The Influence of Human-Systems Integration on the "Fuzzy Front End" of Innovation: A MedTech Case Study

Yaroslav Menshenin
Univ. Grenoble Alpes, CNRS, Grenoble INP, G-SCOP
46 Av. Félix Viallet, 38000 Grenoble, France
+33 7 66 899 507
yaroslav.menshenin@grenoble-inp.fr

Romain Pinquié
Univ. Grenoble Alpes, CNRS, Grenoble INP, G-SCOP
46 Av. Félix Viallet, 38000 Grenoble, France
+33 6 58 336 305
romain.pinquie@grenoble-inp.fr

Abstract. Human-Systems Integration (HSI) can be considered as the combination of Systems Engineering and Human-Centered Design approaches. To support HSI, the system of interest (SoI) and its broader context should be developed with a specific engineering design objective and consider humans part of the system. Using a MedTech industry case study, this paper explores the influence of including MedTech end-users, such as Healthcare Professionals, within the SoI definition. The MBSE approach models the "fuzzy front end" of innovation for the MedTech Combination Product and places the end-users within the SoI boundaries. The paper advocates that such an approach shifts the paradigm of enabling the human factors considerations to the early innovation phases rather than waiting for the first physical prototype.

Systems Engineering Role in Human-Systems Integration

Systems Engineering is a holistic, methodical, and interdisciplinary design approach that establishes a design discipline among New Product Development team members. Formally, INCOSE defines Systems Engineering as a "*transdisciplinary and integrative approach to enable the successful realization, use, and retirement of engineered systems, using systems principles and concepts, scientific, technological, and management methods*" (INCOSE 2023). From this definition, one may notice that discipline is interfacing with engineering, technology, management, and policy, to name a few other fields of knowledge. To realize this growing complexity of going beyond one specific discipline, the INCOSE Human Systems Integration (HSI) Group positions itself at the intersection of people, organization, and technology (INCOSE HSI Working Group 2024). Systems Engineering (SE) is considered a contributing discipline in this paradigm, which is especially necessary for complex product development surrounded by sociotechnical challenges.

Another contributing design approach is human-centered design (HCD), which is "*an approach to interactive systems that aims to make systems usable and useful by focusing on the users, their needs and requirements, and by applying human factors/ergonomics, and usability knowledge and techniques*" (ISO 9241-210:2010). SE and HCD were developed and advanced as logical ways of thinking in many engineering challenges and industrial applications (Fisher and Johansen 2010; Lee et al. 2020; D'Ambrosio and Soremekun 2017). For example, Model-Based Systems Engineering (MBSE) (Madni and Augustine 2023) appeared around three decades ago (Wymore 1993) as an approach backed by SE principles, enabling the digitalization of the product development process, especially in its early conceptual design phases. In this regard, HCD has been investigated as a complementary approach to substitute MBSE diagrams with human-centric 3D representations (Pinquié et al. 2023).

This research considers HSI a combination of SE and HCD (Boy 2022). The hypothesis is that when MBSE is employed at the early phase of product development and when Humans and Systems are considered within the SoI, the analysis of human factors for medical devices can also be shifted to the early phases of product development.

Human Factors in Combination Product Development

According to the FDA, human factors engineering "*focuses on the interactions between people and devices*" (FDA 2022). The main goal of human factors analysis is to minimize the risks associated with the end-user usage of the MedTech device, as the patient's safety is a top priority. The medical device in European regulation is defined as "*any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s)...*" (European Regulation 2017). Therefore, the MedTech Combination Product is relevant to this definition (the detailed definition and example of the Combination Product are provided in the following sections).

Around 95% of the medical technology companies in Europe are estimated to be small- and medium-sized enterprises (SMEs) (MedTech Europe 2022). Although medical devices in the report are only a sub-sector of the medical technology industry, the assumption of the same ratio of SMEs in the medical devices sub-sector illustrates the importance of human factors assessment. The shortage of labor and time and pressure to reach the market at a fast pace could stimulate those companies to compromise on the human factors studies, which would impose the risk for the device safety. Human factors can be difficult for the search for the sources of errors in sociotechnical systems (Wagner 2010), which calls for a more systemic and holistic approach to MedTech product development. Research in this paper proposes the means to mitigate those potential risks through system modeling and HSI at the "fuzzy front end" of innovation. It considers human factors before a design iteration for the prototype is accomplished. Hence, it reduces development costs, as the design iterations due to design errors leading to misuse or unintended uses are avoided, and it reduces time-to-market, which is critical to meet the pharma customer needs. Supporting this early phase of innovation would lead to a continuous digital engineering thread throughout the system lifecycle by establishing a traceable link between the decisions made at the beginning of the innovation process and the system entities and their activities in the later stages, including the Concept of Operations.

The following section presents the research method. The MedTech Combination Product Case Study introduction and the application of the proposed method to follow it. The paper is concluded with the Results & Discussion, as well as the avenues for future work.

Research Method

The research method consists of several steps. The first step is to define the MedTech company's scope of responsibility. It is essential to determine the system boundary for the SoI and clearly define what the MedTech company is responsible for. However, as will be shown later, the MedTech device is part of a larger system. Therefore, a greater system context should also be considered, and the MedTech R&D team should be aware of the interfaces with that greater context. The second step is to build a system context and the SoI decomposition model, which would position the end-users, such as Healthcare Professionals, within the MedTech SoI. The third step is to analyze this SoI decomposition at a lower systemic level to understand how such a paradigm shift could affect human factor and usability engineering studies in relation to the earlier conceptual design phases. The proposal mainly supports the technical processes of ISO 15288 (2023), especially the first four activities: business or mission analysis process, stakeholder needs and requirements definition process, system requirements definition process, and system architecture definition process.

MedTech Combination Product definition

The Combination Product is standardized by the Food and Drug Administration (FDA 2019). There are many types of Combination Products. This study focuses on the drug/device combination product. The critical aspect is that a pharmaceutical company develops the drug, whereas the device is the primary responsibility of the MedTech company. Therefore, for the MedTech industry, the SoI is the MedTech product itself. However, it is only a sub-system for the pharmaceutical company, which is the customer of the MedTech company. The complexity associated with the MedTech device development process has been studied and published in the authors' previous works (Menshenin et al. 2023; Menshenin et al. 2023). An example of a Combination Product is an autoinjector. The purpose of the autoinjector (developed by the MedTech industry) is to inject a specific volume of a drug with a particular viscosity (developed by a pharmaceutical customer).

The Injector Case Study

The global autoinjector market was estimated at $48B in 2020 and is projected to grow to $162B by 2027 (Research and Markets 2022). Autoinjectors enable drug delivery for chronic diseases like rheumatoid arthritis, multiple sclerosis, anaphylaxis, and others. Another vast sector of autoinjectors' application is vaccine delivery. Autoinjectors could wrongly be understood as simple systems comprising only a few components. In the same way as other systems become more connected, this paradigm shift is present in autoinjector product development.

Consider an example of a drug required for patients undergoing chemotherapy. In a traditional setting, the patients must get the chemotherapy in a healthcare facility, after which they are dispatched home and should return to the healthcare facility the next day for another treatment, which prevents the infection associated with the chemotherapy treatment. This is often very challenging for the patients because they may still be sick the next day after the main therapy. To overcome this challenge, on-body devices have been developed to automatically deliver a required drug with a specified time delay in a much more preferable home environment. The patient does not need to return to the healthcare facility from home the next day after chemotherapy in this setting. Instead, the healthcare professional sets up the on-body device after chemo treatment. Subsequently, the MedTech device informs the patient about upcoming drug delivery, its start, processing, and the end.

This context implies that the current generation of MedTech devices requires software-hardware integration, making the devices more complex from the perspective of several components. However, from overall socio-technical aspects, the greater context should be taken into account as the drug injection is to be performed in a home environment. This is precisely where SE is essential in its holistic view of MedTech product development.

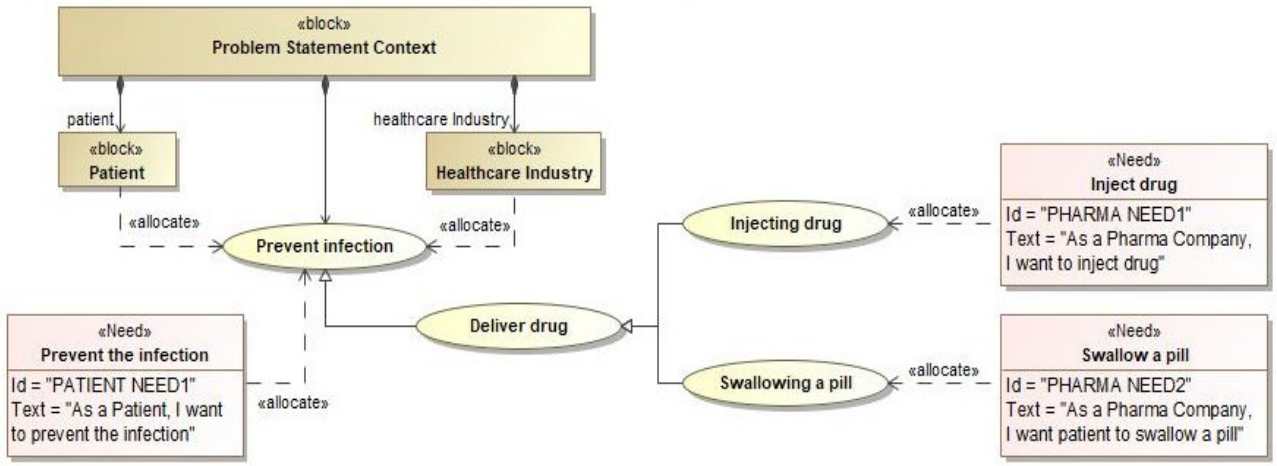

Figure 1. The Problem Statement Context for Injector System

Figure 1 presents the problem statement context for the Injector System in Figure 1. It illustrates a gradual development of the potential solutions to satisfy a high-level patient problem, "*Prevent infection*" associated with the chemotherapy treatment. The patient may not care much about how this prevention will be achieved. A specialization of "*Prevent infection*" to "*Deliver drug*" narrows down the set of potential solutions to drug delivery systems – either the one realized through the "*Injecting drug*" process or the one realized through "*Swallowing a pill*", for example. The SoI enabling the drug injection into the patient's body is chosen (see Figure 1).

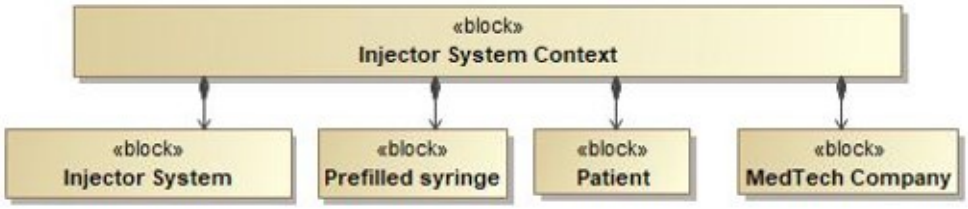

Figure 2. Injector System Context

Figure 2 presents the Injector System context, which includes external entities such as the Injector System, the Prefilled syringe storing the drug, the Patient, and the MedTech Company developing the Injector System. The Healthcare Professional is not present there, as the analysis will show later that he/she is part of the Injector System.

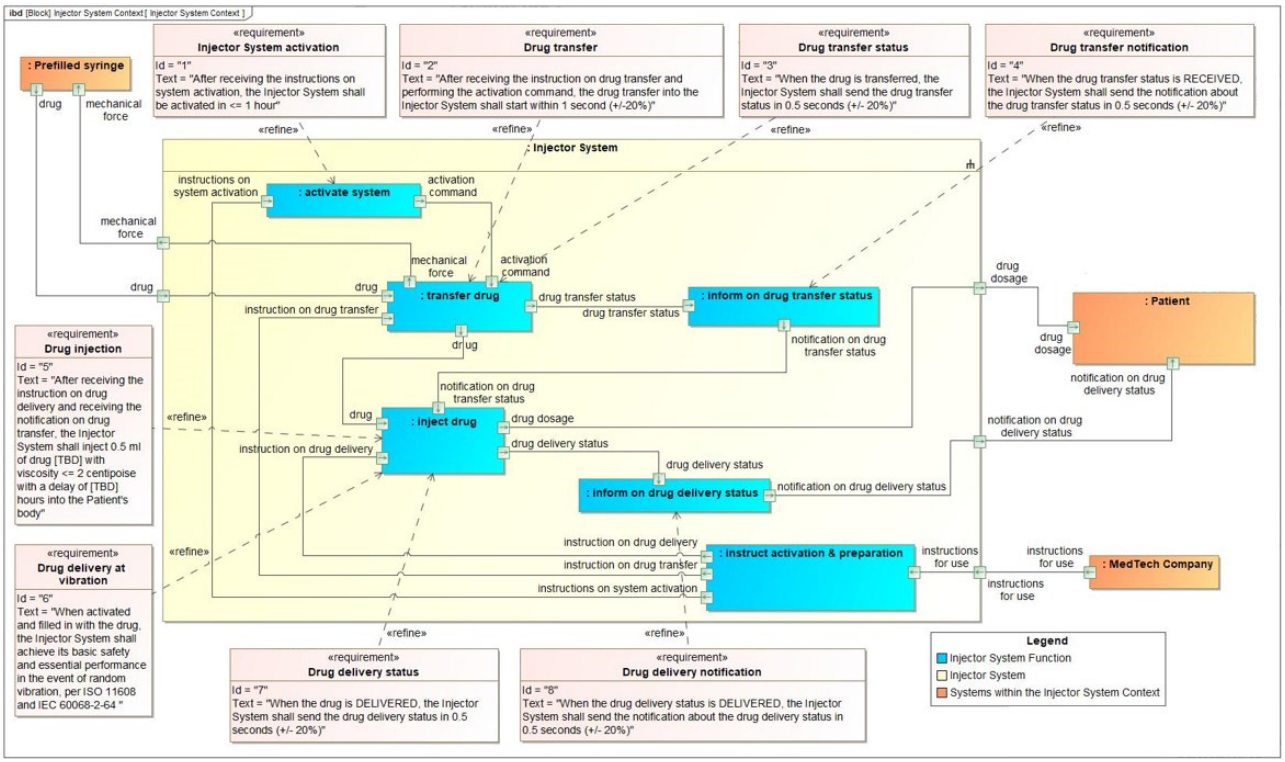

Figure 3. The Injector System Context breakdown decomposition (HCP is inside the SoI)

Figure 3 illustrates the Injector System context and its functions: "*activate system*", "*transfer drug*", "*inform on drug transfer status*", "*inject drug*", "*inform on drug delivery status*", and "*instruct activation & preparation*". The interfaces established between the SoI and external entities, and within the SoI, enable the architect to extract property-based system requirements (Micouin 2008). For example, system requirement #1 extracted from the system function "*activate system*" is "*After receiving the instructions on system activation, the Injector System shall be activated in <= 1 hour*". The system requirement #2 extracted from the system function "*transfer drug*" is "*After receiving the instruction on drug transfer and performing the activation command, the drug transfer into the Injector System shall start within 1 second (+/- 20%)*". Note that all values and numbers presented in system requirements are illustrative and are not linked to any real product. The analysis identifies eight representative system requirements, illustrated in Figure 3. System requirement #6 traces the high-level requirement to the standards, such as in ISO and IEC, ensuring that the Injector System would not lose its basic safety in case of random vibration.

Figure 4 shows the Injector System decomposition, including the interfaces between the system elements. As a recursive top-down process, the internal flows serve as inputs to define the functions and requirements of the system elements. According to ISO 15288 (2023), a system element is a discrete part of a system that can be implemented to fulfill specified requirements. Considering humans outside the SoI as part of the system context is standard practice. We argue that to exploit the full value of HSI, if a human is performing a role that is allocated one or more functions of the SoI for the SoI to satisfy its requirements, then that role should be considered as a system element inside the system boundary. For instance, when used at a hospital, the role of the Healthcare Professional (HCP) is allocated to the function "*activate injector device*" to satisfy the Injector System requirement #1 "*Injector System activation*".

Figure 4 also emphasizes the requirements related to the HCP derived from both HCP functions "*fill in the drug*" and "*activate injector device*". Including the HCP within the SoI allows the system architect to extract the HCP requirements #9 "*Device fill in*" and #10 "*Activation command*". This means that the system architect shall define lower-level system elements – e.g., an HCP training –

that will enable the HCP to satisfy these requirements. These requirements are developed from the end-user perspectives and are enabled by the standardized MBSE representation that helps to trace model elements. Therefore, the role of HCP should be considered as a system element inside the Injector System boundary in addition to the Injector Device and the Directions for Use.

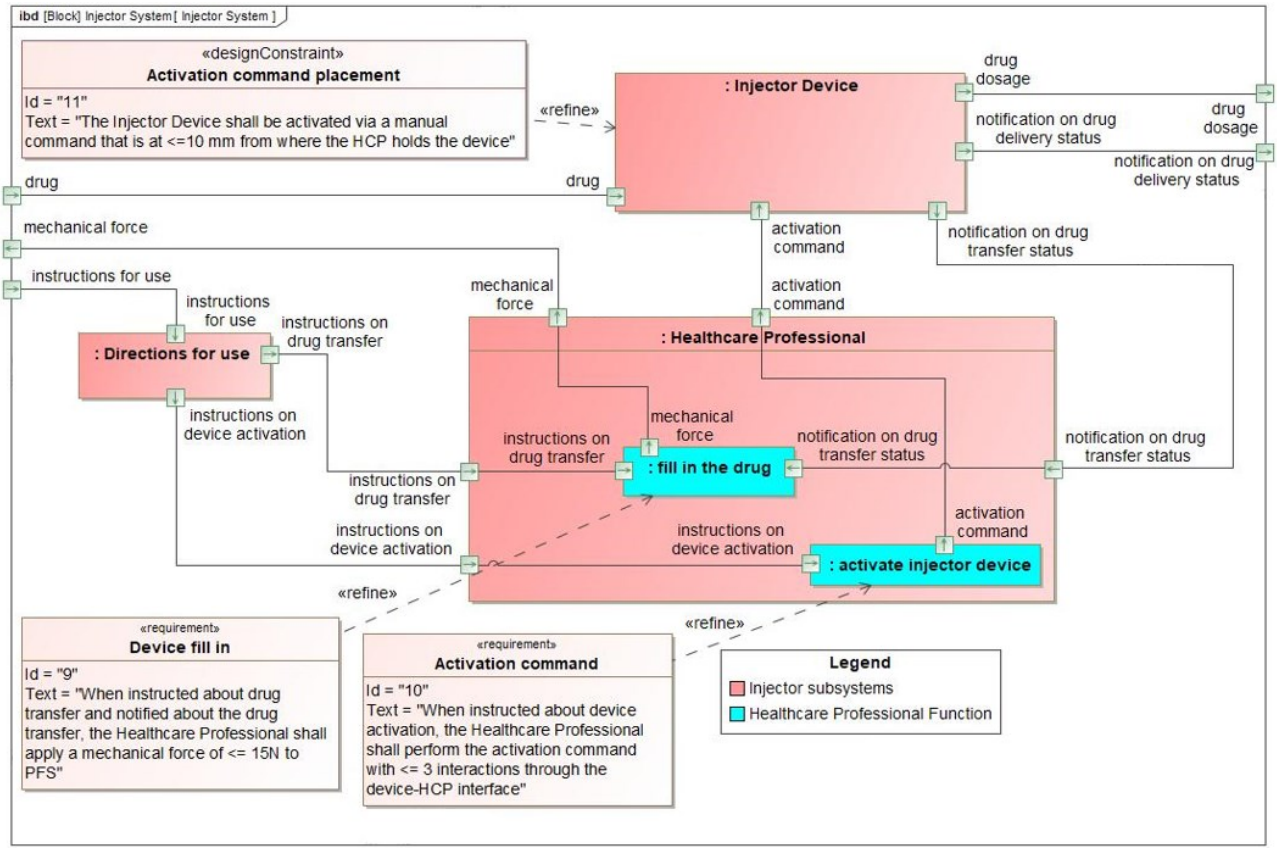

Figure 4. Injector System decomposition

Including the HCP in the early-stage product strategy definition process also enables the design team to start analyzing human factors and usability engineering (HFE/UE) at the early phase of the "fuzzy front end" of innovation. More precisely, it helps to consider user-related hazards, which are medical device hazards associated with user interactions with the device. For instance, considering the HCP as a system element leads to defining safety (function) requirements after a functional Failure Mode and Effects Analysis (FMEA). A functional failure mode is a nonfulfillment of the functional requirements derived from the SoI or a system element functions in response to a relevant initiating event. An initiating event is a technical failure or human error corresponding to a significant deviation from the normal situation that may lead to a system failure or an accident. Nonfulfillment can be due to a loss of function, partial function, degraded function, intermittent function, unintended function, exceeding function, delayed function, or early function (AIAG 2024). Table 1 provides an example of the functional failure mode related to the accidental activation of the Injector Device by the HCP. A potential action to mitigate this risk is to place the activation button at some distance from where the HCP holds the device (see the last column in Table 1). This measure to reduce the risk of accidental activation is translated into a derived safety requirement corresponding to a design constraint on the Injector Device: "*The Injector Device shall be activated via a manual command that is at less than or equal to 10 mm from where the HCP holds the device*" (see Figure 4).

Table 1: Functional FMEA for the Injector Device function "*activate system*"

Failure Mode	Failure Cause	Failure Effect	Likelihood of Occurrence (1-10)	Likelihood of Detection (1-10)	Severity (1-10)	Risk Priority Number	Actions to Reduce Occurrence of Failure
Healthcare Professional accidentally activates the Injector Device	The activation button is placed close to where the HCP holds the device	The patient may start receiving the drug dosage earlier than it is needed	4	7	8	224 (Unacceptable)	Place the activation button outside the diameter of 10 mm from where the HCP holds the device.

Similarly, when used at home, during the temporal period that the patient performs a role that is allocated one or more functions of the SoI – e.g., "*monitor drug dosage delivery*" or "*dispose of the Injector Device*" – the patient should be considered inside the system boundary.

Considering the HCP, and humans in general, as stakeholders outside the Injection System at the system level would mean that all solutions to mitigate user-related hazards would rely only on hardware or software system elements. Figure 5 shows the Injector System context in which the HCP is outside of the SoI. One may notice that the functional prototype of the Injector System would be required to start human factors analysis by the HCP. Designing and providing training to prevent misuse would not be a solution as the actions and performances of the HCP are out of scope – yet, it could be a solution in case of inclusion of the HCP within the SoI. Thus, adopting an anthropomorphic perspective shows that human factors and usability engineering can play a vital role in this early phase analysis instead of the formative studies performed with physical prototypes during the detailed design phase.

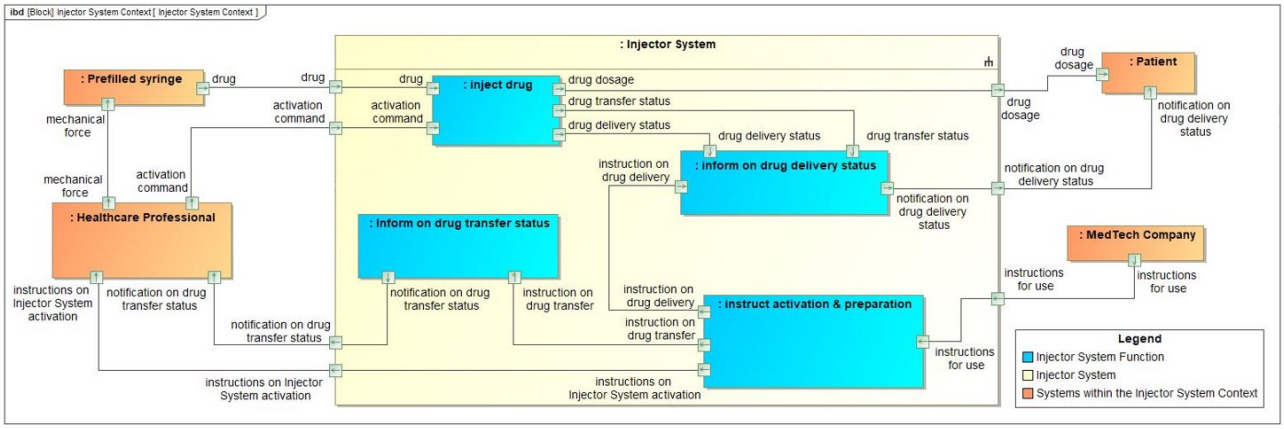

Figure 5. The Injector System Context breakdown decomposition (HCP is outside the SoI)

From the Injector System design perspective, the inclusion of the HCP inside the SoI means that human factors analysis related to the device activation and drug transfer from the PFS to the Injector System could be performed with such system elements as HCP training. The "HCP training", therefore, would be one of the system elements to satisfy high-level system requirement #1 and system requirement #2. Therefore, the impact of putting the HCP inside the SoI is that it allows us to extract the property-based system requirements (for example, system requirement #1 in Figure 1) related to human factors and to define the potential solutions (system elements, such as HCP training) before the functional prototype development. This influences the Injector System development shifting the HFE/UE analysis at the early phase of the "fuzzy front end" of innovation. It is also potentially opening up the avenue for future research related to the inclusion of the human into the preliminary studies on system architecture by combining model-based systems engineering and Human-Centered Design and the use high-fidelity human - in - the - loop simulation technologies

such as Virtual Reality to consider HFE/UE early on in a new scenario-based design method (Boy et al. 2024).

Results and Discussion

This paper discussed HSI as a combination of Systems Engineering (SE) and Human-Centered Design (HCD) practices. We argue that when humans perform a role that is allocated one or more functions of a system to satisfy its requirements, that role is inside the system boundary. The paper focused on the MedTech Injector System as the system of interest (SoI). The paper focused on the role and placement of the MedTech Healthcare Professional as part of the SoI. The paper argues that such a consideration of the end-user, backed by the MBSE approaches, allows the R&D team to shift human factors and usability engineering, especially use-related hazards, to the earlier conceptual design phases where the innovation is traditionally perceived as having the "fuzzy front end."

It was shown how the early phase analysis of SoI (Injector System in current research) allows the systems engineers to establish the proper interfaces between the SoI and the external entities and, subsequently, to extract the system requirements from them. The HCP functions were defined, and the derived requirements were identified. Full traceability between the system context, system decomposition, functions, and system requirements can be established, leading to analysis of the human factors in an early phase. The performed example of the FMEA analysis has illustrated the link between the inclusion of HCP into the SoI and the derivation of a safety requirement, further tracing it to specific system elements such as the DfU. Compared to the traditional approach, this is a novelty when human factors studies are conducted when the functional prototype is available. Finally, the potential solutions could be established and outlined earlier in the product development process – for example, a possible solution for drug delivery safety and compliance with the ISO standards is related to the proper description of the human factors in the DfU.

Future work directions include better integrating human aspects in a Model-Based Systems Engineering (MBSE) approach by developing new HSI views that consider how the human affects the system and how the system affects the human in return. To increase the level of requirements completeness and correctness, we also plan to integrate a conventional SysML modeling environment with a virtual reality environment to enable simulated-use testing where users interact with the device user interface and perform actual tasks following a scenario-based design approach.

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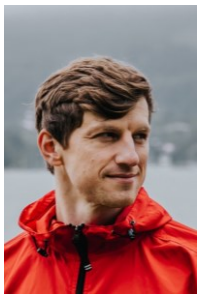
Biography



Yaroslav Menshenin is a Postdoctoral Research Fellow at Grenoble INP, France. His research interests include MBSE, System Architecture Methods to Support Decision-Making Process, and Engineering Management of Complex Systems. He is leading the Systems Engineering Initiative closely partnering in R&D with MedTech industry. Dr. Menshenin received PhD in Engineering Systems from Skoltech in 2020. He was a visiting doctoral candidate in the System Architecture Group at MIT in 2016/17. He received a Specialist's degree (M.Sc.) from Department of Theoretical Physics and Quantum Technologies at MISIS and is also a graduate of Singularity University located at NASA Ames in Silicon Valley.

Romain Pinquié is an Associate Professor in Digitally Mediated Collaborative Engineering Systems Design at the School of Industrial Engineering of Grenoble Institute of Technology and a research fellow at the G-SCOP UMR CNRS Laboratory of Design, Optimisation and Production. His research tries to understand how humans represent and interact with different types of design information, and to develop new human-computer interactions for supporting collaborative digitally-mediated design situations, with the goal of advancing human-centred computing in engineered systems architecting.