5 years 2. Between 5 and 10 years 3. Between 10 and 50 years 4. Between 50 and 100 years 5. More than 100 years	5. More than 100 years	A1-3.5	0	100	< 5 years: 100 points 5 < x < 10: 80 points 10 < x < 50: 50 points 50 < x < 100: 30 points > 100: 0 points	No	NA	No			NA
	Q1-4	Range of employees	1. 1-10 2. 10-50 3. 50-100 4. >100	4. >100	A1-4.4	100	100	1-10: 10 points 10-50: 50-100: >100: 100 points	No	NA	No			NA
	Q1-5	Please, add any relevant information considered	Free text	NA	NA	NA	NA	NA	No	NA	No			NA
		Subsection: Personnel												
	Q1-6	Is there an organigram in the company? If yes, upload the organigram.	1. Yes 2. No	1. Yes		0	50	Yes: 0 points No: 50 points	Yes	Missing proper description of roles and	25	Roles required identified: 25 points Responsabilitie	Critical	
	Q1-7	Is there a quality department in the company? How many people work on it?	1. 0 people 2. 1 person 3. 2 people 4. A department of more than 3 people	3. 2 people		20	100	1. 0 people: 100 points 2. 1 person: 50 points 3. 2 people: 20 points 4. A department of more than 3 people	No	NA				0 people: hire a quality manager
	Q1-8	How many people work in the product development process?	Choose one answer: 1. Less than 5 people 2. Between 5 and 10 people 3. Several departments of 5 people each	2. Between 5 and 10 people		40	100	1. 20 points 2. 40 points 3. 100 points	No	NA				NA
OUTPUTS				Total		160	450							
				Score out of 100		35,56								

SQS, based on this excel created a system which enabler a scoring used to estimate the effort of the Implementation Plan to be deployed. The effort units are hours needed to complete the task.

The results from DTI (this pilot´s scope) questionnaires are presented in Table 2.

Form	Automatic Score	Estimated effort	Manual Score	Estimated effort
Q1. Company information	160	240	170	255
Q2. Existing QMS	280	560	300	600
Q3. Tools	255	510	220	440
Q4. Products	113	113	90	90
Q5. Manufacturing lines	56	56	100	100
Q5.1 Additive manufacturing - ISO 52920	200	200	150	225
Q6. Documentation	50	50	60	60
Q7. SW Qualification assessment	100	150	150	225

Table 2. Scores from DTI (pilot 4)

	Automatic Score	Estimated effort	Manual Score	Estimated effort
TOTAL	1214	1879	1240	1995

Figure 40. Compressed scores from DTI

The conclusions were obtained following the legend below.

Effort units	Range
1	0-100
1,5	100-200
2	200-450
2,5	450-800

Table 3. Legend Effort Units Vs Range

Based on the Gap analysis performed winter 2021/2022, several tasks have been defined. Since a full transfer to QMS is not intended for the pilot, no final certification is required. The trial will not focus on products, but on the demands to the manufacturing site in terms of quality management activities. The base ISO standard for managing AM lines for critical parts such as class 3 medical devices is ISO 52920 the activities for implementing the trial will be focused on this standard.

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

3.2.2.1 Technical Information

As observed during first acute part of COVID 19 pandemic one of the relevant issues was the deep niche character of medical devices with limited number of manufacturers and with reduced capability to scale for exceptional situations. This aspect has consequently the absence of shared predefined designs of special parts for medical devices, making highly difficult to order and buy spare pieces for intensive care units, for example. As observed that lead to hard to manage situations, stress and difficulties to manage clinical risks.

A catalogue of predefined and pre-validated parts lead to a faster capability to define a demand and a potential provider in a space where designs are pre-validated for implementation.

AMN was designed before the pandemic having the purpose to connect demand of buyers of AM on demand products with certified suppliers. In addition, a design validation service is offered that provide a check of realisability of a certain piece. This service aim to support suppliers to connect for RFQ to suppliers that can offer the implementation.

AMN Catalogue comes in place to accelerate the connectivity between suppliers and buyers for specialized products where existing catalogue entries are already specified as in following picture.

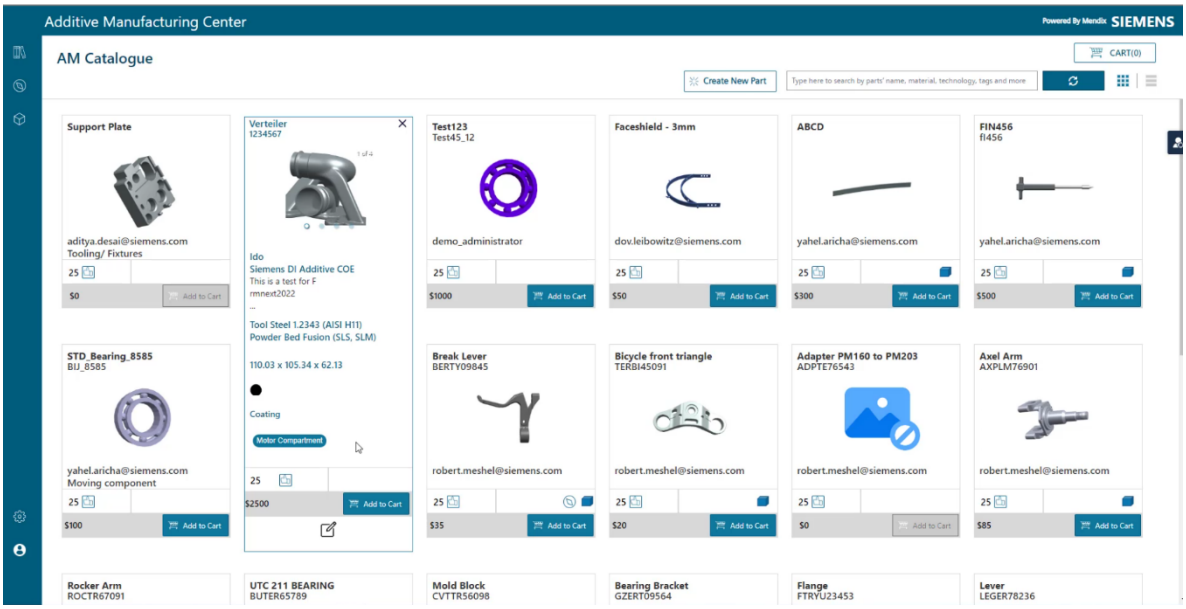


Figure 41 Detais of AMN Catalogue entries

From the technical point of view AMN is implemented as a web platform running on the AWS. The catalogue is implemented using Mendix platform and run in cloud as a separate component using specialized APIs to communicate with AMN.

To synthetize, IT components expose the following features:

ID			**(I need help with coding!)**
Responsible partner			Siemens
Tool name			AMN Catalogue
Overall Description			Application offering structured capability to store, search and manage validated design of AM products. The purpose is to facilitate fast RFQ of niche buyers' roles toward suppliers managed by AMN platform. If a fitted supplier is not matched then request is redirected towards a SQS AWS message queue to be redirected to peer matchmaking engines (like Smart Factory Web).
Details	Functionalities offered		1. Trusted Connector towards Mendix environment (limited version) 2. DB like access via UI in Catalogue 3. AMN API access for the Catalogue 4. RFQ process between buyers and suppliers 5. JSON data push towards AWS SQS message queue
	Data input(s)	Description	• Validated design • Supplier description • Material
		Format	STL, JSON
	Data output(s)	Description	RFQ data, agreement, message queue
		Format	JSON
	Integration requirements		Many possible integration, current implementation in Mendix
	Current execution environment		Mendix, AWS

3.2.2.2 Deployment

Platform is deployed in Mendix (mendix.com) offering a web UI interface. Is integrated with AWS deployed AMN offering a built-in RFQ interface as the one in the following picture.

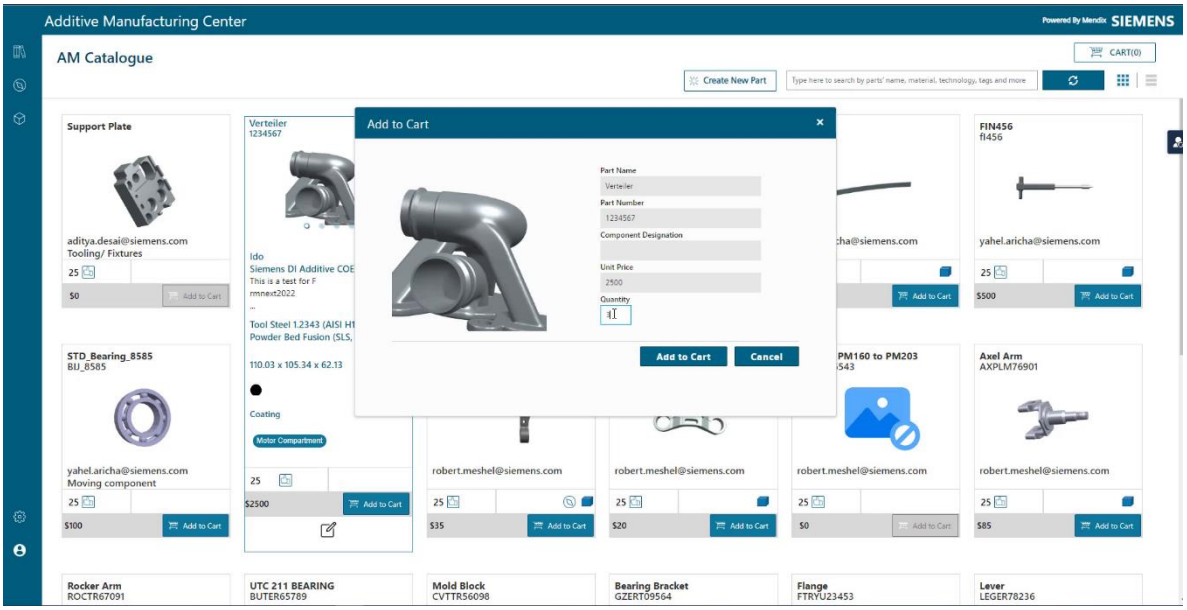


Figure 42 Selection of a product

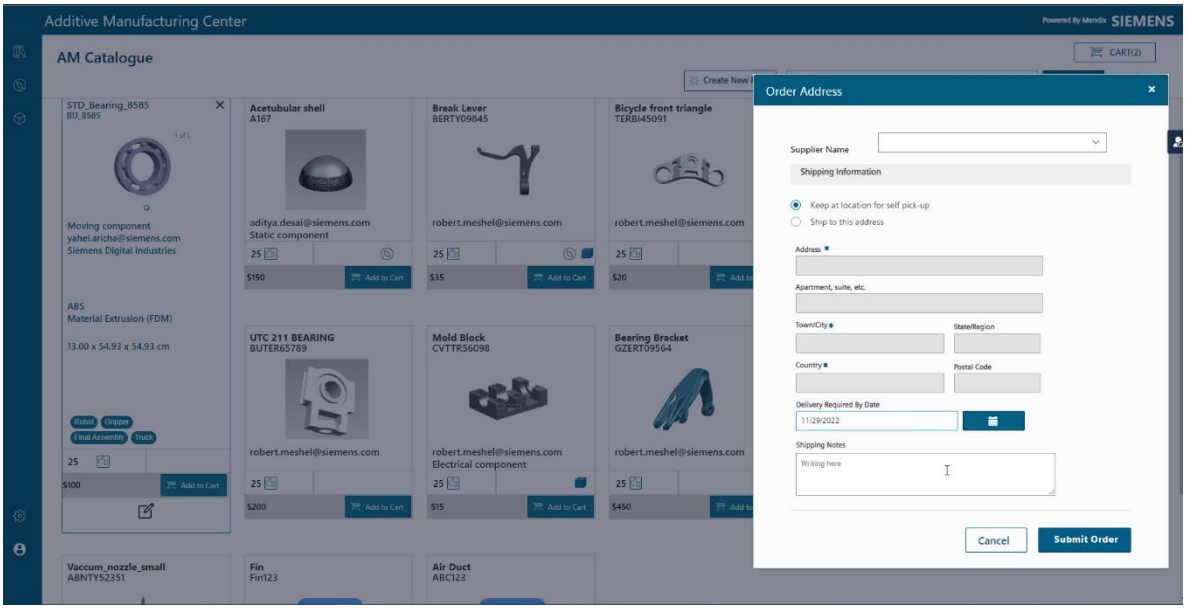


Figure 43 Communication with the buyer

3.2.3 Pilot #6. Crowd Production and Validation

3.2.3.1 Technical Information

Eur3Ka technologies included: AMN Catalogue, Eur3ka Certified Assets Catalogue, Certification Support Tools, Virtual Training and Remote Support.

The current components of the IT infrastructure are the following:

ID			BC-CIR-4
Responsible partner			CIR
Tool name			Online slicer & Marketplace
Overall Description			Sites targeting maker 2nd generation to get them to easily go from “toy 3D printer” to a crowd production mode
Details	Functionalities offered		5. Slicing API 6. User interface, Online slicer & Marketplace 7. Automated 3DP expertise 8. Software Auto extraction
	Data input(s)	Description	• 3D objects • Printer model • Material
		Format	STL, selection
	Data output(s)	Description	3D Print file output, instructions
		Format	Gcode
	Integration requirements		Many possible integration but optional
	Current execution environment		Leveraging existing low cost 3D printer hardware in the field by software features that transform the hobby 3D printer into a production equipment.

The current DataSets employed are the following:

Dataset name	Slicing usage data
Type	Product data, process data, machine data, production logistics data

Details	APIs		REST API
	Data	Description	6. Mixpanel Dashboard
		Format	Website
		Date to make the dataset available to the Consortium	01/12/22
		Mechanisms to make the dataset available to the Consortium	Data on usages of the slicing service (API used by all services)
		Speed of production	Realtime
		Availability to derive an open dataset from it	No

3.2.3.2 Deployment

The different technology bricks to ensure the feasibility of the 3D printer journey are all available to CIR for a 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.
The content was chosen based on 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.
CIR also categorized makers:

- 1st generation makers. Early adopters technically strong. Don't mind the technical difficulties and can easily tweak the technology

- 2nd generation are early majority and need more guidance. Just want to use the technology

The maker's journey was also designed:

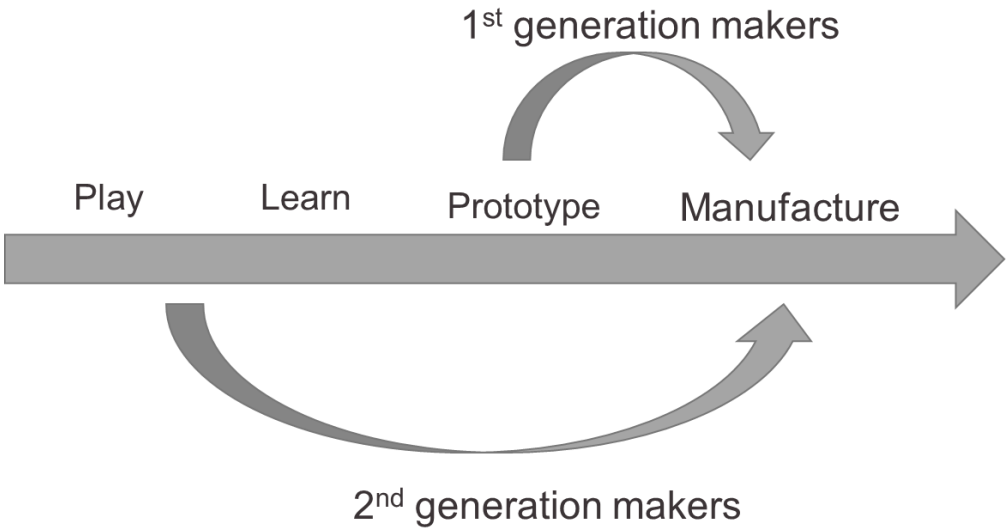


Figure 44. Maker's journey

The enabling of crowd production relied in the idea of making the 2nd generation maker successful:

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

Finally, the concept of a print universe was also created as shown in the image below.

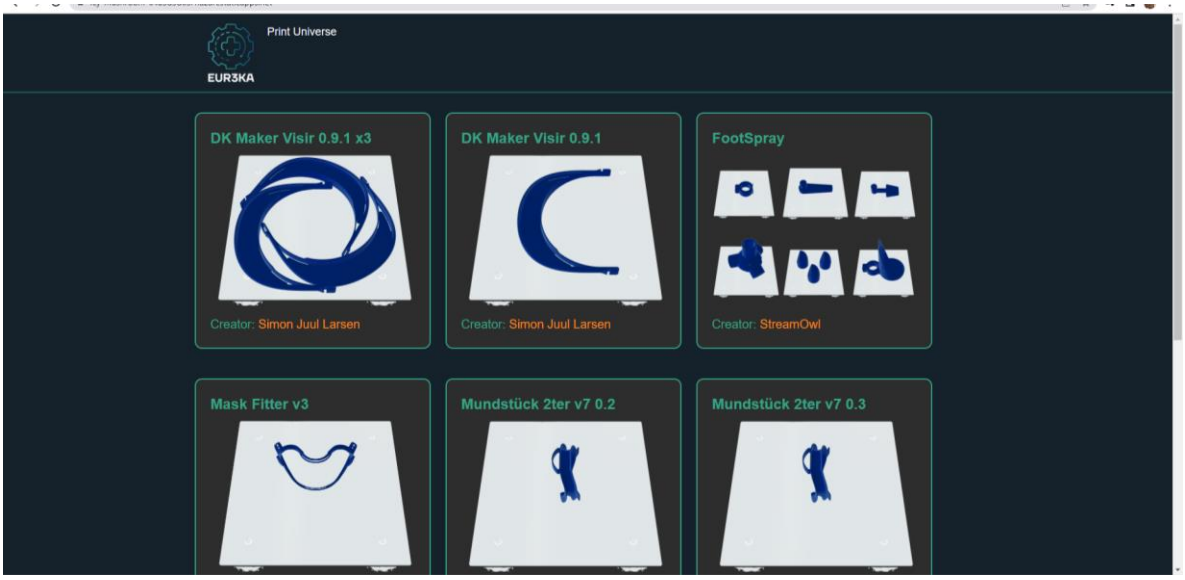


Figure 45. Print Universe (1)

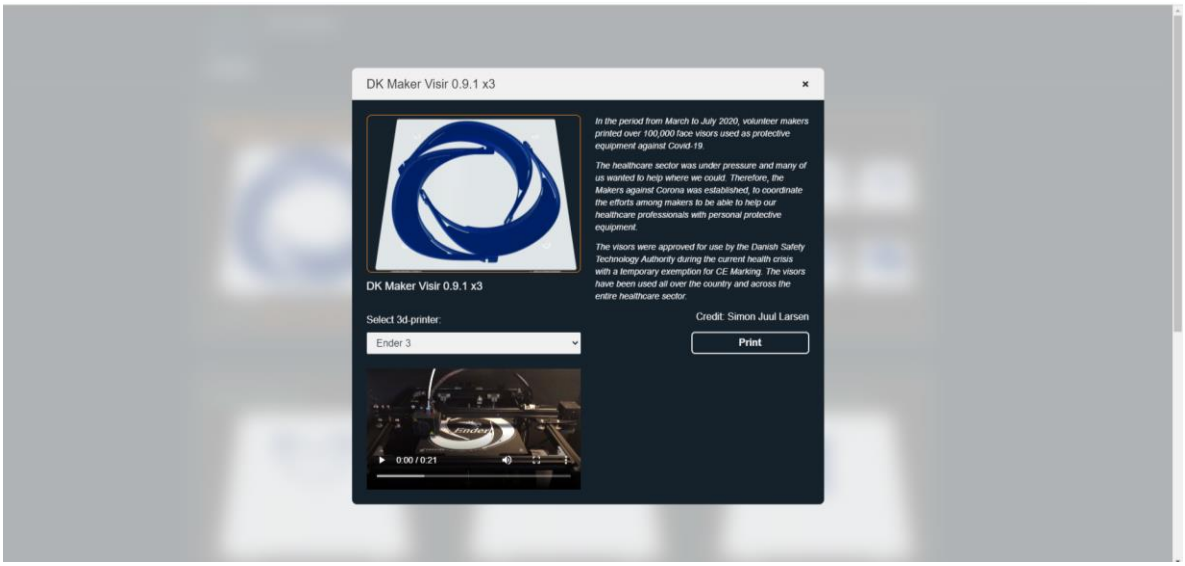


Figure 46. Print Universe (2)

4 Certification Framework

4.1 Strategy for Verification and Validation (V&V) of the Components

Q-Med Tech is a web platform based on Mango Apps that has been created by SQS to address the component verification and validation strategy. The different agents participating in the platform are: Technology Providers and Certification Team.

The components that can be validated are products and production processes. Within products we can find tools (also called enablers) (e.g., simulation software), and we can also find intermediate or final medical devices (e.g., masks). Within processes we have as an example a production process with additive manufacturing in the factory Z of the company Y. Product providers and process providers will be called Technology Providers from now on. The Certification Team is the one that creates the Validation Plan for the Tech Provider.

On the tech provider side, the certification process of their technology will be through the Q-Med Tech platform (described in the next section).

SQS as Certification Team has created the following internal strategy to perform this validation:

1. Use the Q-Med Tech forms to be filled in by the Tech Providers to define:
    a. The GAMP5 software category (1-5).
    b. Whether a formal certification is required (Independent Validation Plan)
    c. The validation plan needed.
2. With this classification the tech providers will be asked for the necessary input.

Activity	CATEGORY			
	1	3	4	5
User requirements	N/A	Yes	Yes	**Yes**
System validation plan - Test plan	N/A	N/A	N/A	**Yes**
Risks evaluation	N/A	N/A	Yes	**Yes**
Supplier Evaluation	N/A	N/A	N/A	**Yes**
Functional specifications (Technical documentation)	N/A	N/A	Yes	**Yes**
Configuration specifications (Technical documentation)	N/A	N/A	Yes	**Yes**
Design specifications (Technical documentation)	N/A	N/A	N/A	**Yes**

Figure 47. Documents/activities to be asked according to the category

In addition, SQS will ask every tech provider wanting to participate in the DFA for the development life-cycle process evidences (CMP, SECURE DEVELOPMENT PRACTICES) & evidence of ISO27001 or similar. Furthermore, even if a formal certification implying the correspondent notified bodies it is not needed the minimum validation plan required in Q-Med Tech is called Validation Lite. In this case, Tech Provider must submit at least the following documents: user requirements, system validation plan - Test plan, functional specifications (Technical documentation), configuration specifications (Technical documentation).

3. Produce a series of validation reports to be submitted to the relevant bodies.

Activity	CATEGORY			
	1	3	4	5
Development and execution of design protocol (DQ). These are the only ones that do not apply for legacy system	N/A	N/A	N/A	**Yes**
Development and execution of installation protocol (IQ) / Configuration testing	N/A	N/A	Yes	**Yes**
Development and execution of operation protocol (OQ) / Functional testing	N/A	N/A	Yes	**Yes**
Development and execution of performance protocol / Requirements testing (PQ)	N/A	Yes	Yes	**Yes**
Traceability matrix	N/A	N/A	Yes	**Yes**
Validation report - Summary test report	N/A	N/A	N/A	**Yes**
Deviation management	N/A	Yes	Yes	**Yes**

Figure 48. Documents/activities to be produced according to the category

When Validation Lite SQS will produce the following documents: development and execution of installation protocol (IQ) / configuration testing, development and execution of performance protocol / requirements testing (PQ), traceability matrix, validation report - summary test report, deviation management.

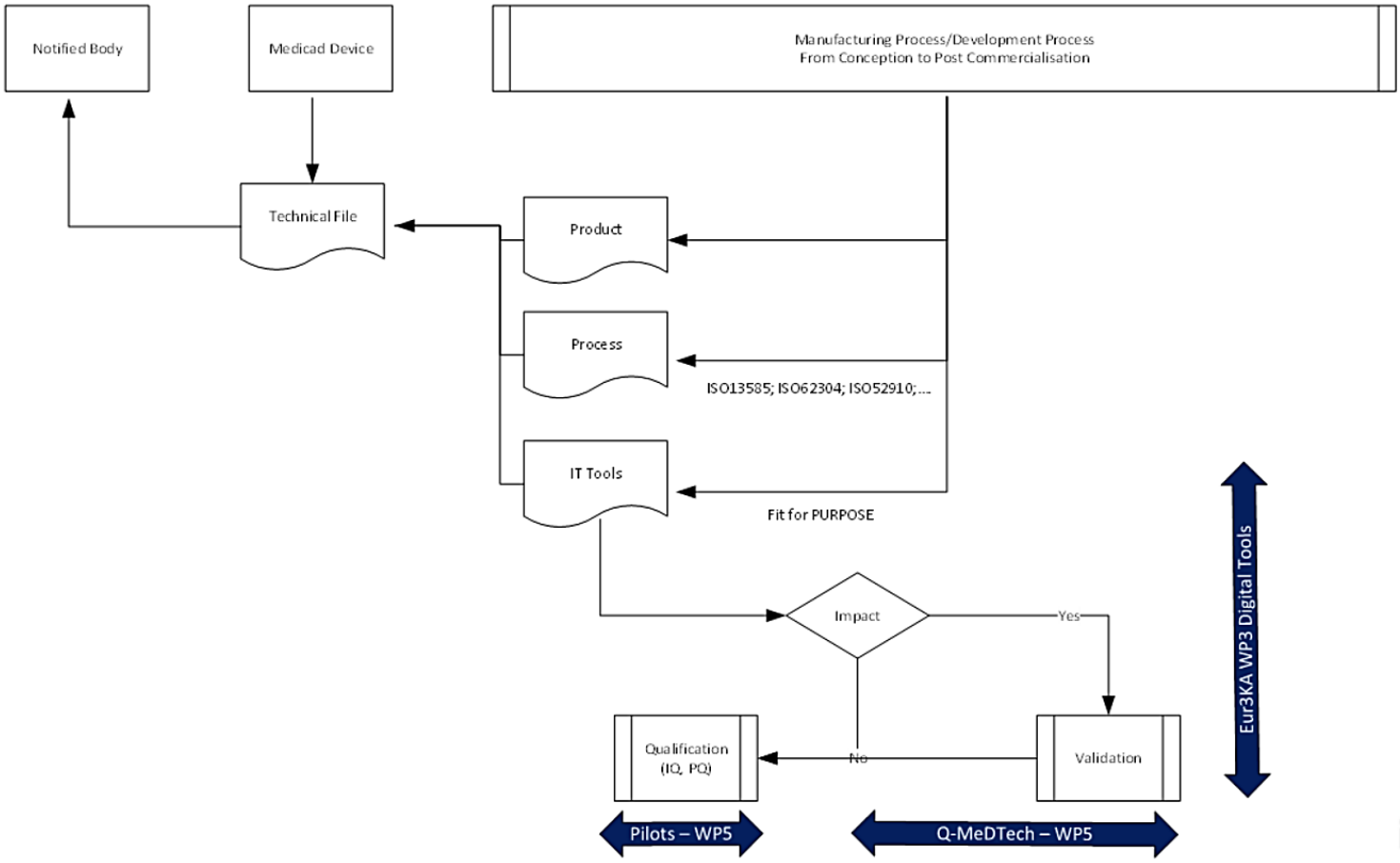


Figure 49. V&V Service Scope

Code	Name
2017/745	Medical devices EU regulation
2017/746	In vitro diagnostic medical devices EU regulation
13485:2021	Medical devices - Quality management systems - Requirements for regulatory purposes
ISPE - GAMP5	A risk-based approach to testing of GxP Systems
Europe's GMP: Anex 11	Computerised Systems
Europe's GMP: Anex 15	Qualification and Validation
MDCG 2019-16 Rev.1	Guidance on Cybersecurity for medical devices

Figure 50. Ref. Standards

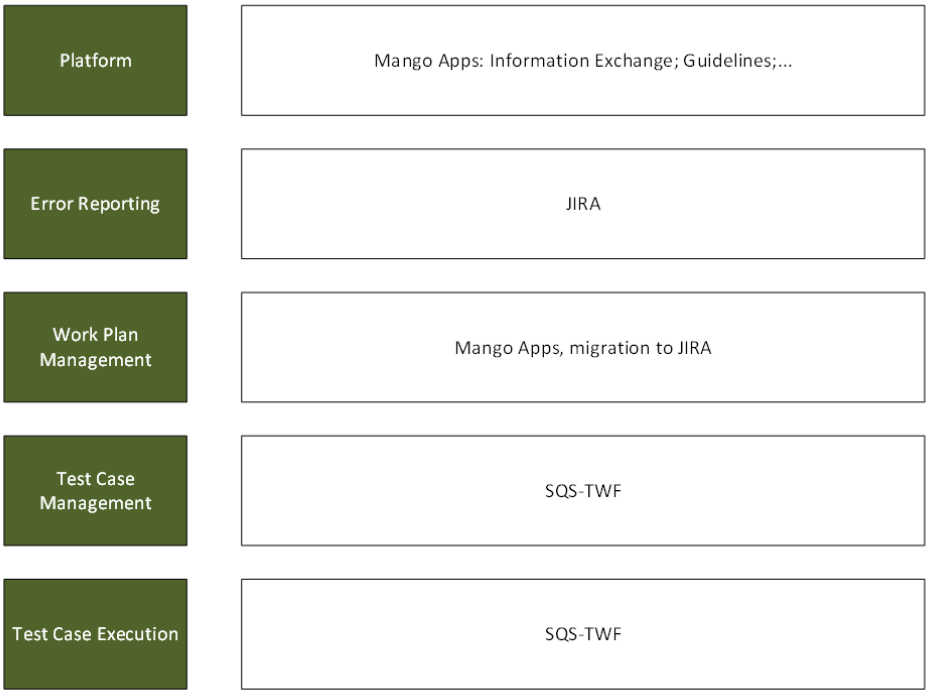


Figure 51. Tools used in the V&V Service

4.2 Certification Roadmap

All tools, products or processes that are going to be offered in Eur3ka must be certified in order to be part of the DFA Marketplace. SQS has therefore developed a platform called Q-Med Tech to address certification.

Q-Med Tech can be used for 3 different options: certification process (certify an asset), registration process on the platform (register a certified asset) and Marketplace (assets catalogue).

To carry out the certification process of their product or service, the Technology Provider must follow the following steps:

1. **(Optional) Access to the catalogue of Enablers for certifications.** Currently Q-Med Tech platform offers the following enablers:
    a. **Standards & Best Practices**, where Technology Providers can find information about the regulations involved in the certification process (ISO 13485, ISO 52920, GXP and 21 CFR part 11).
    b. **Self-assessment Toolbox**, where Technology Providers can find assessment tools (Questionnaires assessments about regulations, GAP analysis, Templates and the automated Test Suite.
2. **Request for certification.** The Technology Provider must fill in a form providing the following information:
    - Company: company name.
    - Address: company address.
    - Certification Type: select what is going to be certified, product or process.

- Reference Standard: select the corresponding regulation for the product or process.
- Documentation: files to be attached in the request, that will be used by the Certification Team during the certification process.
- Contact Person: email from the contact person in the Technology Provider. This person is in charge of the communication between the Technology Provider and the Certification Team.

3. **Wait for an acceptance by the Certification Team assigned to them.** Once all the information is provided, Technology Provider must click on submit to send it to the Certification Team, which will review everything and will notify if it's accepted or not. If it is not accepted, Certification Team notifies what must be done prior to start the certification process, and Technology Provider must update the request information with it. If it is accepted, Certification Team notifies that the registration is complete.
4. **Read and Accept the Proposed Verification and Validation Plan**. Certification Team will elaborate a personalised plan for each asset willing to be certified.
5. **Wait for the plan to be executed and finalised.** Certification Team may need some additional information which will be provided by the Technology Provider. The Technology Provider can check the status of their certification process anytime. Information regarding the Certification Team in charge of their certification process is also available.

In order to register a process, a product or a tool, it is necessary to have completed certification via Q-Med Tech. Once this certification has been completed, the asset can be added to the Q-Med Tech catalogue, which feeds the DFA's own Marketplace.

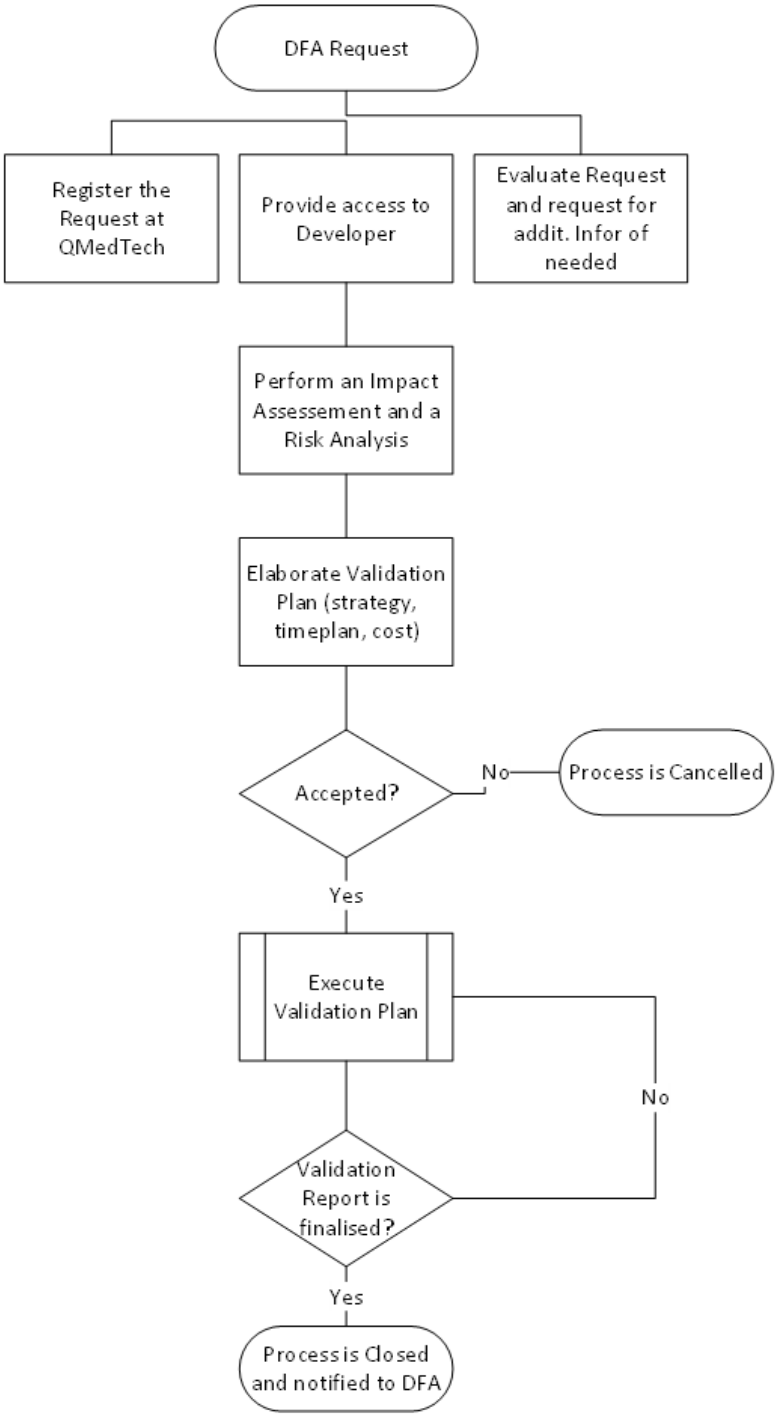


Figure 52. Q-Med Tech as a DFA service

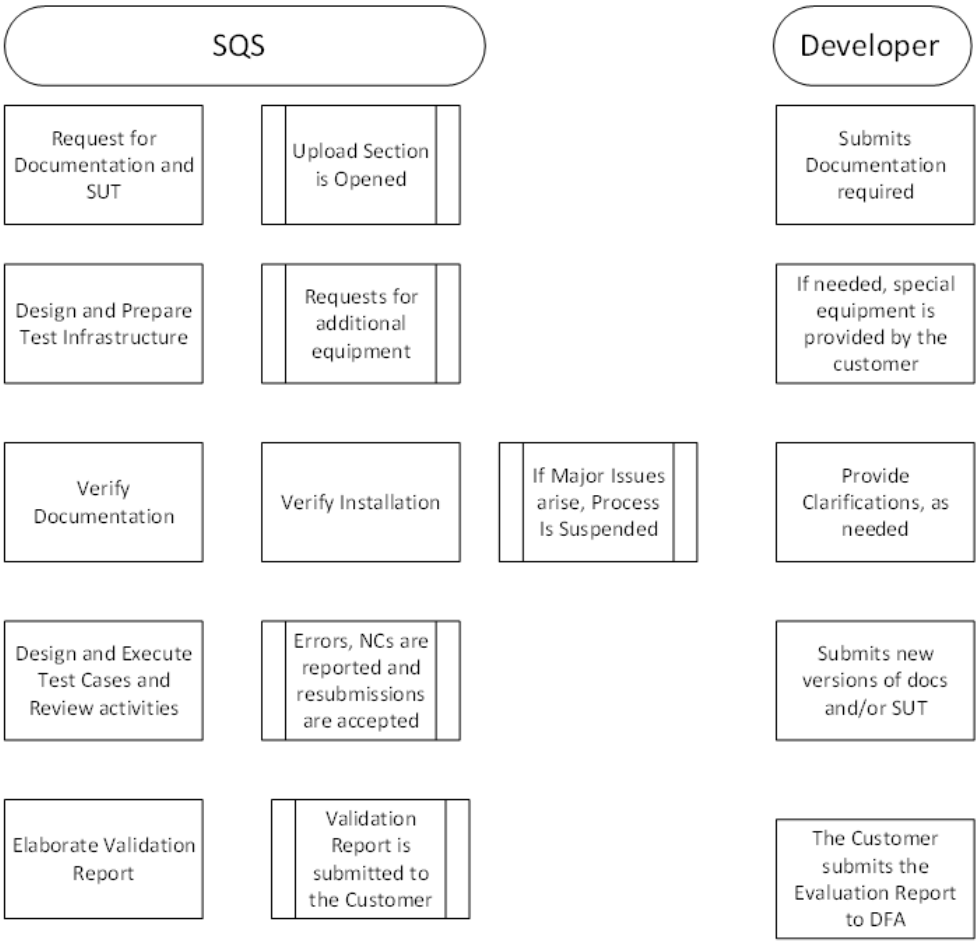


Figure 53. SQS (Certification Team) and Developer (Technology Provider) framework

4.3 Q-MedTech Platform as a Certification Tool

The development of the Q-Med Tech platform has enabled us to create a tool that can certify tools, products and processes. All assets to be offered on Eur3ka must be certified here. Thus, thanks to this tool, all assets created during the Eur3ka project can be certified and added to the DFA Marketplace for use.

The Q-Med Tech platform must also be validated as useful Certification Tool. The pilots have been used for this purpose. The pilots' tools and their validation allow us to iterate in the improvement of the platform (e.g., forms to fill in, standards, templates) in order to achieve the certification of the tools. These tools are being in the first place the ones used in the pilots, then will be those developed throughout the Eur3ka project and finally for all those tech providers who are interested in participating in the DFA.

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