GUIDELINE FOR THE DESIGN AND IMPLEMENTATION OF HUMAN-CENTRIC DIGITAL TWINS IN MANUFACTURING

HumanDT Guideline

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Executive Summary

Digital Twin (DT) technology remains at an emerging maturity level within the manufacturing domain, where its deployment is primarily associated with advanced functions such as process optimisation and production planning, energy-efficiency management, quality assurance and zero-defect manufacturing strategies, dynamic process reconfiguration, predictive maintenance, and new business models. In the occupational safety and health (OSH) context, DT applications have predominantly focused on dynamic and continuous risk monitoring and assessment, safety assurance in human–robot collaborative (HRC) environments and immersive virtual training.

The introduction of the new Industry 5.0 (I5.0) paradigm places the human at the center of production systems, which requires the explicit integration of the human factor (HF) into the design of advanced technologies such as DT. However, this integration is not straightforward: it demands a deep understanding of workers' real limitations, capabilities, and needs—an aspect that has not traditionally been a priority in industrial systems engineering. The transition toward truly human-centric (HC) designs requires new methodologies, multidisciplinary tools, and close collaboration among engineering, ergonomics, and behavioral sciences, highlighting that placing humans at the core is essential, but not easy.

In this context, the objective of this Guideline is to provide practical guidance and recommendations for the design and implementation of safe, ethical, and human-centric digital twins (HC-DT), fully aligned with the principles of I5.0.

This Guideline is intended as an introductory resource, providing a preliminary screening-level overview of the key aspects of human-centric digital-twin design. While it offers an initial conceptual and methodological framework, it cannot address the full range of challenges involved in effectively integrating the human factor into such systems. Achieving a truly human-centric design (HCD) requires deeper multidisciplinary analysis and advanced tools beyond the scope of an introductory document; therefore, this Guideline should be understood as a starting point rather than a comprehensive solution.

The Guideline represents the main result of the HumanDT project, developed in the period 2024-2025 by Fundación TECNALIA Research and Innovation (TECNALIA) and the Finish Institute of Occupational Health (FIOH), and funded by the Basque Institute for Occupational Safety and Health (OSALAN) and the Finnish Work Environment Fund (FWEF), under the SAFERA 2024 call "Health and safety implications of industrial digital twins and algorithmic management".

The document is structured into three building blocks:

1. Fundamentals and applications of Digital Twin technology, which describes the digital-twin concept and its key characteristics.
2. Human factors and Digital Twin: towards Industry 5.0, which introduces the principles of HF and HCD and explains their application in the new Industry 5.0 context; and

3. Practical implementation of Human-centric principles in Digital-Twin design, which provides guidance on how to apply these concepts to develop genuinely human-centric digital twins.

The Guideline is complemented by an extensive Annex section that includes vocabulary, a non-exhaustive list of standards applicable to the HCD of the DT, the tools used by the Guideline, and a compendium of use cases featuring real experiences from manufacturing-sector companies in the application of DT technology to improve industrial processes.

This Guideline is primarily intended for designers and integrators of DT technology within manufacturing environments, who must incorporate an HC approach from the earliest stages of DT design. It is also applicable to companies deploying DT solutions, which may use the document as a reference framework to evolve their current practices toward an HC-oriented model. Finally, the Guideline may serve additional stakeholders—including safety and occupational-risk professionals, prevention services, competent authorities, and research organizations—by providing structured guidance to support the safe, effective, and human-centric adoption of DT technology.

Presentation

Digital Twin (DT) is an enabling technology in the industrial transformation of manufacturing environments, with a wide range of emerging applications, from operational optimization to organizational innovation. In the specific field of occupational safety and health (OSH), applications are also in their early stages and have focused on the dynamic monitoring and assessment of occupational risks, safety in collaborative environments with robots, and immersive virtual training.

Digital technologies like DT can significantly improve productivity and safety in the new Industry 5.0 manufacturing environments, but they can also introduce new risks that may hinder their adoption. One suggested strategy to prevent and mitigate occupational risks arising from digitalization is to adopt a Human-Centric (HC) approach from the digital system design stage and considering its entire lifecycle (HC by design).

Human – centric design approach (HCD) places people at the centre of the design process and seeks to optimize human-machine interaction to ensure solutions that meet users' actual capabilities and limitations, preserving their autonomy and control and strengthening the human role in the industrial process.

HCD aims to minimize the physical and mental workload of operators, reduce the risk of human error and operational failures, and increase the safety and productivity of the industrial system. In this context, design focuses on the real needs of operators, not just "for the machine." The ultimate goal is to achieve efficient and competitive manufacturing environments that simultaneously promote the safety and well-being of operators (Industry 5.0 environments).

The core and driving force of HCD are Human Factors (HF). HF originates from the social sciences and aims to understand and improve human-system interaction. Although HF has been incorporated into the design of industrial systems in sectors such as aerospace and energy, its consideration in the field of manufacturing engineering (Industry 4.0) is limited and primarily focused on aspects of physical ergonomics.

Both HCD design and associated HF represent substantially novel elements for designers, and their knowledge, evaluation, and implementation in the design of advanced systems face technical, organizational, and cultural challenges. Thus, HCD methodologies (e.g., ISO 9241-210) incorporate contextual research, cognitive modelling, iterative prototyping, and usability testing to ensure interfaces tailored to users' perceptual and cognitive capabilities. This leads to the need to manage multidisciplinary design teams.

A DT for manufacturing (ISO 23247) is a complex digital system that combines hardware and software to create a dynamic and connected digital representation of the process, capable of monitoring, predicting, and optimizing its behaviour. DT technology focuses primarily on the performance and operational efficiency of the process. However, a HC digital twin (HC-DT) adds a new functional layer to the DT design - the HF layer - with the aim of improving human interaction with the manufacturing system and facilitating its adaptation to the capabilities of the operators.

In this context, this Guideline has been developed with the overall purpose to provide general principles, methodological guidelines, and practical recommendations for applying the concepts of HCD and HF in the design and implementation of DT technology, seeking safer, more ethical, HC digital solutions aligned with the principles of Industry 5.0. In practice, the Guide attempts to answer three basic questions for the designer:

1. What is a DT in manufacturing, and what are its main characteristics?
2. What are HF and HCD, and how are these concepts applied in the development of new Industry 5.0 systems?
3. How can these principles be integrated to create a HC design approach for DT?

These matters will be addressed to the greatest extent possible throughout the three sections that comprise this document.

This Guideline is introductory in nature and therefore cannot cover all the issues associated with the HCD of DT. This means that, for complex industrial systems, the designer will likely require the use of more advanced tools.

The document is structured in three sections and an additional appendix chapter. The first section introduces the concept of DT and its applications in the manufacturing sector. The second section explores the HF-based HCD approach and its alignment with the I5.0 approach. The third section presents a screening methodology to quickly identify HF that may affect the design and provides initial guidelines for addressing them, in order to ensure HCD of the DT. Finally, the appendix chapter provides additional tools and resources, showcasing a series of real-world use cases that demonstrate the practical implementation of DT technology across various industrial manufacturing processes

This Guideline is primarily intended for designers and integrators of DT technology in manufacturing processes, who need to deploy an HC approach from the DT design stage. The document also applies to companies using DT technology, who can use it as a reference to evolve their current processes toward an HC approach. Finally, the Guideline can also benefit other stakeholders, such as safety professionals, prevention services, competent authorities, and research organizations, among others.

The HumanDT Guideline is the final result of the SAFERA 2024 project, "*Safe, Sustainable and Human-Centric design and implementation of Digital Twin technology to improve occupational health and safety in new Industry 5.0 manufacturing processes and workplaces (HumanDT)*" and was jointly developed by TECNALIA Research and Innovation Foundation (TECNALIA) and the Finnish Institute for Occupational Health (FIOH).

The document focuses on manufacturing, a strategic sector of European industry. DT technology is expected to be a key driver of the sector's twin digital and green transition towards a more circular and competitive economy. However, the approach presented in this Guideline can also be extended to other digital solutions and/or industrial sectors.

The ultimate goal of the Guideline is to promote the adoption of the HC-DT approach in the manufacturing industry, aiming for more conscious, flexible, and collaborative production processes that improve competitiveness, safety, and well-being in manufacturing environments. In this respect, the Guideline has a significant industrial component because it has been enhanced by contributions from companies that develop or apply DT technology to improve their manufacturing processes.

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Abbreviations

AI	Artificial Intelligence
CEN	European Committee for Standardization
DT	Digital Twin
EC	European Commission
EU-OSHA	European Agency for Safety and Health at Work
GDPR	General Data Protection Regulation
HC	Human-centric
HCbD	Human-centric by design
HCD	Human-centric design
HC-DT	Human-centric Digital Twin
HF	Human factor
I5.0	Industry 5.0
ISO	International Standardization Organization
OSH	Occupational Safety and Health
SbD	Safe-by-Design
SSbD	Safe and Sustainable by Design
UNE	Spanish Association for Standardisation

Objective and Scope of the Guideline

The purpose of this Guideline is to provide structured guidance and practical recommendations for the design and implementation of safe, ethical, and human-centred Digital Twins (HC-DT), fully aligned with the principles and values underpinning Industry 5.0.

Human factors (HF) are fundamental to human-centred design (HCD), and neglecting them introduces significant risks that must be addressed from the earliest stages of Digital Twin (DT) development through a Safety-by-Design (SbD) approach. Integrating HF from the outset is essential to avoid negative impacts on the safety, health, and well-being of workers involved in manufacturing processes where DT technologies are deployed.

This Guideline provides an introductory, screening level overview of the key principles of HC-DT design. It outlines a preliminary conceptual and methodological baseline but does not cover the full complexity of integrating human factors into DT systems. Achieving truly human centric solutions requires deeper multidisciplinary analysis and advanced methods beyond the scope of this document. Accordingly, this Guideline should be regarded as an initial contribution to the development of HC-DT design practices.

The document focuses on manufacturing, a key sector in Europe where DT are expected to drive the digital and green transitions. The proposed approach, however, can also be applied to other digital solutions and industrial domains.

Chapter 1. Fundamentals and applications of Digital Twin technology for advanced manufacturing

Digital Twin (DT) are strategic tools for improving operational efficiency, enabling predictive maintenance, optimizing the product life cycle, and promoting sustainable and human-centric practices. Although large companies are leading their implementation, SMEs are showing growing interest when provided with tailored frameworks and guidelines.

This section brings together the fundamental concepts of DT in the manufacturing sector, aiming to describe in a practical and simple way what a DT is, what benefits it offers, and what its applications are in the sector.

The European manufacturing sector is one of the strategic pillars of the European Union's economy, comprising approximately 2.2 million enterprises, employing more than 30 million people, and generating €9.9 trillion in annual turnover, contributing around 23% of the total value added of the EU business economy. This sector encompasses a wide diversity of industrial activities—from traditional manufacturing to advanced and highly technological production [18].

1.1 Digital Twin concept

The term DT was first introduced by Michael Grieves in the early 2000s during a presentation on Product Lifecycle Management (PLM) at the University of Michigan. Grieves proposed the idea of having a digital counterpart to a physical product to improve lifecycle management.

The concept gained traction when NASA adopted it for spacecraft simulation and monitoring, especially during the Apollo program and later formalized in their 2012 roadmap for advanced modelling and simulation.

Since then, the term has evolved to encompass bi-directional data exchange between physical and virtual entities, enabling real-time synchronization, predictive analytics, and optimization in Industry 4.0 contexts.

Despite their increasing relevance, defining DT remains a complex concept due to the wide variety of interpretations found in the literature. Different fields—specially manufacturing—offer distinct definitions and perspectives. Table 1 presents two DT definitions developed from the corresponding ISO standards: one based on the general approach described in ISO/IEC 30173 [38], and another derived from the manufacturing-oriented framework established in ISO 23247-1 [28]. Both definitions are considered relevant for this work. In addition, Figure 1 presents the conceptual framework for DT in manufacturing as proposed by the second standard.

Table 1. DT definitions

Standard	Definition
ISO 23247-1:2021 [28]	A DT is a digital model tailored for a specific use, that mirrors an observable manufacturing component and stays synchronized with its real-world counterpart, as stipulated in ISO 23247-1:2021.
ISO/IEC 30173:2023 [38]	A DT is a digital representation of a physical asset in which data connections keep the virtual and real states aligned at an appropriate synchronisation rate. The digital twin may incorporate various capabilities, including connectivity, integration, analysis, simulation, visualisation, optimisation, and collaborative functions, as prescribed by ISO/IEC 30173:2023.

Drawing on the two standard-based definitions and the definition proposed by the Digital Twin Consortium [8], the Guideline provides a concise definition of the DT concept, presented below.

A Digital Twin (DT) is a data-driven virtual model of a physical entity or process, designed to stay synchronised with its real counterpart and to provide dedicated services through continuous interaction between both environments.

To meet this definition, a DT must include the following dimensions, known as the 5D Conceptualization of the DT [54] (see Figure 1):

- Physical Entity – a real entity with a hierarchical composition of subsets of other physical entities.
- Virtual Entity – modelling to represent the physical entity in virtual space.
- Data – DT management.
- Connections – enables the interconnection of different components within a reference architecture.
- Services – refers to the functionality required from the DT.

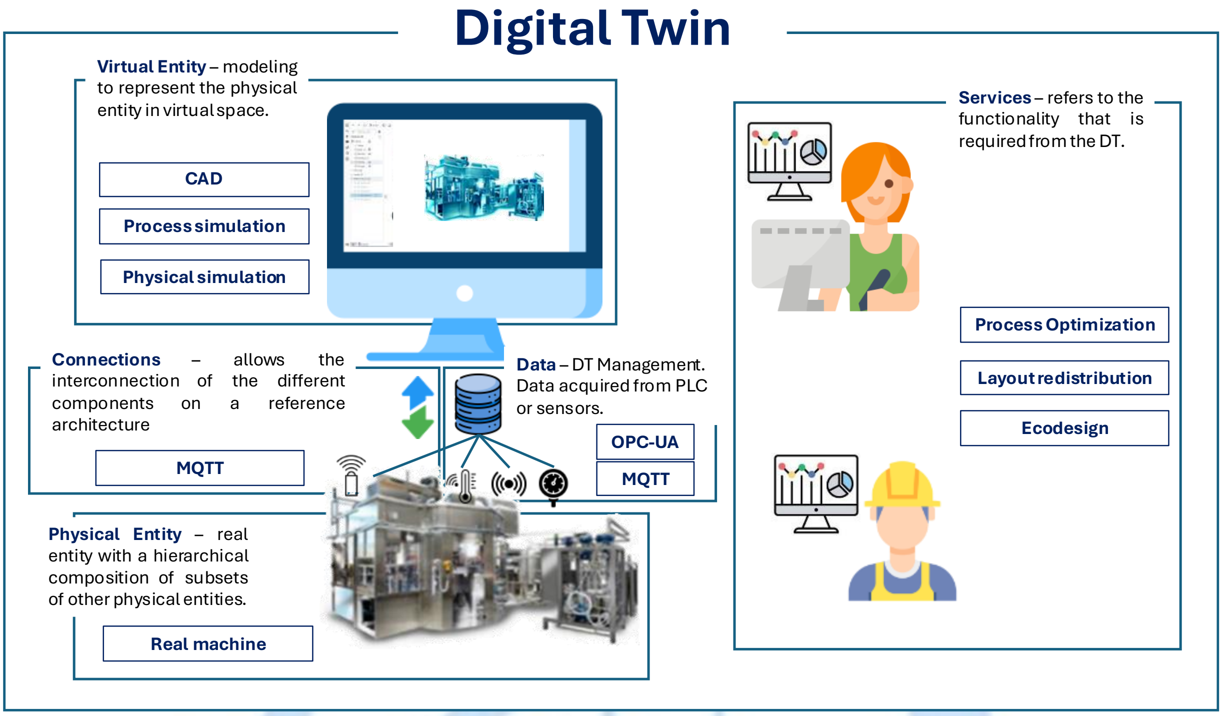


Figure 1. 5D Digital Twin Conceptualization

Following this conceptualization, a DT of a machine tool, such as a CNC machining centre, is a virtual representation that mirrors the real machine's behaviour, condition, and performance in real time to optimize operation and maintenance. It is structured according to the five dimensions of the 5D conceptualization:

- the Physical Entity, which refers to the actual machine and its components.
- the Virtual Entity, represented by a 3D model and simulations of mechanical and process behaviour.
- Data, including real-time sensor readings and historical performance records.
- Connections, enabling bidirectional communication with manufacturing systems and cloud platforms; and
- Services, which deliver functionalities such as real-time monitoring, predictive maintenance, process optimization, and operator training through virtual environments.

This conceptualization may lead to the following question: Have I implemented, or am I truly implementing a DT?. There are different levels of digitalization that can help identify where you currently stand and what is still missing to have a fully implemented DT.

1.1.1 Levels of digital representation: Digital Model, Digital Shadow, and Digital Twin

These three concepts describe different levels of digital representation of physical systems, and they are commonly defined by Grieves and Vickers (2017) [20], who formalized the DT concept.

Digital Model

A Digital Model is a static or dynamic digital representation of a physical object or system, but without any automatic data exchange between the physical and digital entities. Updates are manual.

Example: A CAD drawing of a machine.

Digital Shadow

A Digital Shadow is a digital representation that receives data from the physical system automatically, but the flow is one-way (physical → digital). The digital entity reflects the state of the physical system but cannot influence it.

Example: A sensor-equipped machine sending operational data to a monitoring dashboard.

Digital Twin

A DT is the most advanced concept: a bi-directional connection between the physical and digital entities. Data flows both ways, enabling simulation, prediction, and control. The digital twin can influence the physical system and vice versa.

Example: A smart factory machine whose digital twin can adjust parameters in real time based on predictive analytics.

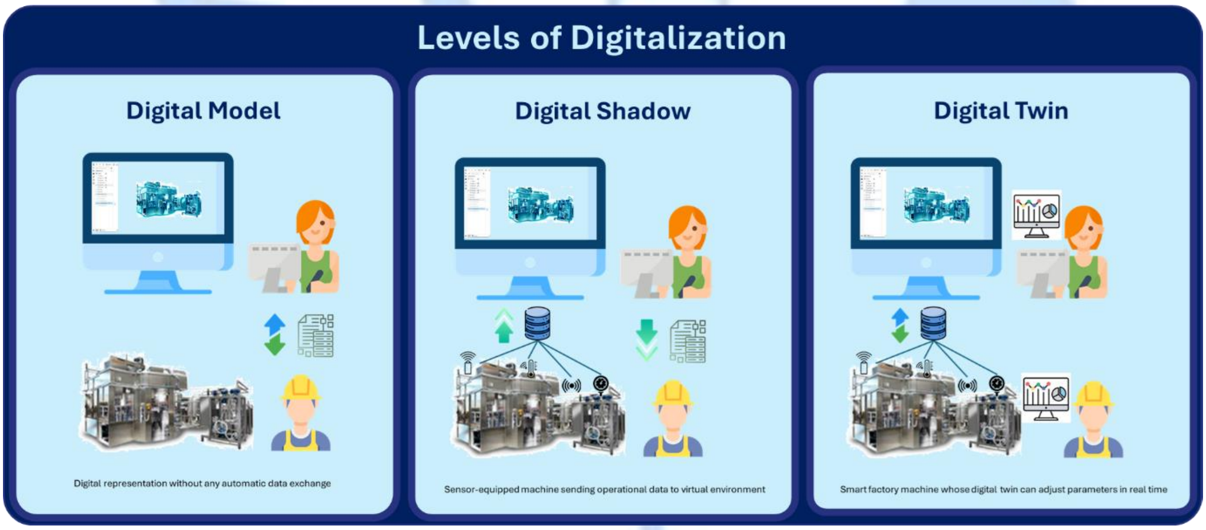


Figure 2. Difference between Digital Model, Digital Shadow and Digital Twin

1.2. Digital Twin Benefits and Implementation Barriers

Among the perceived benefits are improved decision-making, cost reduction, traceability, and real-time simulation, while the main barriers include technical complexity, lack of standardization, data integration issues, and organizational resistance. Furthermore, the social dimension of sustainability remains underexplored, highlighting the need for more inclusive approaches aligned with the concept of Industry 5.0.

To overcome these challenges, it is recommended to apply structured methodologies, involve key stakeholders, and foster interdisciplinary collaboration, along with research into adaptive architectures, automated modelling, and robust validation frameworks for scalable and sustainable adoption.

1.3. Applications of Digital Twin in Manufacturing

DT technology has become a cornerstone in the transformation toward smart, sustainable, and resilient manufacturing environments. Its ability to connect virtual models with real-time data from physical systems enables a wide range of applications, from operational optimization to organizational innovation. In the field of sustainability and energy efficiency, DT are used to improve energy performance, reduce emissions, and optimize resource utilization. Several platforms aim at net-zero manufacturing by integrating modular architectures that facilitate adoption by SMEs, while DT models at the work-centre level contribute to increased productivity and reduced energy consumption.

DT also play a key role in quality assurance and Zero-Defect Manufacturing (ZDM). By using simulations to map performance and anticipate failures, they support strategies that reduce rework and improve traceability. Recent methodologies combine DT technology with deep reinforcement learning, enabling adaptive dynamic scheduling and real-time fault prediction. These approaches strengthen process robustness and support continuous quality improvement.

In process optimization and planning, DT facilitate hierarchical equipment monitoring, layout optimization, and the integration of simulations with MES systems to enhance responsiveness. They are increasingly applied in flexible robotic systems, supporting real-time scheduling and mass customization. Evolutionary algorithms and multi-agent models further expand their capabilities by enabling anomaly detection, bottleneck identification, and optimized task allocation, which together improve productivity and quality in complex manufacturing environments.

DT also contribute significantly to dynamic system reconfiguration. They support the design and simulation of reconfigurable manufacturing systems, enabling the evaluation of alternative reconfiguration scenarios and ensuring operational flexibility. In areas such as smart assembly and human–robot collaboration, DT enhance adaptability and efficiency by facilitating the integration of advanced technologies.

The adoption of DT is further driving the emergence of new business models, such as Manufacturing-as-a-Service (MaaS). These models promote distributed and resilient production ecosystems, allowing the simulation of strategic scenarios and improving supply-chain planning, ultimately strengthening competitiveness and sustainability. Overall, DT applications span sustainability, quality, planning, and organizational innovation, contributing to efficiency, traceability, and the broader transition toward smart factories aligned with Industry 5.0 principles.

Although DT technology is rapidly evolving within the manufacturing sector, its application to Occupational Safety and Health (OSH) is still emerging. A review of the scientific literature shows that most deployments remain at laboratory or pilot scale, with few fully industrial implementations. The main OSH-related applications to date have focused on dynamic risk monitoring and assessment, safety in collaborative robot environments, and immersive virtual training. Table 2 summarizes these DT-based applications within the OHS domain as identified in the current state of the art.

Table 2. Application areas of DT technology in OSH

OSH domain	Applications of DT technology in OSH
Safety	▪ Dynamic safety risk assessment ▪ Real-time hazard monitoring ▪ Support for OSH decision-making ▪ Safety in collaborative environments with robots (HRC) ▪ Detection of hazardous situations with machinery and processes ▪ Detection of stationary workers ▪ Prediction of risks and potential accidents ▪ Immersive safety training for operators ▪ Virtual training in hazardous environments ▪ Monitoring of PPEs use ▪ Simulation of accidents and emergency situations ▪ Work with exoskeletons ▪ Design of safe layouts, machinery, and processes ▪ Proactive risk and OSH management
Industrial Hygiene	▪ Dynamic, real-time assessment of hygiene risks ▪ Real-time monitoring of emissions and exposures to chemical agents ▪ Simulation and prediction of air emissions, exposures and contaminant dispersion in work environments ▪ Development of predictive hazard maps ▪ Management of alarms and ventilation systems
Ergonomics	▪ Dynamic, real-time ergonomic risk assessment ▪ Real-time monitoring of ergonomic hazards (physical and cognitive) ▪ Stress detection ▪ Assessment of physical and cognitive fatigue

Regarding the expected benefits and identified barriers to the implementation of DT technology in the field of OSH, tables 3 and 4 summarize the information provided by the analysed state-of-the-art sources. In all cases, improvements in OSH, worker well-being, and quality of life are highlighted as the main expected benefits, while security, privacy, and ethical aspects of personal data are identified as the most relevant barriers to the implementation of DT technology in manufacturing.

Table 3. Expected OSH benefits from the deployment of DT Technology

Expected benefits
▪ Improves OSH, well-being, and quality of life for workers ▪ Promotes proactive OSH management instead of traditional reactive OSH management ▪ Identifies potential safety gaps in risk management ▪ Prevents risks, accidents, and health damage ▪ Enables dynamic adaptation of the manufacturing system to worker conditions and needs ▪ Promotes safer, healthier, more inclusive, and more productive workplaces ▪ Enables real-time alerts from the OSH management system ▪ Strengthens OSH decision-making ▪ Facilitates monitoring and tracking of regulatory compliance ▪ Optimizes the design of machinery, processes, and workstations ▪ Reduces human error ▪ Reduces the presence of workers in hazardous areas ▪ Enhances the effectiveness of OSH training ▪ Reduces non-safety costs

Table 4. Barriers to Implementing Digital Twin Technology

Implementation barriers
▪ Security, privacy, and ethics of personal data ▪ Intrusiveness of DT technology ▪ Transparency and ethics in the use of AI ▪ Significant implementation costs (equipment, training, personnel, maintenance) ▪ Complex technological implementation ▪ Significant digital infrastructure required ▪ High digital skills required by the workforce ▪ Acceptance of change by workers ▪ Limited standardization ▪ Significant challenge for SMEs ▪ Very limited technological experience in the OSH application field

1.4. Stakeholder perspectives: digital twin manufacturers, integrators and end users.

The interviews conducted by HumanDT project with designers, end-users, and public authorities between September 2025 and January 2026 provided a comprehensive picture of how DT technology is currently being applied and how its use is expected to evolve. Across all participants, there was a clear consensus that DT are already supporting a wide variety of applications and that their adoption will continue to grow in the coming years. The interviews also highlighted the increasing importance of user-centred design approaches, in which collaboration with end-users throughout the development and implementation process is considered essential. Ethical aspects—particularly those related to data protection—were consistently mentioned as a key component of DT system design.

The results show that DT are being deployed across a remarkably broad spectrum of products and services. Interviewees described applications ranging from water supply management, energy storage and electricity production to automotive systems, consumer products, healthcare diagnostics, civil infrastructure and building automation. They are also widely used in manufacturing and industrial processes. This diversity illustrates the cross-sector relevance of DT, although their applicability in highly manual or low-automation production environments may be more limited.

Participants identified several core purposes and benefits associated with DT adoption. Profitability emerged as the primary driver, with end-users emphasising that DT help reduce operational costs and maximise performance. Improved decision-making was also highlighted, as DT provide structured data and visual insights that support operational and strategic choices. Interviewees noted significant advantages in situational awareness through real-time monitoring of facilities and machinery, which contributes directly to reduced downtime and improved process stability. Predictive maintenance was repeatedly mentioned as a strong benefit, enabling early detection of anomalies and preventing equipment failures. The ability to test new production solutions in virtual environments was considered an important enabler of innovation. Additional advantages were noted in occupational safety—such as the use of heatmaps to detect potential collision risks—and in ergonomics, where AI-assisted feedback helps workers adopt safer postures.

A recurring theme in the interviews was the importance of close collaboration between designers and end-users. Many companies utilize human-centred design principles, some even explicitly follow the ISO 9241-210, promoting iterative development cycles and continuous refinement based on field feedback. Designers emphasised that understanding operational needs is critical for tailoring effective DT solutions. However, they also recognised that initial resistance to new technologies is a common challenge. Overcoming this requires demonstrating, through practical evidence, that DT solutions genuinely alleviate day-to-day operational difficulties. Gaining the trust of operators is essential, and collaborative processes play a central role in achieving this.

Designers emphasised that understanding operational needs is critical for tailoring effective DT solutions.

The interviews also revealed that different user groups operate DT systems with distinct access levels and information needs. Operators typically interact with production-specific data, maintenance personnel rely on machinery-related information, supervisors' access operational dashboards, and top management focuses on key performance indicators. This diversity reinforces the need for interfaces that are adapted to different roles and tasks. Interviewees stressed that usability, relevance of content, and clarity of presentation are critical requirements for ensuring that DT tools effectively support each user group.

Ethical considerations emerged as a significant dimension of DT implementation. Designers consistently monitor privacy risks and compliance with General Data Protection Regulation (GDPR), especially when personal data may be collected during system operation. Many developers support clients in defining appropriate data-collection practices and in limiting the scope of personal information processed. Routine risk analyses covering data security and privacy are commonly integrated into DT development workflows to ensure that ethical requirements are met throughout the system lifecycle.

Interviewees stressed that usability, relevance of content, and clarity of presentation are critical requirements for ensuring that DT tools effectively support each user group.

Overall, the interviews reveal a rapidly expanding and increasingly mature ecosystem of DT applications, where technical benefits—profitability, decision-making, situational awareness, predictive capabilities, safety improvements—are accompanied by strong user-centred and ethical considerations. The insights gathered offer a clear view of both the opportunities and the practical challenges associated with the adoption of DT technology across diverse industrial contexts.

1.5. Challenges and deployment recommendations for Digital Twins in manufacturing environments

DT technology is considered a key enabler for materializing the principles of Industry 5.0, especially the human-centric strategy. DTs allow workers to be integrated into the digital cycle through virtual replicas (Human Digital Twin), which not only reproduce external characteristics but also internal aspects such as physical, cognitive, and emotional states. This facilitates real-time monitoring, task optimization, risk prevention, and the improvement of workplace well-being, aligning with OSH objectives.

Stakeholder insights reveal a rapidly expanding and cross-sector adoption of Digital Twin technology, driven by clear technical benefits—profitability, improved decision-making, real-time monitoring, predictive maintenance, safety and ergonomics, while strongly emphasising user-centred design and ethical considerations, especially data protection. Close collaboration between designers and end-users consistently emerges as a critical factor for the successful deployment and effective adoption of DT solutions.

Moreover, DT contribute to industrial resilience and sustainability through the integration of technologies such as blockchain, IoT, explainable AI, and decentralized architectures, which strengthen security, traceability, data protection, and energy efficiency. For example, the paradigm of Decentralized Autonomous Manufacturing (DAM) and blockchain-based smart contracts enable safer and more flexible processes, reducing single-point failure risks and improving production elasticity.

However, significant challenges still persist, such as:

- Lack of granular models to represent HF (cognitive load, fatigue, emotions).
- Privacy risks and GDPR compliance, especially in the collection of personal data through wearable devices.
- Technical complexity in integrating DT with existing systems and ensuring interoperability.
- Organizational resistance to changes in processes and roles.

To address these challenges, several recommendations are proposed:

- Adaptive methodologies for designing HC-DT.
- Explainable and secure algorithms to ensure transparency and trust.
- Robust regulatory frameworks integrating Safe and Sustainable by Design (SSbD) principles.
- Interdisciplinary collaboration strategies involving designers, operators, ergonomics experts, and regulatory authorities.
- Research into resilient architectures, automated modelling, and validation systems for scalable adoption.

These recommendations and the introduction of I5.0 principles into DT technology aim to generate benefits such as:

- Better decision-making through real-time data.
- Cost reduction and optimization of the product life cycle.
- Advanced traceability and simulation for complex scenarios.
- Workplace well-being through human-machine cooperation and intelligent ergonomics.

In conclusion, DTs are essential for advancing toward smart factories that prioritize human-machine collaboration, sustainability, and resilience, consolidating the transition toward I5.0.

Chapter 2. Human factors and Digital Twin: towards industry 5.0

2.1 Human-centred design (HCD)

Human centred design (HCD) is a practical way of developing products and systems by starting with people – their needs, tasks, and real-world environments. According to the ISO 9241-210 standard [27], HCD aims to make systems usable, useful, and safe by focusing on users throughout the entire design and development process. It emphasizes understanding what people actually do, the conditions they work under, and the challenges they face, rather than assuming what they might need. The standard highlights that a human-centred approach improves effectiveness, efficiency, user satisfaction, and overall well-being.

A core idea in HCD is to base the design on an explicit understanding of users, their tasks, and their operating environment, and to involve users continuously as the design evolves. ISO 9241-210:2019 [27] sets out key process activities (Figure 3): (1) understanding and specifying the context of use, (2) specifying user requirements, (3) producing design solutions, and (4) evaluating those solutions with users. This cycle is iterative, meaning designers create early prototypes, gather feedback, and refine the concept step by step. The standard also stresses multidisciplinary teamwork to establish thorough focus on Human Factors (HF), bringing together design, engineering, ergonomics, and domain expertise to ensure the solution fits people at every level.

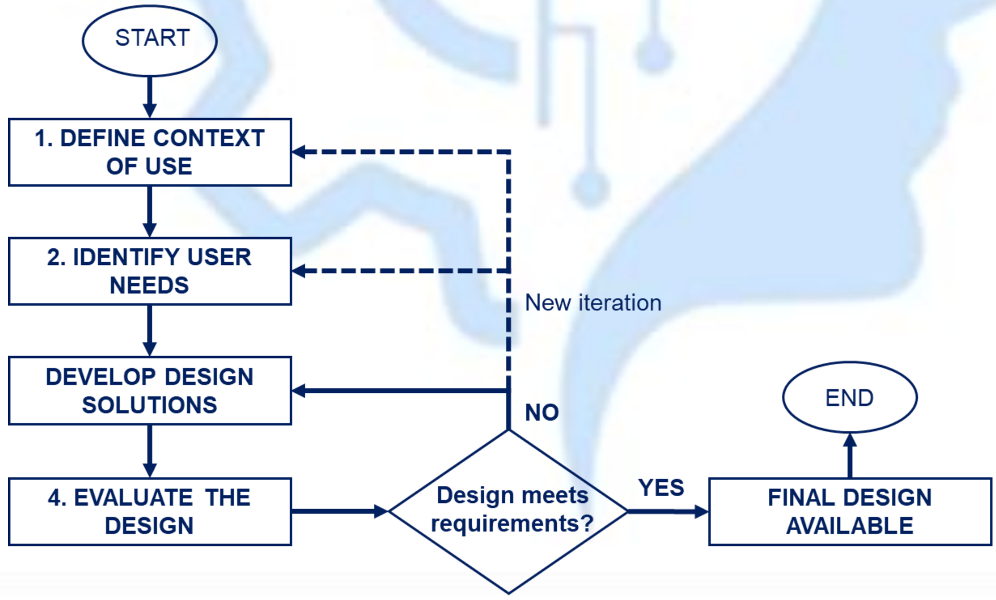


Figure 3. High-level conceptual framework for the implementation of HC interactive digital systems design activities (inspired by EN ISO 9241-210)

Although HCD is valuable in industrial settings, the approach is intentionally broad and applicable to any design domain. Theoretical foundations of the human-centric (HC) approach are intertwined with ‘design thinking’, an approach that points to the benefits of close collaboration with the end-users in the design processes of products and services in various fields [5],[41][42]. Studies in manufacturing and digital transformation show that HC methods lead to better usability, higher productivity, and smoother adoption of new tools [45]. Its focus is not on technology first, but on people first, ensuring that digital tools, physical products, and hybrid systems adapt to human capabilities and limitations.

HCD provides a general approach that is also applicable to DT design. It encourages designers to engage with end-users, gain an understanding of the use context and the tasks the design strives to support, and develop initial drafts that are iteratively refined in collaboration with end-users. However, the specific content of this collaboration is largely left unspecified – to be considered by those in charge of the design process.

The HF approach closes the gap by offering a solid and tested foundation for the content to be utilized in design collaborations. Answering the call for “interdisciplinary” teams’ participation, the HF tool collects viewpoints from various fields of science. Their utilization is, however, fully possible without thorough academic knowledge. In essence, they are factors that influence the possibilities of successful work – a topic all professionals can reflect in relation to their own work. Research has found the HF tool is found easy to use by non-experts.

In considering HF from a viewpoint of the end-users, designers can foreground factors that would not likely not surface in the interactions between designers and end-users without introducing a structure and content that supports addressing the content of end-users’ work and related HF.

Addressing the work processes the DT is planned to support on a task-level, from the viewpoint of those responsible for the successful completion of those tasks, sets DT designers a step closer to the daily challenges of the users. Utilized at the early stages of the DT design process, it increases designers’ chances to gain understanding of end-users’ needs and find design solutions accordingly. Applying the HF perspective at the risk analysis phase helps mitigate the risk related to the DT solution falling short of the target of supporting users in successfully meeting their goals.

Human-centric design (HCD) aims to make systems usable, useful, and safe by maintaining a continuous focus on users throughout the entire design and development process. It requires basing design decisions on an explicit understanding of users, their tasks, and their operational environment, and involving users continuously as the solution evolves.

2.2 Human Factors

HF is commonly defined as the field that studies how people interact with their tasks, tools, technologies, and working environments, with the aim of improving safety, well-being, and overall system performance. It looks at physical, cognitive, and organizational aspects of work to ensure that systems are designed in ways that support human capabilities and minimize the potential for error [23]. This definition aligns with established HF research across safety critical industries, where the discipline is understood as an integrated view of individuals, teams, and organizations working within complex systems [21], [51].

According to the International Ergonomics Association [61], HF (or synonymously ergonomics, sometimes also abbreviated as HFE) is the scientific discipline concerned with understanding interactions among humans and other elements of a system. The professional, human factors engineering, applies theory, principles, data, and other methods to design to optimize human well-being and overall system performance. The Health and Safety Executive (HSE) in the United Kingdom (UK) has defined HF as the environmental, organizational and job factors combined with the human and individual characteristics that influence behavior at work in a way that can affect health and safety. Within the Federal Aviation Administration (FAA) in the United States (US), HF is defined as a multidisciplinary effort to generate and compile information about human capabilities and limitations, as well as to apply that information to equipment, systems, facilities, procedures, jobs, environments, training, staffing, and personnel management for safe, comfortable, and effective human performance. A core principle of HF is systems thinking: HF professionals consider the network of interactions between individuals and various elements of their environment (or work system) [61]. The knowledge required to design, implement and disseminate HF is diverse. It relies on knowledge of basic scientific disciplines, such as physiology, sociology and psychology, as well as on knowledge of such applied sciences as industrial engineering, business and management [6].

In practical terms, HF (Figure 4) are aspects that can either support or hinder the success of people in accomplishing work tasks safely and fluently. In practice, HF treats work as a multi layered system. Instead of focusing only on individual performance, it examines a broad set of influences: the characteristics of the work itself, team communication and coordination, organizational resources, and the surrounding operational environment. Structured tools have been developed to help organizations make these elements visible and easier to analyse. These tools guide practitioners in identifying factors that strengthen or weaken safety, efficiency, and well-being at different levels of the system—individual, work, group, and organizational. They are designed for everyday use, making HF an accessible part of normal operations rather than a specialized activity reserved only for experts [55], [57].

HF has been widely applied across sectors such as aviation, air traffic management, nuclear energy, maritime operations, and railways. These domains use HF to improve how information flows, how teams coordinate, how tasks are structured, and how technology supports human performance in demanding conditions. Research in these areas shows that applying HF systematically leads to clearer work processes, better communication, more reliable decision making, and increased capacity for learning and adaptation. It also highlights the importance of designing workplaces where competence development, feedback, and continuous improvement are built into everyday practices [40].

By understanding the factors that shape human performance and by treating work as a dynamic, interconnected system, HF supports the design of environments and tools that allow people to succeed – even in complex or high-risk settings. This holistic view helps ensure that safety, efficiency, and well-being are built into systems from the ground up, rather than added as afterthoughts [6].

In this Guideline, we call the failure to consider a HF in the design of a DT as HF risk. Considering the HF related to a given DT design requires active collaboration with those who utilize the DT. Utilizing the end-user's viewpoint is essential in understanding how DT will support accomplishing the work tasks safely and fluently. The end-user's contribution is needed to point the attention of designers to HF that arise from the use context.

Human Factors (HF) address the physical, cognitive, and organizational dimensions of work to ensure that systems are designed in ways that support human capabilities and minimize the potential for error. HF represent characteristics of the work system that can either enable or hinder a person's ability to perform tasks safely, efficiently, and reliably. In this Guideline, any omission or inadequate consideration of a relevant HF during the design of a Digital Twin (DT) is referred to as an HF risk.

2.3 Human-centric design and Human Factors in the new I5.0 paradigm

Industry 5.0 places humans and their well-being at the centre of industrial development, emphasizing systems where people and technology work together rather than in competition [4]. DT play an important role in this vision by providing virtual representations of processes and environments that help operators understand, predict, and influence what happens on the factory floor. This aligns with the Industry 5.0 (I5.0) goal of developing HC, sustainable, and resilient production systems where technology supports human decision making and strengthens situational awareness [5].

HCD offers a practical foundation for shaping DT into tools that genuinely support operators. Following HCD principles ensures that the DT is based on a clear understanding of operator tasks, work environments, and constraints, and that operators are involved in its development throughout the design process. According to established HCD standards, design activities should include specifying the user context, identifying user requirements, creating solutions, and evaluating them iteratively with real users. Applied to DT, this means developing models and interfaces that are intuitive to interpret, easy to interact with, and directly relevant to the operator's daily activities – as well as utilizing the end-users' perspective in controlling the risks related to the design.

HF strengthens this approach by offering a systemic understanding of how individuals, teams, tasks, and organizational structures influence performance [55], [57]. HF frameworks help identify how DT should be integrated into work so that they reduce cognitive load, clarify communication, and improve coordination. HF tools developed for safety critical domains provide structured ways to examine the factors that support or hinder effective operator action, including workload, clarity of procedures, ergonomic fit, and information flow. When applied to DT, these insights help ensure that the twin enhances—not complicates—the operator's task performance and supports safe and stable system behaviour during normal operations as well as disturbances.

DT already fit naturally into the I5.0 emphasis on close human–technology collaboration. They make complex processes more transparent and allow operators to run scenarios, anticipate emerging issues, and adjust production parameters before problems escalate. In I5.0 discussions, DT are highlighted as one of the technologies that can contribute to more adaptive and HC manufacturing by improving insight and enabling more informed operator decisions. When shaped through HCD and HF principles, DT become tools that extend human capability: they help operators stay ahead of variability, maintain system resilience, and guide processes in ways that support sustainability goals [19].

Together, HCD and HF lead the way for that DT to fulfil the I5.0 vision of technology that supports operators rather than replaces them [9]. They provide the methods and perspectives needed to design DT that fit real work, respect human strengths and limitations, and enhance the operator's ability to manage complex industrial systems. In doing so, they turn I5.0 from a technological ambition into a practical approach where people remain central and empowered in future factories.

2.4 Human Factor tools for Human-centric design

2.4.1 The Human Factors tool (HF Tool)

The HF Tool developed by Prof. Anna-Maria Teperi is a practical way to understand how people, their work, and their organisation influence everyday operations and safety [55]. It is a holistic, practical framework for understanding, analysing, and improving human performance and systemic safety in complex environments. The idea behind the tool is simple: events at work – both successes and problems – rarely come from just one cause. Instead, they grow out of many connected factors, ranging from individual skills to teamwork and organisational support.

The HF Tool helps workers, supervisors, and management look at these different layers in a structured but easy-to-use way. It has been applied in several safety-critical industries such as aviation, nuclear energy, maritime transport, railways and construction, where it has helped organisations move from focusing mainly on errors to understanding what helps things go right. It also supports the newer Safety-II thinking, which highlights human adaptability and strengths.

The text in the centre of the tool, "mastering dynamic, complex situations", sums up the central idea: HF enable all of us to succeed in work. The tool includes structured HF items covering different levels and can be used to analyze successes and failures in operational events. HF are organized by the HF Tool into four quadrants named (Figure 4): 1) Individual´s actions and characteristics (Individual level), 2) Work actions, characteristics of work (Work level), 3) Group-level factors (Group level) and 4) Organization-level factors (Organization level).

1) Individual Level (Items 1-12)

The first level of the HF Tool looks at the individual worker. This includes a person's skills, knowledge, motivation, attitudes, and overall readiness to perform tasks. Rather than blaming individuals for mistakes, the tool encourages understanding how people vary in their performance from day to day and how this variation affects work. It helps identify when a person's strengths—such as good anticipation or problem-solving—

contribute to safe and smooth operations, and when factors like unclear expectations or fatigue might hold them back.

2) Work Level (Items 20-29)

The second level focuses on the work itself: the tasks, tools, instructions, and conditions under which employees operate. The HF Tool looks at how work is organised, whether instructions are clear and realistic, how tasks are divided, and whether workers have the resources they need. By examining the actual "work-as-done," not just "work-as-imagined," the tool helps identify where procedures might be overly complicated, contradictory, or not well aligned with real-life demands. This makes it easier to improve work processes in ways that support both safety and efficiency.

3) Group Level (Items 30-36)

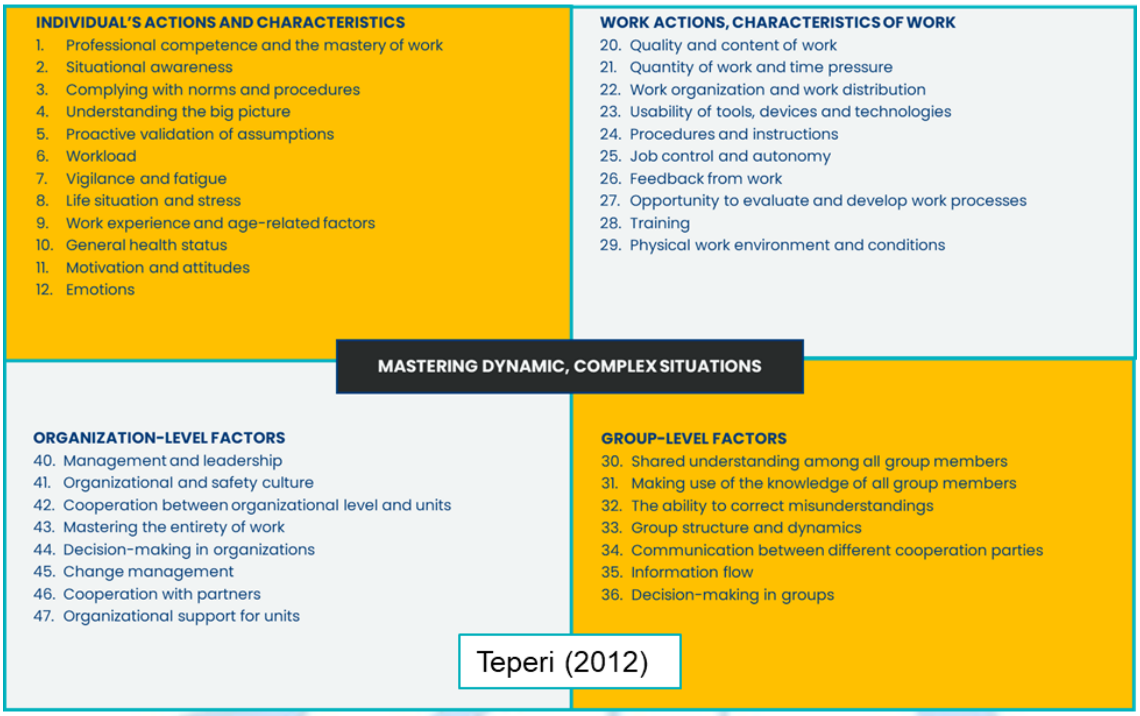
The group level examines how people work together. Communication, teamwork, information sharing, and trust all play a major role in how well a team handles its daily tasks and unexpected situations. The HF Tool helps reveal whether team members have a shared understanding of their goals, whether communication flows smoothly, and how well people coordinate their actions. This level shows how teamwork can amplify strengths—such as collective problem-solving—or create problems if information does not move to the right person at the right time.

4) Organization Level (Items 40-47)

The fourth level considers the broader organisation: leadership, policies, structures, and the overall culture. This includes how well the organisation supports learning, whether management provides sufficient resources, and how safety is valued in day-to-day decisions. The HF Tool helps organisations see how high-level decisions and long-term practices shape what happens on the front line. It draws attention to underlying patterns—such as conflicting priorities, weak safety practices, or limited opportunities for learning—that influence employee performance. This organisational view is central to the tool's aim of seeing people as part of a larger system rather than isolated actors.

In summary, the HF Tool:

- Helps users perceive the "big picture" and the systemic nature of human contribution to operations.
- Break down human factors into four levels:
- individual, work, group, and organization.
- Was originally developed for Finnish air traffic management in the 2000s.
- Widely used in the analysis of safety abbreviations and proactive safety management.
- It is designed to be:
  - Easy to use for operational personnel (not just HF professionals)
  - Integrated into daily safety management systems
  - Holistic and positively oriented



INDIVIDUAL'S ACTIONS AND CHARACTERISTICS

1. Professional competence and the mastery of work
2. Situational awareness
3. Complying with norms and procedures
4. Understanding the big picture
5. Proactive validation of assumptions
6. Workload
7. Vigilance and fatigue
8. Life situation and stress
9. Work experience and age-related factors
10. General health status
11. Motivation and attitudes
12. Emotions

WORK ACTIONS, CHARACTERISTICS OF WORK

20. Quality and content of work
21. Quantity of work and time pressure
22. Work organization and work distribution
23. Usability of tools, devices and technologies
24. Procedures and instructions
25. Job control and autonomy
26. Feedback from work
27. Opportunity to evaluate and develop work processes
28. Training
29. Physical work environment and conditions

MASTERING DYNAMIC, COMPLEX SITUATIONS

ORGANIZATION-LEVEL FACTORS

40. Management and leadership
41. Organizational and safety culture
42. Cooperation between organizational level and units
43. Mastering the entirety of work
44. Decision-making in organizations
45. Change management
46. Cooperation with partners
47. Organizational support for units

GROUP-LEVEL FACTORS

30. Shared understanding among all group members
31. Making use of the knowledge of all group members
32. The ability to correct misunderstandings
33. Group structure and dynamics
34. Communication between different cooperation parties
35. Information flow
36. Decision-making in groups

Teperi (2012)

Figure 4. The HF Tool [55], used by the HumanDT project to identify, evaluate and integrate HF in the context of the DT design cycle.

2.4.2 The Human Factors checklist (HF Checklist)

The HF checklist has been developed by project HumanDT and supports evaluating the risks related to omitting HF in the DT design. The checklist is in the form of a table and comprises of the items of the HF tool (Column 1), short description of the content of each item (Column 2) and an assertion describing a risk related to omitting this factor in the DT design (Column 3). In addition, the HF checklist also includes several additional columns for documenting the HF ultimately selected in the DT design (Column 4) as well as the initial and final risk levels assessed (Colum 5 and 7), as well as the risk mitigation strategies implemented in the design (Column 6). Table 5 includes an example of the HF checklist; the full version is found in Appendix 3.

The HF checklist can be used by the designers and the end users independently in evaluating the DT design and seeking possibilities for improvement.

The assertions that are evaluated as ‘yes’, that is the person doing the evaluation sees a potential risk or weakness in the design, should be given due attention. Assertions related to individual characteristics are best addressed in close collaboration with users. Interviews with users and visits to the sites are encouraged to grasp the local circumstances. Assertions related to work characteristics are best addressed in collaboration with managerial and operational levels of the user organizations. Group factors are best addressed by establishing connection with the group that operates the DT, e.g. group discussions and -interviews. Organizational factors should be evaluated in close collaboration with the managerial level of the user organization.

Table 5. Structure of the HF checklist. See Appendix X for the complete version.

HF CHECKLIST								
Nº		**ITEM**	**SPECIFICATION**	**ASSERTIONS**	**APP.**	**IRL**	**MEASUREMENTS**	**FRL**
1. INDIVIDUAL LEVEL	1	Competence, mastery of work	The knowledge, skills, and expertise required in a given job	The DT challenges user's skills, knowledge or capabilities	Y/N			
	2	Situation awareness (perception, memory, decision-making, response/execution)	On-going process of perceiving, understanding, and projecting what is happening in the individual's work environment (attention, observation, memory, decision-making, and action)	The DT challenges users' attention and memory The DT challenges users' sustaining an up-to-date understanding of what is happening in the work environment				
	3	Complying with norms and procedures	Norms can be official instructions, such as written work guidelines, safety regulations, or industry-specific standards, or they can be unofficial practices developed within the work community.	The DT contradicts with norms and procedures the user needs to comply with The DT contradicts with established practices in the user's work community				
	4	Understanding the bigger picture/overall situation	Having a view of the system or process one is part of. This goes beyond moment-to-moment situational awareness and involves a stable, long-term grasp of how different elements interact.	The DT interferes with user's awareness of aspects in the work system or work process				

The HF checklist for DT designers is meant to be used when evaluating the manufacturing focuses DT-design in the different maturity levels of the design and the implemented DT solution: first version (mockup) review, pre-implementation review or post-implementation improvements.

The first version may be a simple visual, physical, digital or text description of the planned DT solution. The form of the first version is not predefined, and imaginative illustrations are encouraged. The main purpose of the first version is to illustrate the possibilities of the design and allow mindful, context-rooted consideration in finalizing the product in collaboration between designers and end users. Not much resources should be invested in compiling the first version to avoid creating a threshold for major reorientation. Rather, it should be drafted quick-and-dirty to create shared understanding of the central aspects of the design solution in the fuzzy front end of the design process. Iterations to the first version should follow in case a sufficient agreement on the coarse outlines of the design are not reached. The HF checklist can be used to evaluate the first version of the design, highlighting aspects requiring further attention. Iteration should follow to improve the design to meet user needs.

Before implementing the design to its intended use, a stricter evaluation to the design should be conducted. Catching deficiencies in the design at this point allows iteration to ensure fluent implementation and reduce the need for inevitably more resource-demanding and time pressured post-implementation changes, which can also result in difficulties for end-user operations. The HF checklist can be used with more scrutiny to ensure a solid overall evaluation of the design.

The need for post-implementation improvements is likely to occur for many reasons. However well planned and executed the design process is, needs for improvement are often revealed upon first use experiences. Changes in e.g. manufacturing equipment will also need to be accommodated and updates planned. The HF checklist can be used in planning major revisions or when high risk tasks or related technology are introduced to the end-user organizations' workflow.

2.5 How to use the HF tool and the HF checklist in DT design?

The HF tool is intended to provide a vocabulary for directing attention to the HF related to the intended use of the DT. It can direct attention to factors that would otherwise not be considered during the design process. It is intended to be used as a part of collaboration with end-users to establish design goals. The following steps should be conducted:

1) Organise a site visit to the premises where the DT will operate. As a lighter alternative, you can arrange a meeting with those who will operate the DT once it is implemented.
2) Ask the participants to describe the task processes in which the DT will be a part. Focus on the tasks and processes the DT is planned to support.
3) Instruct to describe the process as it unfolds currently. Seek for detailed information to gain understanding of the process from the viewpoint of those who participate in the process as a part of their work: a) WHO, b) Does WHAT, c) To/with WHAT.

4) Refer to the HF Tool to ask clarifying questions and ensure a good overall understanding of the process from the viewpoint of HF.
5) Ask the participants to name three HF from each of the four content areas of the HF Tool (Work, individual, group, organisation) that are especially important to consider in the design of the DT.
6) Ask for concrete descriptions of how the HF should be considered in the final design.
7) Refine the information to compile concrete design specifications.

The **HF checklist** facilitates the evaluation of risks that may result from excluding Human Factors in the development of the digital twin. The following steps should be conducted:

1) Collaborate with end-users to evaluate the risks related to the DT design. Ask the participants to go through the checklist and evaluate the assertion of column 3.
2) Focus on the "Yes" -answers, as they represent issues that the end-users find troublesome.
3) Ask follow-up questions to clarify the elements that need to be worked on.
4) Evaluate the risk using a matrix included in the checklist
5) Focus on assertions that are evaluated as "Medium risk" and "High risk"
6) Iterate the design and repeat the evaluation until reaching a "Low risk" level

Chapter 3. Practical Implementation of Human-Centric Principles in Digital Twin Design

The conceptual model deployed by the EN ISO 9241-210 standard for the design of human-centric (HC) interactive digital systems has been used in this Guideline as the high-level model for the human-centric Digital Twin (HC-DT) design (Figure 3). The conceptual model offers a structure but leaves open practical solutions for accomplishing the goals of each stage.

The methodology presented below applies primarily to stages 1, 2, and 3 of the activity cycle proposed by this standard for the development of a new human-centric design (HCD) product or system (Figure 3). However, the design-evaluation stage (Stage 4) should be considered for the different intermediate and final versions of DT design. Design evaluation is an essential activity within HCD. A broad range of evaluation methods can be applied to assess the quality and suitability of design solutions (see ISO/TR 16982). Anyway, some of the methods proposed by EN ISO 9241-210 are: User-based testing, inspection-based evaluation and long-term monitoring.

Methodologically, failing to consider the HF component in the design of a DT is a risk factor to be considered from the design stage of the DT, since its omission can have negative impacts on the safety, health, and well-being of workers as well as the fluency of work in the manufacturing process where the DT operates.

This section of the Guideline intends to provide a screening methodology to assess the risks arising from HF and integrate their treatment into the DT design process to achieve an HCD. Consequently, this Guideline applies a risk-based approach to design (Safe-by-design approach), using widely recognized methods and procedures in the field of risk management. The Safety-by-Design (SbD) concept, also known as Safety Integration or Prevention through Design, among other names, is a widely recognized concept in the field of safety design for industrial equipment, systems and processes. In all cases, it refers to the elimination of hazards or the minimization of risks in the early stages of the product design process. SbD is therefore a universal concept applicable to the design of any type of product, such as a manufacturing system based on DT technology. This approach enables the analysis and evaluation of HF risks, as well as the proposal of design strategies for risk mitigation to achieve an HC-DT.

This Guideline seeks to provide a light and simple way to foreground HF during the DT design process. To avoid complicating the design processes, it utilizes three phases already present in most DT design processes (Figure 5): 1) Discussions with the end-users to establish design goals and gather relevant information (Information gathering), 2) Evaluating the risks related to the implementation of the DT (Risk assessment) and 3) Providing strategies to reduce the HF risk to acceptable levels (Risk reduction).

The Guideline provides four methodological tools encapsulated in Annex 3: the HF Tool and the HF Checklist, which have already been described in the previous section, and the 3x3 Risk Matrix and the Compendium of Technical Strategies for Managing HF Risks, which will be described in this section. All of these tools will be used to implement the methodological approach proposed in this section of the Guideline (Figure 5).

Identifying the key stakeholder groups from end-users as well as engaging in active collaboration is required to use these tools. To achieve this, knowledge of end-user organizations' management needs to be utilized to identify the key stakeholders who will operate the DT once it is implemented. Based on the interviews of the HumanDT project, the key stakeholders are typically: a) Operators, b) Maintenance staff, c) Management, d) Foremen.

Anyway, the methodology described here is introductory in nature and should be scaled up to consider complex issues of HC 5.0 industrial systems.

The Guideline provides four methodological tools: 1) the HF Tool, 2) the HF Checklist, 3) the Risk Matrix and 4) the Compendium of Technical Strategies for Managing HF Risks. All these tools are used to implement the methodological step-by-step approach proposed by the Guideline to integrating human-factors into a human-centric digital twin design

3.1 Step-by-step approach to integrating HF into a HC-DT design

The three-step approach to integrating HF into a HC-DT consists of the following steps (Figure 5):

3.1.1 Step1: Information gathering

The objective of this activity is to collect relevant information from stakeholders in order to define the DT use context with the highest possible level of detail, and to provide clear and accurate input for the subsequent stages of the process. This information may come from existing documentation or be gathered through interviews, meetings, and workshops with the stakeholders. The key stakeholder groups to be engaged are the management, supervisors, operators and maintenance of the DT end-user company.

As this stage:

- Arrange a meeting or a site visit with the key stakeholders of the end-user company. Prior to the meeting, instruct them to present the context in which the DT will operate.
- To gather information on HF risks, it is advisable to collaborate with different profiles depending on the nature of the risk: with supervisors for HF risks related to work; with operators and maintenance personnel for risks focused on the individual; with supervisors for risks linked to equipment; and, finally, with management for HF risks of an organizational nature.
- After the participants have presented the use context from their viewpoint, present the HumanDT tools and their methodology of use (HF Tool, HF Checklist, Risk Matrix and Compendium of risk reduction strategies).
- Ask the participants to name the most central items of the HF tools that should be considered when designing the DT
- Ask the participants to explain how the identified HF Tools items should be considered in the design
- Utilize their insight to form concrete design requirements
- Gather any other relevant information to define the context of use of the DT.

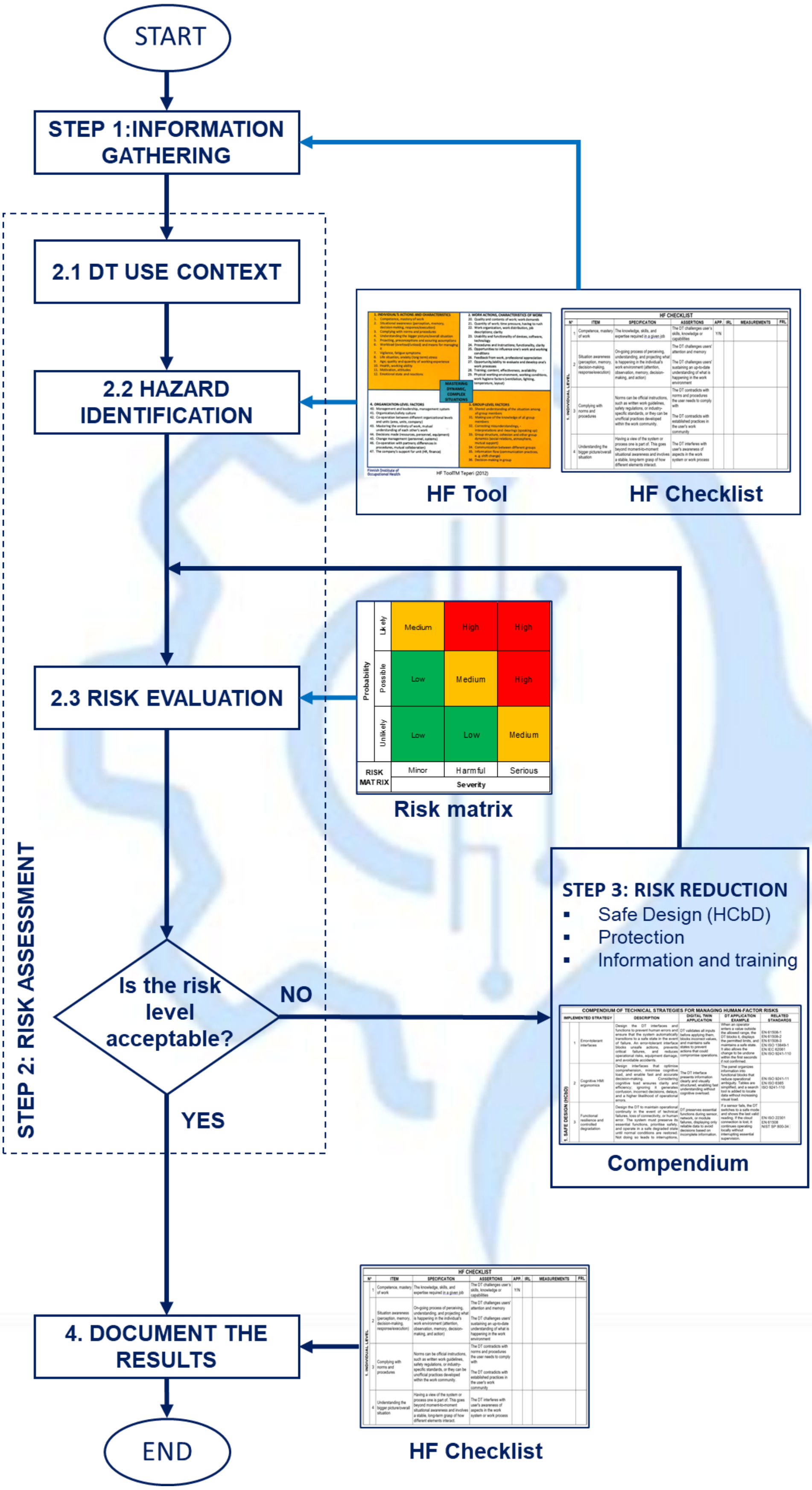


Figure 5. Step-by-step procedure for the evaluation and reduction of HF risks and their integration into the HC-DT design, using the four tools provided by the Guideline

Stakeholders may conclude their involvement after this step, continue to participate actively in subsequent phases, or limit their contribution to reviewing the documents produced by the designer at each stage. The degree of stakeholder engagement will determine whether the process is highly participatory or more designer-driven.

3.1.2 Step 2: Risk assessment

This stage encapsulates the following activities: DT Use context, hazard identification, risk estimation and risk evaluation.

2.1 DT use context. At this stage, the characteristics of the DT to be designed, the application environment, the specifications and expected conditions of use, and the characteristics of the users and the variability of the expected human-system interactions will be defined. The designer will review all the information gathered in the previous step and update a first version of the DT use context.

2.2 Hazard identification. This stage addresses the systematic identification of hazards and hazardous situations that may arise from omitting HF in the design of the DT. Both, the HF Tool and the HF checklist, are tools to be used in this stage to analyze, confirm, and document those hazards that must ultimately be considered in the DT design (flagged as “Yes” in the HF Checklist App. column). The analysis will consider all stages of the DT lifecycle (design, installation and testing, operation, maintenance and adjustment, and decommissioning) as well as the intended operating modes.

2.3 Risk evaluation. In this stage, the risk level for each of the hazards and hazardous situations identified in the previous stage will be estimated and assessed. To facilitate this process, the Guideline proposes, in addition to professional judgment, the use of a 3x3 Risk Matrix (EN 30010). However, the designer is free to use any other risk assessment tool they routinely employ and with which they feel comfortable.

A 3x3 Risk Matrix (Annex 3) is a simple, visual, semi-quantitative tool that allows the designer to assess risks by combining two variables: Probability of occurrence (P) and Severity of impact (S). The matrix generates nine possible combinations, resulting from crossing the three Probability levels (Unlikely, Possible, Likely) with the three Severity levels (Minor, Harmful, Serious). Risks are classified as Low, Medium, and High and are coded in the matrix with green, orange, and red, respectively. High risks must be addressed immediately, medium risks require the implementation of reasonable mitigation measures, and low risks are generally accepted and monitored occasionally. This methodology facilitates a quick overview of risks requiring priority attention (see the IRL column in the HF Checklist) and standardizes decision-making.

The simplicity and rapid interpretability of the results provided by the 3x3 matrix allow for agile and understandable assessments, consistent with the screening methodology proposed by this Guideline. However, the three-level risk scale may be limited for addressing complex risks. In this case, more precise risk matrices (e.g., 5x5) or other more rigorous risk assessment methods can be used (see EN 30010).

Table 6. Strategy compendium for designers to reduce HF risks in DT design

COMPENDIUM OF TECHNICAL STRATEGIES FOR MANAGING HUMAN-FACTOR RISKS						
IMPLEMENTED STRATEGY			**DESCRIPTION**	**DIGITAL TWIN APPLICATION**	**DT APPLICATION EXAMPLE**	**RELATED STANDARDS**
1. SAFE DESIGN (HCbD)	1	Error-tolerant interfaces	Design the DT interfaces and functions to prevent human errors and ensure that the system automatically transitions to a safe state in the event of failure. An error-tolerant interface blocks unsafe actions, prevents critical failures, and reduces operational risks, equipment damage, and avoidable accidents.	DT validates all inputs before applying them, blocks incorrect values, and maintains safe states to prevent actions that could compromise operations.	When an operator enters a value outside the allowed range, the DT blocks it, displays the permitted limits, and maintains a safe state. It also allows the change to be undone within the first seconds if not confirmed.	EN 61508-1 EN 61508-2 EN 61508-3 EN ISO 13849-1 EN IEC 62061 EN ISO 9241-110
	2	Cognitive HMI ergonomics	Design interfaces that optimise comprehension, minimise cognitive load, and enable fast and accurate decision-making. Considering cognitive load ensures clarity and efficiency; ignoring it generates confusion, incorrect decisions, delays, and a higher likelihood of operational errors.	The DT interface presents information clearly and visually structured, enabling fast understanding without cognitive overload.	The panel organizes information into functional blocks that reduce operational ambiguity. Tables are simplified, and a search tool is added to locate data without increasing visual load.	EN ISO 9241-11 EN ISO 6385 ISO 9241-110
	3	Functional resilience and controlled degradation	Design the DT to maintain operational continuity in the event of technical failures, loss of connectivity, or human error. The system must preserve its essential functions, prioritise safety, and operate in a safe degraded state until normal conditions are restored. Not doing so leads to interruptions, data loss, and risks to personnel and equipment.	DT preserves essential functions during sensor, network, or module failures, displaying only reliable data to avoid decisions based on incomplete information.	If a sensor fails, the DT switches to a safe mode and shows the last valid reading. If the cloud connection is lost, it continues operating locally without interrupting essential supervision.	EN ISO 22301 EN 61508 NIST SP 800-34

The designer/design team will estimate, according to their professional judgment, the P and S values for each hazard identified in the HF Checklist and document the resulting value in the IRL column. The designer will then evaluate this result and, if the IRL value is Medium or High, should investigate reasonable strategies to reduce it to a Low level.

In this Step 2, if applicable, involve key stakeholders in the activities of DT context use definition, Hazard Identification, Risk evaluation, or in the review of documents prepared by the designer on these topics. Refresh stakeholders' knowledge of the HF Checklist and Risk Matrix tools to facilitate active participation.

3.1.3 Step 3: Risk reduction

To assist the designer at this stage, the Guideline proposes a simple tool called the Compendium of Technical Strategies for Managing Human-Factor Risks (Table 6 and Annex 3). This tool provides 32 tabulated risk reduction strategies, classified into three hierarchical categories: Safe Design (9 strategies), Protection (18 strategies), and Training/Information (5 strategies). For each strategy (Column 1), the table specifies: a technical summary of its operational context and scope (Column 2); implementation guidance for its integration into DT design (Column 3); an applied example demonstrating its use within a DT scenario (Column 4); and a non-exhaustive set of relevant standards and reference documents (Column 5) that designers may consult to further support its application within the DT development process.

The designer can use the Compendium as a simple tool to identify, select, and test risk reduction strategies until an acceptable level of risk is achieved for the DT. The designer will prioritize safe design strategies over protection strategies, and the latter over information/training strategies, in accordance with the widely recognized hierarchy for risk control measures.

Once one or more strategies have been selected to address the HF risk reduction, the designer will recalculate the expected risk level after implementation. If the new estimated risk level is acceptable (Low), this value will be documented in the HF Checklist (FRL) along with the selected strategies. Otherwise, the designer will iteratively repeat the described process, testing new strategies, until the risk is acceptable. The same procedure will be followed for the remaining HF identified as applicable to the design of the DT in the HF Checklist.

In this Step 3, if applicable, involve key stakeholders in the activities of Risk reduction, or in the review of documents prepared by the designer on this topic. Refresh stakeholders' knowledge of the Compendium tool to facilitate active participation.

Conclusions

Digital Twin (DT) technology remains at an emerging maturity level in manufacturing, where it is mainly applied to advanced functions such as process optimization, production planning, energy efficiency management, quality assurance, zero defect strategies, dynamic process reconfiguration, predictive maintenance, and innovative business models. In the occupational safety and health (OSH) domain, DT applications have mainly concentrated on dynamic, real-time risk monitoring and assessment, ensuring safety in human–robot collaborative (HRC) environments, and supporting immersive virtual training.

The emergence of the Industry 5.0 (I5.0) paradigm reinforces the need to place humans at the core of industrial systems, demanding the explicit integration of human-factor (HF) considerations into the design of advanced technologies such as DT. However, such integration is far from straightforward: it requires a rigorous and evidence-based understanding of workers' actual limitations, capabilities, and operational requirements—an area that has historically received limited attention within industrial systems engineering practices. Achieving truly human-centric (HC) solutions therefore requires new methodological frameworks, multidisciplinary tools, and close collaboration among engineering disciplines, ergonomics, and behavioural sciences. This highlights that, while the centrality of humans is essential for Industry 5.0, its practical implementation is neither trivial nor automatic.

This Guideline is intended as an introductory resource, providing a preliminary screening-level overview of the key aspects of human-centric digital-twin (HC-DT) design. While it offers an initial conceptual and methodological framework, it cannot address the full range of challenges involved in effectively integrating the human factor into such systems. Achieving a truly human-centric design (HCD) requires deeper multidisciplinary analysis and advanced tools beyond the scope of an introductory document. Therefore, this Guideline should be regarded as an initial contribution—a foundational step in the right direction—rather than a fully comprehensive or final solution.

The overarching objective of the Guide is to promote the adoption of HC practices in the design of DT and other industrial systems, thereby enabling more conscious, adaptable, and collaborative production environments that enhance competitiveness, safety, and worker well-being.

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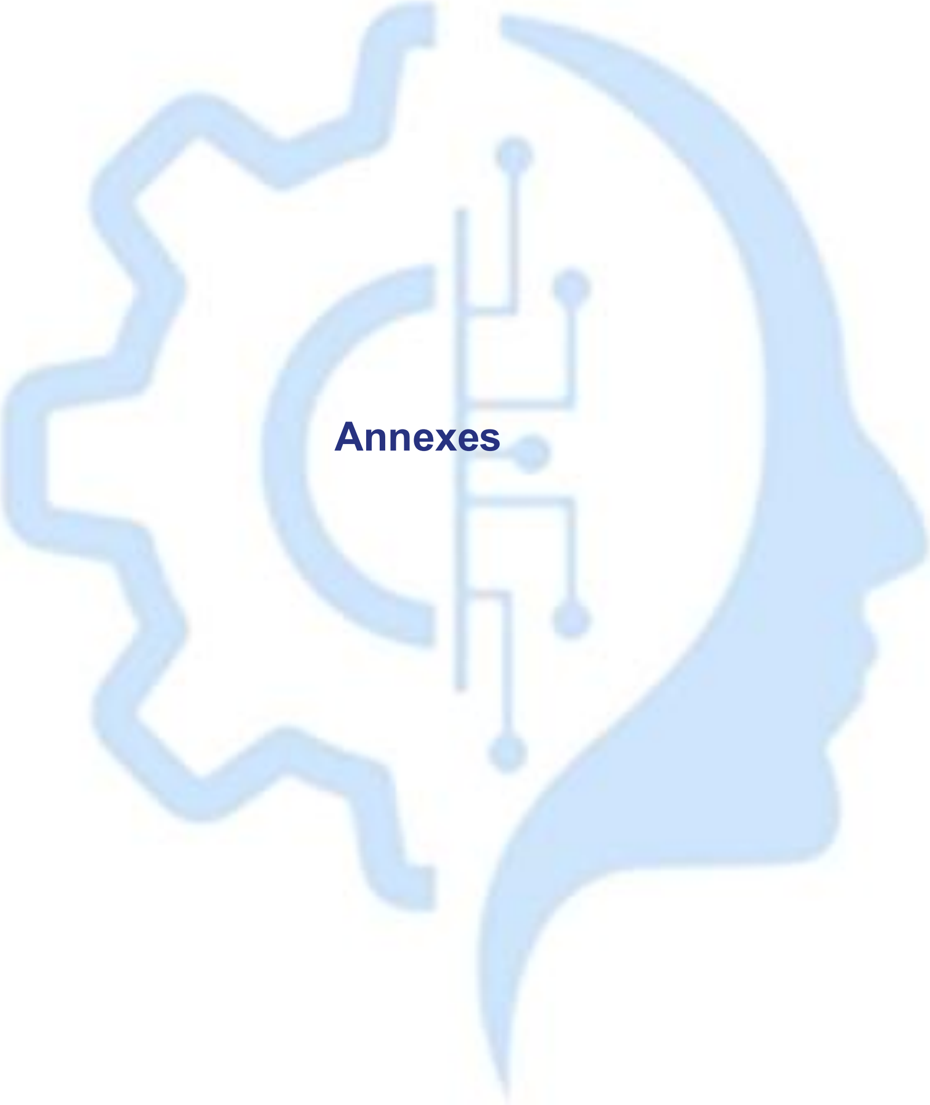
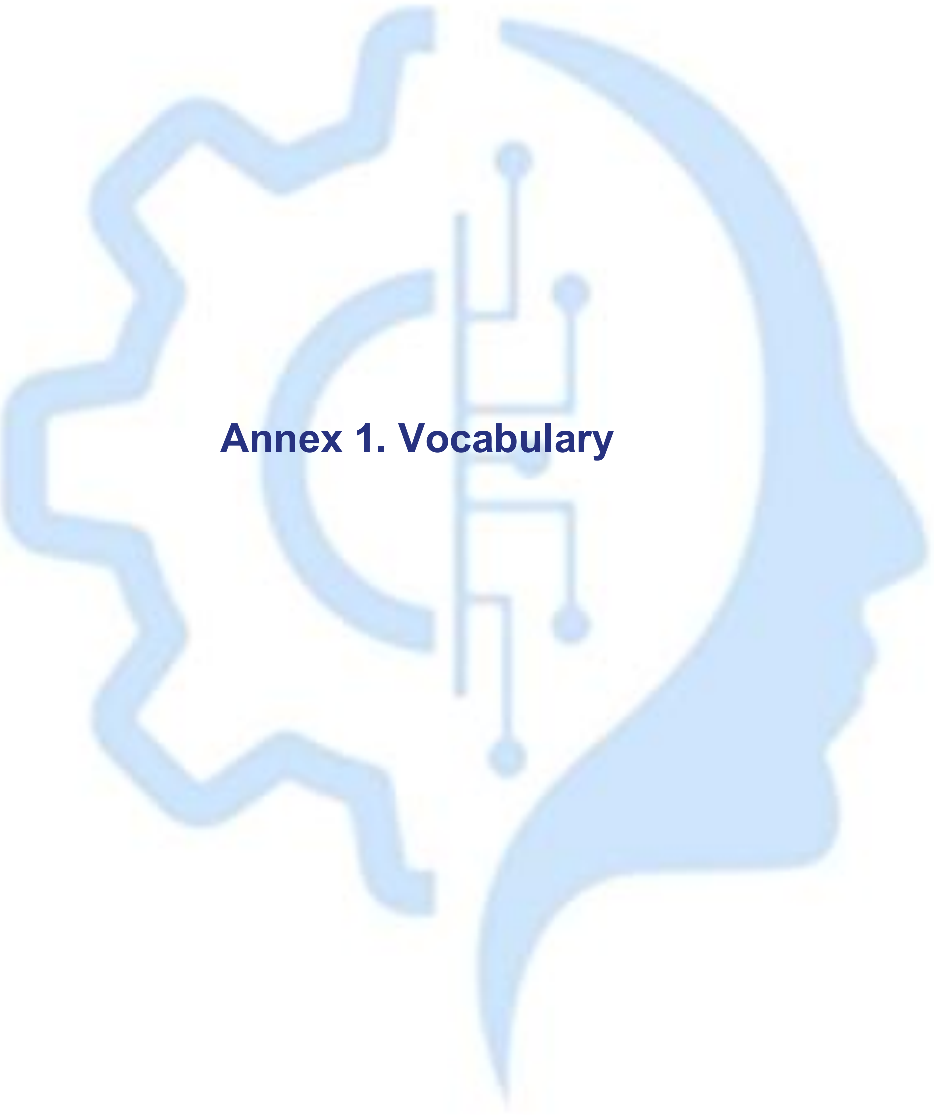


Annexes



Annex 1. Vocabulary

Accessibility (definition adapted from EN ISO 9241-210:2019): The degree to which a product, service, environment, facility, or system can be effectively used by the broadest possible range of people, considering diverse needs, abilities, and characteristics, so they can meet intended goals in their specific contexts of use. This context may involve direct interaction or the use of assistive technologies.

Anonymized data (definition adapted from EN ISO/IEC 29100:2020): Information that results from a process designed to remove personal identifiers, such that the output can no longer be linked to an identifiable individual.

Consent (adapted from EN ISO/IEC 29100:2020): A data subject's voluntary, informed, and specific decision to allow the processing of their personal information.

Digital twin (definition adapted from ISO/IEC 30173: 2023): A digital representation of a physical asset in which data connections keep the virtual and real states aligned at an appropriate synchronization rate. The digital twin may incorporate various capabilities, including connectivity, integration, analysis, simulation, visualization, optimization, and collaborative functions.

Digital twin (definition adapted from ISO 23247-1:2021): A digital model tailored for a specific use that mirrors an observable manufacturing component and stays synchronized with its real-world counterpart.

Digital twin system (definition adapted from ISO/IEC 30173:2023): A system that delivers digital twin capabilities through the interaction of physical entities, digital elements, data exchange mechanisms, models, and interfaces that support synchronized data operations.

Ergonomics / Human factors (definition adapted from EN ISO 9241 210:2019): A scientific and professional field that studies how people interact with other components of a system and applies this understanding to design solutions that improve well-being, safety, and overall system performance.

External workload / Work stress (definition adapted from EN ISO 6385:2016): The set of external demands and conditions in a work system that influence a person's physical or mental load.

Hazard (definition adapted from EN ISO 45001:2023): A source, situation, or condition with the potential to cause harm, including injury or ill health.

Human centered (**sin. Human centric**) **design** (definition adapted from EN ISO 9241-210:2019): A design approach that prioritizes how people use a system and applies principles from human factors and usability to enhance system usability and reduce risks. While emphasizing user needs, it also considers the impact on all stakeholders.

Human factors (definition adapted from ISO/IEC TR 24028:2020): A combination of environmental, organizational, and job-related influences, together with cognitive and human characteristics, that shape how individuals or organizations behave.

Injury and ill health (definition adapted from EN ISO 45001:2023): Any harmful effect on a person's physical, mental, or cognitive state, including occupational diseases, illnesses, and fatalities.

Interactive system (definition adapted from EN ISO 9241-210:2019): A configuration of people, hardware, software, and services that users interact with to accomplish defined objectives, including associated packaging, documentation, and assistance resources.

Manufacturing process (definition adapted from ISO 23247-1:2021): A set of activities within a manufacturing environment involving the transformation or movement of materials, data, energy, control signals, or other elements.

Occupational health and safety (OH&S) risk (definition adapted from EN ISO 45001:2023): The combination of the likelihood of work-related hazardous events or exposures and the potential severity of resulting injury or ill health.

Pseudonymization (definition adapted from EN ISO/IEC 29100:2020): A technique that substitutes identifiable personal information with a pseudonym or alias to reduce direct identifiability.

Personally identifiable information (PII) (definition adapted from EN ISO/IEC 29100:2020): Any information that either directly identifies or could potentially be linked to a natural person to whom personal information pertains.

Sensitive personally identifiable information (SPII) (definition adapted from EN ISO/IEC 29100:2020): Personal information considered sensitive because of its intimate nature or its potential significant impact on the individual. In some jurisdictions, this includes data about racial or ethnic origin, political or religious views, health, sexual life, or criminal history.

Strain / Internal load (definition adapted from EN ISO 6385:2016): An individual's internal reaction to external workload, influenced by personal characteristics such as age, body size, skills, or physical and cognitive capacities.

Usability (definition adapted from EN ISO 9241-210:2019): The extent to which a system, product, or service enables designated users to achieve intended goals effectively, efficiently, and satisfactorily within a defined context of use. The term also covers design expertise and methods that support the creation of usable systems.

User interface (definition adapted from EN ISO 9241-210:2019): All system components—hardware or software—that convey information to users and allow them to control the system to carry out tasks.

Well-being (definition adapted from EN ISO 6385:2016): A sustainable internal condition arising from the fulfillment of a worker's physical and cognitive needs, contributing to overall quality of work life.

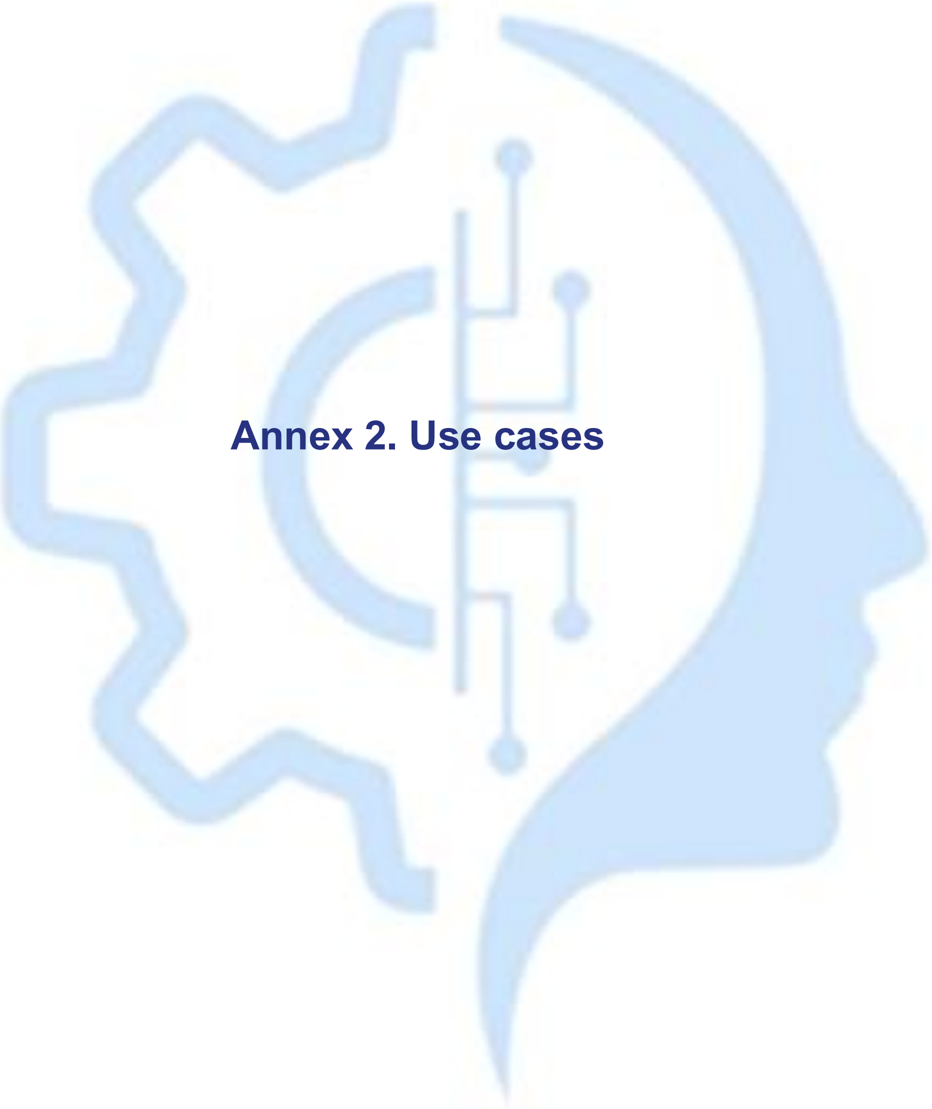
Work environment (definition adapted from EN ISO 6385:2016): The set of physical, chemical, biological, organizational, social, and cultural conditions surrounding a worker.

Work fatigue (definition adapted from EN ISO 6385:2016): A reversible, non-pathological decline in performance or capability due to work related strain, which may be physical, mental, local, or general.

Work process (definition adapted from EN ISO 6385:2016): The time and space-based sequence in which workers, equipment, materials, energy, and information interact within a work system.

Work system (definition adapted from EN ISO 6385:2016): A configuration of one or more workers and equipment operating together in a defined environment to accomplish a work task.

Worker / Operator (definition adapted from EN 16710-2:2025): A person who performs one or more activities within a work system to achieve specific objectives.



Annex 2. Use cases

Use Case No. 1: Advances of Digitalization on Interior Automotive Manufacturing

1. Organization Overview

ANTOLIN is a leading global supplier in the automotive industry, specializing in the design, development, and manufacturing of interior components for vehicles Headquartered in Burgos, Spain. The company has a substantial global footprint, operating in 25 countries and employing over 20,000 people. ANTOLIN's mission is to be a premier provider of technological solutions for car interiors, emphasizing innovation and sustainability. Their activities focus on creating integrated solutions that enhance the user experience, utilizing environmentally friendly practices and lightweight materials to reduce CO2 emissions. Through these efforts, ANTOLIN aims to shape the future of vehicle interiors and contribute to a more sustainable automotive industry.

2. Context and Problem Statement

Just to illustrate the DT implementation we can set an use case up from the doors manufacturing business unit, where for the sake of the clearness we focus only in two core steps. In sort, the first step is to produce the part, afterwards lamination and assembly.

1) ***Forming – Injection Moulding***
   Plastic granules are melted in an injection moulding machine. The molten plastic is injected into precision moulds to form the door parts. After cooling, the parts are ejected and trimmed.
2) ***Assembly – Lamination and Ultrasonic Welding***
   Some parts can be processed in lamination machines so as to add value to the part. At the end, all parts are joined using ultrasonic welding. High-frequency vibrations generate localized heat, melting and fusing the contact surfaces. The process ensures strong, accurate, and clean joints without adhesives or screws.

Broad Pain

The everyday objective in a factory is to reach optimal productivity in every manufacturing process. Despite the operator's knowledge and the technology deployed in along the machines, all the standard KPIs such as OEE or TRS always have place for improvement. Perhaps someone, in the digital era can dreams that by a fully digitalized (lights-off) plant all the problems can disappear, nonetheless, reality tell us that this is far away from the reality in complex industrial processes such as the ANTOLIN's ones. So, the question is: how digitalization technologies can support industrial processes to overcome every day's issues to improve the KPIs?

Cross Company Solution: Digital Twin 5.0

ANTOLIN has human centric digitalization strategy. The industrial knowledge of the company relies on the wide mass of operators and engineers across the company. Therefore, the faster way to improve the manufacturing processes is by providing accurate and useful information in real time to the experts in the factories. Operators and engineers know perfectly how to solve every issue (if they are aware of it). Thence, the overall solution to our pain is a hybrid solution between industrial processes digitalization and human intelligence cooperation for problems solving and KPIs processes improvement.

Below sketch illustrates the process of the use case with some visualizations available in the DT System of ANTOLIN.

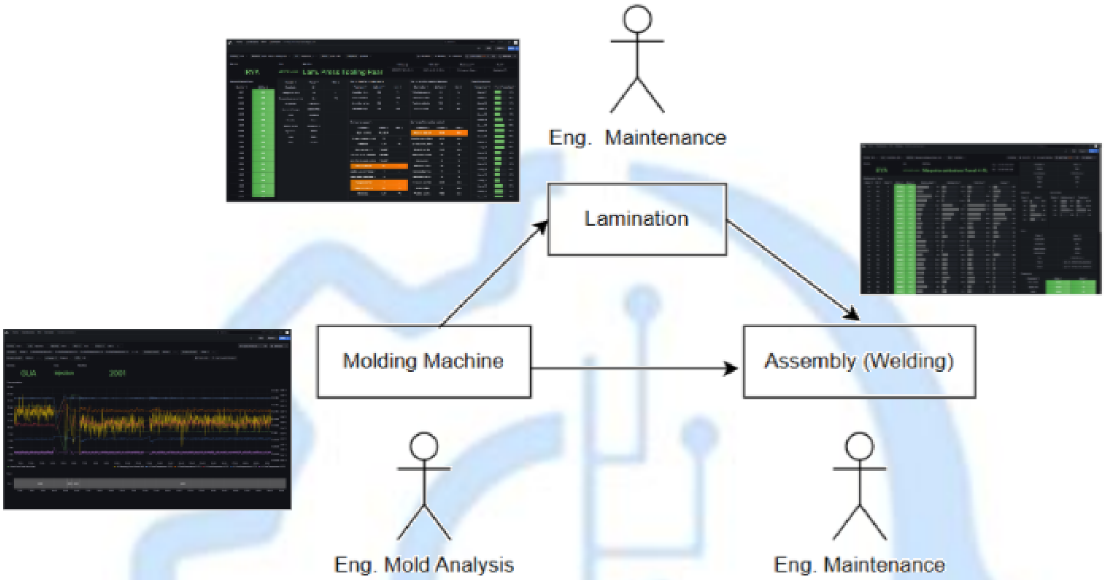


Figure 1. Process monitoring. Data is collected from all the machines involved in the manufacturing process and the most relevant information is projected in real time on the dashboards.

3. Digital Twin Solution Description

Digital Twin is the logical representation of physic assets. ANTOLIN is implementing the DT solution by means of several data components. Some of them on premise, in the factories and other ones on cloud. The first one is on hands of OT engineers whereas the second ones are managed by IT experts.

On the plants the key component is the Industrial EDGE. This artifact is responsible for data acquisition, and it is mainly used by OT engineers (the people who knows the industrial reality). On cloud there are several components for the Industrial Big Data implementation among them the highlighted are:

- Data **storage** services such as blobs or databases
- **Microservices** where ETLs are implemented
- **AI / analytics** tools where data mining explorations, KPIs implementations and MLOPS processes are implemented
- **Visualization** tools where information served in near to real-time.

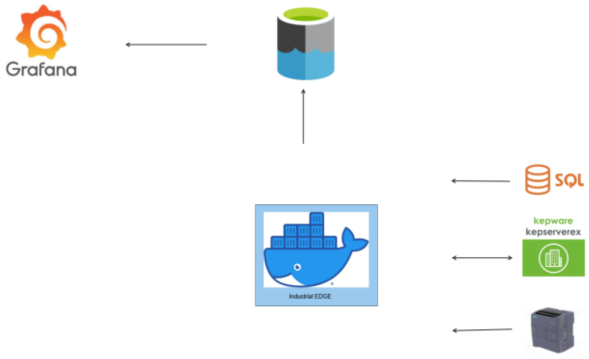


Figure 2 IIOT Data Flow.

Data is collected from several sources such as PLCs, MES, OPC and other. The Industrial EDGE is responsible of standardization and quality control. Once, data is well-formed, it is sent to cloud resources. On cloud repositories data is available for monitoring and analysis.

4. Benefits and Costs

Benefits:

- KPIs improvements by real time process monitoring, where the operator is aware of the state of the manufacturing process at any time.
- People engagement
- Process improvement

Costs:

- PLC machinery re-programming according to the standard of the company
- Industrial EDGE deployment (virtual machines or industrial PCs)
- Cloud resources: data storage and data processing
- Visualization tools
- Third IIOT providers.

5. Key Success Factors and Implementation Challenges

- **IT/OT integration:** everyone should lead its area of knowledge with no loss of understanding
- **Plant adoption:** usually plant pains are not related to digitalization processes, therefore this kind of technology is never a priority.
- **Impact:** It is very important to provide advances in the processes in a sort time, so as to catch the involvement of the plant in long terms.

6. Lessons Learned

We are at the beginning of the digital era in industry. Almost everything is pending to do.

7. Transferability and Scalability

The DT Strategy in ANTOLIN is in basis to standards and transversality, so as to apply the same solution across the five business units and more than one hundred manufacturing plants.

8. Contact Information

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Use Case No. 2: Virtual Reality and Human Simulation at General Motors

Based on the Siemens Tecnomatix blog post: "Virtual Reality and Human Simulation at GM"

1. Organization Overview

Company: General Motors (GM)

Sector: Automotive Manufacturing.

Size/Scope: One of the world's largest automotive companies, with global operations. The case focuses on their Global Manufacturing Engineering team.

Relevant Mission: To optimize manufacturing processes to improve efficiency, quality, and crucially, the safety and ergonomics of their workers on assembly lines.

2. Context and Problem Statement

Operational Context: GM, as an automotive manufacturer, faces the constant challenge of designing and optimizing complex assembly lines for new vehicle models. Traditionally, this involved creating costly and time-consuming physical mock-ups to validate processes and ergonomics.

Specific Challenge/Need:

- Reduce worker injuries on assembly lines.
- Improve the quality of the final product.
- Increase manufacturing productivity.
- Minimize costs and time associated with process development, avoiding expensive changes in late production stages.
- Identify and resolve design and ergonomic issues at an early stage, before physical implementation.

3. Digital Twin Solution Description

Implemented DT Solution: GM has implemented a "Digital Twin" solution that combines Virtual Reality (VR) with Human Simulation software (specifically, Process Simulate Human, part of Siemens' Tecnomatix suite). This combination creates a digital twin of the manufacturing process and the human worker interacting with it.

Technologies Used:

- ➢Virtual Reality (VR): For complete immersion in the virtual manufacturing environment, allowing engineers and workers to "experience" the assembly line.
- ➢Human Simulation Software (Process Simulate Human): Used to analyze the movements, postures, forces, and reach of workers in the virtual environment, evaluating ergonomics and task feasibility.
- ➢3D Models: Of vehicles, tools, components, and the plant environment.

Integration into Workflows: The solution allows engineering and manufacturing teams to validate and optimize assembly processes in a virtual environment. This is done before physical lines are built, enabling proactive identification and correction of design, efficiency, and ergonomic issues.

4. Benefits and Costs

Benefits Gained:

- Injury Reduction: Design of safer and more ergonomic processes for workers.
- Quality Improvement: Validation of processes to ensure the final product meets standards.
- Productivity Increase: Optimization of workflow and tasks.
- Cost Savings: By avoiding costly changes to the physical production line, the need for physical mock-ups, and rework.
- "Right the First Time" Design: Ability to design processes correctly from the outset.

Order of Magnitude of Costs: The blog post does not provide specific figures for incurred costs, but the mentioned benefits (injury reduction, quality improvement, productivity increase, savings from avoiding late changes) imply a significant return on investment.

5. Impact on Occupational Health and Safety (OHS)

Impact: The solution has a highly positive impact on occupational health and safety. In fact, one of the primary goals is injury reduction.

Improvements in Risk Prevention:

- Early identification of awkward or dangerous postures for workers.
- Analysis of repetitive movements and excessive forces.
- Detection of potential injury points (e.g., the blog mentions identifying potential shoulder injuries from overhead work).
- Proactive design of workstations and tasks that are inherently safer and more ergonomic.

Emergence of New Risks: The blog post does not mention the emergence of new risks because of implementing this technology.

6. Key Success Factors and Implementation Challenges

Key Success Factors:

- ➢Interdisciplinary Collaboration: Close collaboration between manufacturing engineers, safety experts, and production personnel is fundamental.
- ➢Commitment to Innovation: GM's willingness to adopt advanced technologies like VR and human simulation to transform its design processes.
- ➢Visualization and Analysis Capability: The combination of VR immersion with the analytical capability of human simulation allows for deep understanding and problem-solving.
- Difficulties Encountered: In general, adopting new technologies can involve challenges such as staff training, data integration, and adapting to new workflows.

7. Lessons Learned

- Early Validation is Key: The ability to validate and optimize processes in a virtual environment before physical manufacturing is crucial for achieving "right the first time" design and avoiding costly errors.
- The Power of Hybrid Simulation: Combining the immersion of Virtual Reality with the detailed analysis of human simulation offers a very powerful tool for ergonomic and process optimization.
- Engage Stakeholders: Allowing engineers and workers themselves to experience the process in VR improves problem identification and acceptance of solutions.
- Reduced Reliance on Physical Mock-ups: Virtual tools can replace or significantly reduce the need for physical mock-ups, saving time and resources.

8. Transferability and Scalability

Replication Potential: Very high. The principles of using VR and human simulation for ergonomic and process optimization are applicable in any industry involving:

- Manual assembly or operational tasks.
- Human-robot interaction.
- Workstation design.
- Need to improve safety, quality, and productivity in manufacturing.
- Examples from other sectors: aerospace, heavy machinery, consumer goods, electronics, etc.
- Prerequisites/Adaptations:
- Availability of accurate 3D CAD models of products and manufacturing environments.
- Personnel trained in the use of simulation software and VR.
- Hardware infrastructure for VR (headsets, workstations).
- Adaptation would involve configuring simulation scenarios for the specific products and processes of each context.

9. References and Supporting Materials

The Siemens Tecnomatix blog post: "Virtual Reality and Human Simulation at GM" (previously provided link: Virtual reality and human simulation at GM - Tecnomatix).

10. Contact Information

Siemens Digital Industries Software

Mike Rouman

Senior Marketing Manager in the Digital Manufacturing business segment at Siemens Digital Industries Software.

https://www.siemens.com/en-us/

11. Visuals and Illustrations

The original blog post (to which reference is made) would contain images or videos illustrating the virtual reality environment, digital human representations, and Process Simulate Human interfaces. To view these illustrations, it would be necessary to visit the blog link.

Use Case No. 3: Optimization tool based on virtual environment scenarios

1. Organization Overview

TECNALIA is the largest applied research and technological development centre in Spain, a European benchmark and member of the Basque Research and Technology Alliance. One of TECNALIA's research areas focuses on the Digital Twin (DT) concept, developing methodologies for DT design and implementation as well as creating virtual environments aimed at improving industrial efficiency. These environments support tasks such as resource optimization and production scheduling.

2. Context and Problem Statement

The use case presented is part of the FABRICARE project, a nationally funded programme for research centres in which TECNALIA achieved recognition for Excellence in Advanced Manufacturing. This use case focuses on the virtual-environment component of a Digital Twin (DT) designed to improve optimization and scheduling performance in industrial processes.
It addresses the production of assembled references resulting from a combination of injection and machining processes, as shown in the figure, where all resources, injection machines, machine tools, and AGVs, are variable.

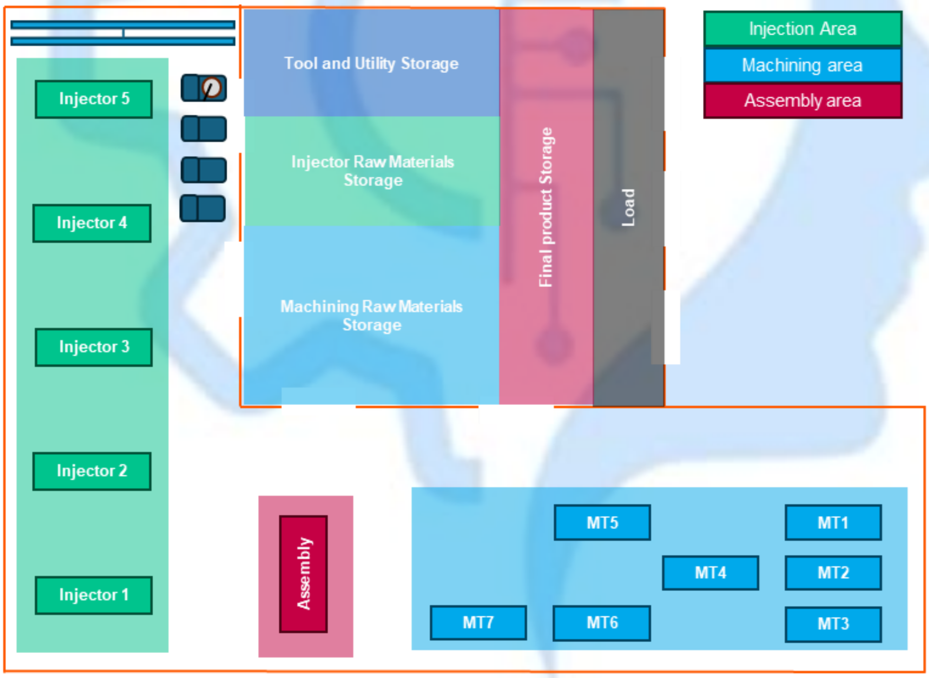


Figure 1. Use case process

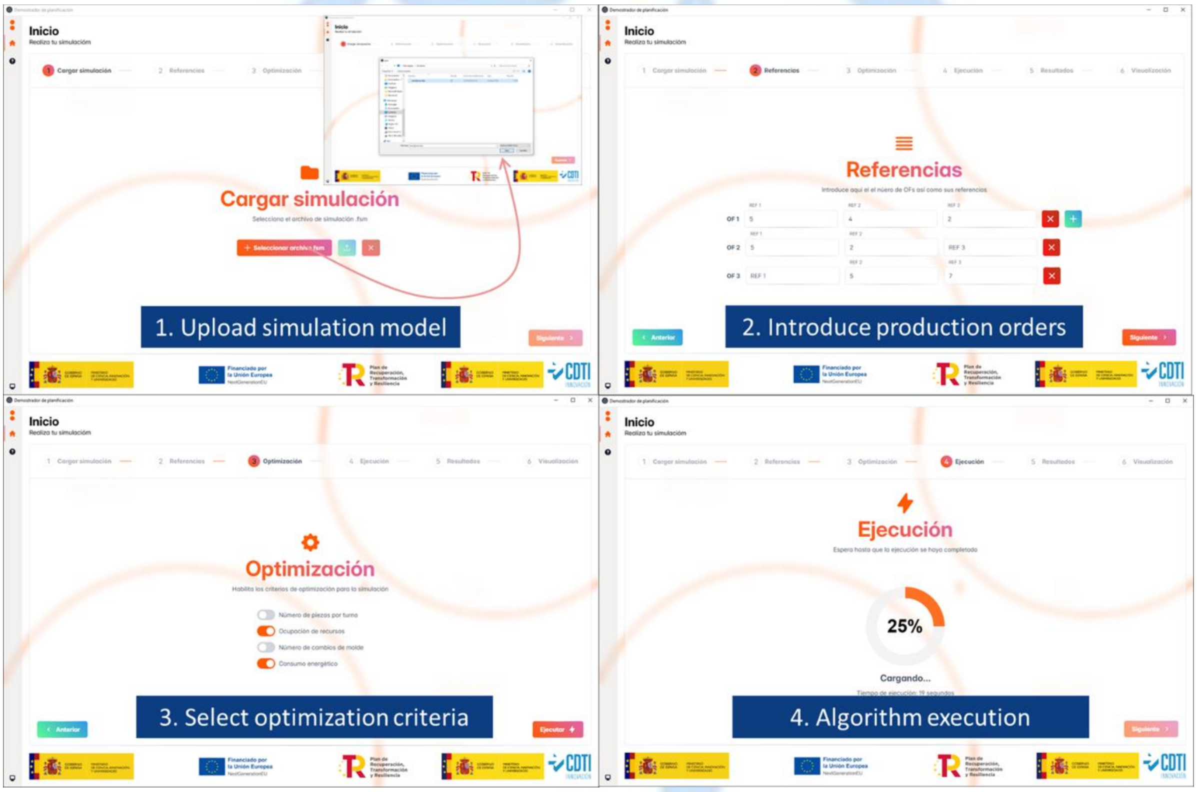
The main challenge lies in the difficulty of defining virtual environments that accurately reflect real-world complexity, which is essential for developing optimization and scheduling tools capable of solving complex scenarios rather than simplified ones.

- With this in mind, the complexity of this use case can be characterized by the following parameters:
- Variability of references, both in quantity and type.
- Variability of machines, in terms of number and capabilities.

- Variability and flexibility of resources, including AGVs, AMRs, and operators.
- Mold and tooling changes.
- Warehouse layout constraints.
- Demand variability.
- Quality inspections and rework.

3. Digital Twin Solution Description

Considering the five dimensions of the Digital Twin (DT) presented in the Guideline, this solution is framed within the virtual-environment dimension, simulating the process described in Section 2 using FlexSim (simulation software) and connecting it with an optimization algorithm developed in Python. Together, these components form a desktop application for optimizing complex processes, which operates as follows:



1. Upload simulation model

2. Introduce production orders

3. Select optimization criteria

4. Algorithm execution

Introduce aquí el núero de OFs así como sus referencias

	REF 1	REF 2	REF 3
OF 1	5	4	2
OF 2	5	2	REF 3
OF 3	REF 1	5	7

Habilita los criterios de optimización para la simulación

○ Número de piezas por turno
● Ocupación de recursos
○ Número de cambios de molde
● Consumo energético

Espera hasta que la ejecución se haya completado

25%

Cargando...

Tiempo de ejecución: 19 segundos

Figure 2. Optimization tool interface

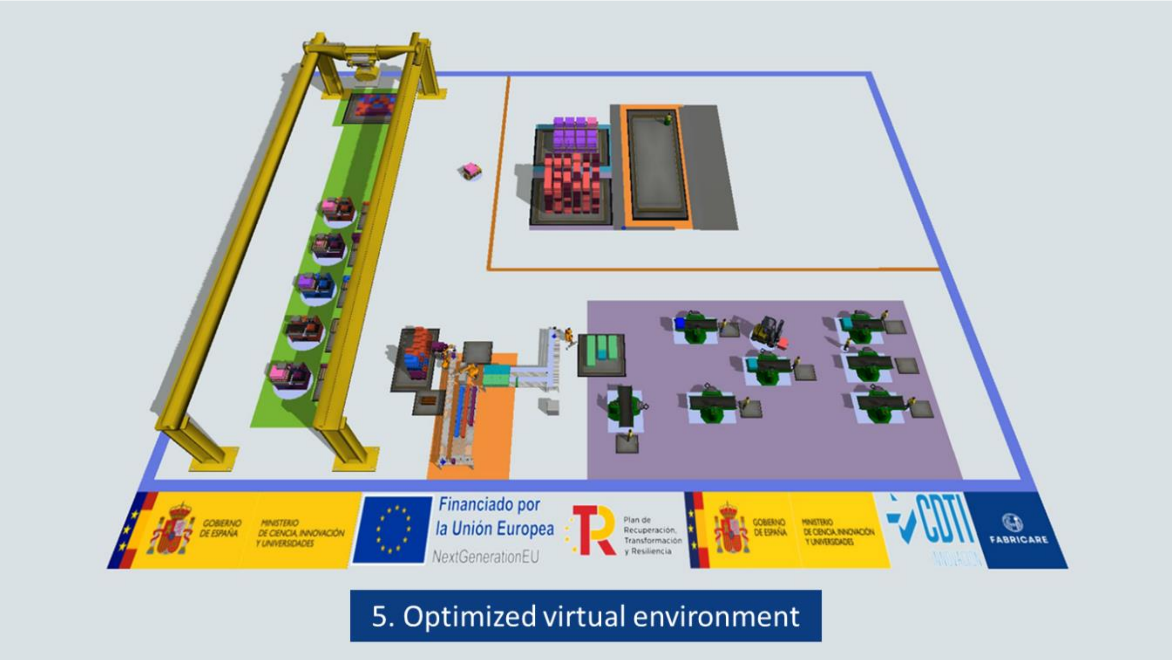


Figure 36. Optimized virtual environment FlexSim

4. Benefits and Costs

Because this is a research project and the use case does not correspond to a real industrial environment, it is not possible to provide a quantitative assessment of the solution's benefits. However, it is considered that this type of solution can significantly enhance process efficiency and reduce costs, as the number of resources required for proper project execution is optimized.

5. Impact on Occupational Health and Safety (OHS)

Although it does not have direct positive impacts on OSH, the developed solution enables non-experts to use optimization algorithms. This can help reduce risk factors such as stress associated with adopting new technologies and resistance to change.

6. Key Success Factors and Implementation Challenges

For real implementations, it is essential to involve end users throughout the design and implementation phases to ensure proper and effective use of the application.

7. Lessons Learned

It is important to begin with a thorough and detailed description of the production process before starting the virtualization phase.
Involving users throughout the entire process is also crucial to ensure the usability and acceptance of the application.

8. Transferability and Scalability

This project is transferable and scalable to any context or sector, provided that the new process can be modelled in FlexSim.

9. References and Supporting Materials

More information about FABRICARE project:

- Aznar Lapuente, G., Morella Avinzano, P., del Agua, J., Borro, D., González, A., García García, R., & Lambán, M. P. (2025). Simplified five-dimensional modelling for the conception of digital twins: a use case for battery decommissioning process. In 11th Manufacturing Engineering Society International Conference (MESIC 2025), Bilbao, Spain.
- https://www.tecnalia.com/proyectos/fabricacion-colaborativa-robotica-gemelos-digitales-fabricare

10. Contact Information

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11. Acknowledgment and disclaimer

FABRICARE

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Use Case No. 4: Real-time Optimization of vertical cement mill

1. Organization Overview

Founded in 2009, OPTIMITIVE is a software company dedicated to enhancing industrial efficiency and sustainability through Closed-Loop AI Optimization.

The company helps industrial organizations reduce energy consumption, improve production profitability, and meet regulatory and emissions-reduction targets. With a presence across seven major global regions, OPTIMITIVE operates in a wide variety of sectors, including cement, oil & gas, chemicals, power generation, pulp & paper, mining, glass, metals, and water treatment. Its technologies currently optimize more than 65 industrial facilities across diverse processes.

OPTIMITIVE is deeply committed to the global transformation of industrial operations, leveraging Artificial Intelligence to make processes more efficient and more sustainable—ultimately contributing to a better world.

The company envisions a future in which every complex industrial asset is complemented by an “Optimizer Brain”: a system capable of ensuring operational efficiency under any circumstances. In this future, Real-Time AI-Driven Optimization will be a key enabler of industrial excellence worldwide.

2. Context and Problem Statement

This use case is based on the needs of an international cement group which operates in several countries. The vertical raw mill is the first component in the cement production chain and is responsible for grinding and drying the raw material before being fed into the kiln. The vertical raw mill is the equipment used to crush and grind the raw material into small particles. The raw meal is fed onto a rotating table and crushed by the vertical pressure applied by the rollers. The small particles exit under the action of the current flow produced by an air exhauster fan. These particles go through a separator device which acts as a filter. The filtered particles are stored in silos ready to be fed into the kiln. The main energy consumption is caused by the motor of the rotating table.

Maximising the vertical raw mill throughput is targeted without compromising the quality of the final product and ensuring that the power limits of the different components are not exceeded. Vibrations must be kept within range and the operation maintained stable without interruptions.

3. Digital Twin Solution Description

OPTIMITIVE has developed a real-time optimization AI solution capable of collecting information from control systems, called OPTIBAT RTO (Real-Time Optimization). OPTIBAT enables the following:

- Use Artificial Intelligence to improve industrial processes
- Recommend optimal setpoints in real time
- Assist operators in open-loop mode and operate in closed-loop mode with autopilot
- Dynamically optimize KPIs while keeping constraints within their limits
- Be suitable for any type of equipment or process, regardless of the manufacturer
- Operate 24/7, 365 days a year—ideal for continuous processes

- Continuously improve through adaptation

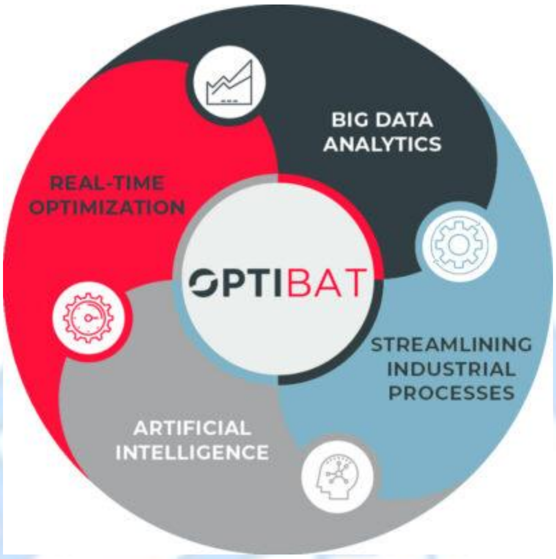

Figure 1. OPTIBAT® Solution

Regarding this use case, the OPTIBAT® Real-Time Optimization (RTO) installed in plant considerably increased production rates and improved system runnability, while maintaining product quality and operation standards. OPTIBAT® RTO is connected to the existing control system, continuously learning from plant operation data, and recommending in closed loop the optimum set points for the following operative variables:

- Product feed (variable to maximise)
- Separator speed
- Inlet temperature
- Water spray
- Grinding pressure
- Differential pressure

Constraints are strictly respected, including vibrations of the mill, thickness of grinding layer, quality of the final product, operating limits of the mill, production rates and process stability.

4. Benefits and Costs

Particularly in this use case, the results show a throughput increment of 6% plus a specific energy consumption reduction of 2%. Additionally, the stability of the mill improved by decreasing vibrations level around 6%.

In general, by integrating advanced real-time optimization technologies, the benefits show:

- Significant reductions in energy consumption, directly lowering operating costs and contributing to more sustainable production.
- Increases in production throughput, enabling higher output without compromising product quality or process stability.
- Substantial cost savings, derived from greater efficiency, reduced variability, and optimized use of existing assets.

- Thousands of tons of CO_2 emissions avoided every year per optimized asset, supporting compliance with environmental regulations and helping organizations advance their decarbonization strategies.

5. Impact on Occupational Health and Safety (OHS)

Operator stress due to the need of responding to instabilities of the process or excessive level of vibrations, was significantly reduced, since the optimizer takes care of maintaining operation stable and within operational limits.

6. Key Success Factors and Implementation Challenges

Run Factor above 70%. Run Factor is the % of time that the optimizer was working with respect to the time the Mill was operating. Energy Savings and Throughput increase above 1% were required.

7. Lessons Learned

Vibrations is a key stability factor in this kind of asset.

Autonomous operation is needed to get the acceptance of operators and plant staff.

8. Transferability and Scalability

This solution is transferable to Finishing Mills in cement production, and also to Mills in Mining.

9. Contact Information

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Optimitive - OPTIMITIVE

10. Visuals and Illustrations

Figure 1. Vertical Cement Mill

Use Case No. 5: Towards safer and more sustainable graphene oxide manufacturing

1. Organization Overview

Founded in 2004, AVANZARE provides its customers with advanced, high-performance materials. AVANZARE's headquarters are located in the village of Navarrete, La Rioja (Spain). Our capabilities and 50.000 m^2 of full equipment production plants allow us to act in a wide range of possibilities, allowing us to have flexibility in dealing with our clients.

AVANZARE specializes in the development, production and commercialization of functional advanced materials for different applications, mainly plastics, rubber, and resin with international presence across different industries: automotive, aeronautics, safety equipment, footwear, painting, building, wire and cable sector, fabrics, packaging and paper, and more. The company possesses a robust capability in functionalities such as antistatic performance, electrical conductivity, thermal dissipation, flame retardancy and fire resistance, antibacterial properties, and hydrophobic behavior.

AVANZARE has extensive industrial expertise in the research and production of 2D nanomaterials and specializes in the production of different bulk graphene and graphene nanoplatelets grades for industrial purposes.

2. Context and Problem Statement

The dry graphene oxide (GO) manufactured by AVANZARE is refined and packaged using a four-stage semi-automatic process, carried out by an operator inside a front-extraction filtration cabin (Figure 1). The process includes grinding and vibratory sieving stages, to homogenize the particle size before packaging.

Figure 1. Filtration cabin in the manufacturing room, with the operator performing GO refining and packaging tasks inside.

GO is a black, 2D nanomaterial produced through the oxidation and exfoliation of graphite, characterized by micro- to nanoscale particles exhibiting a laminar morphology composed of one nanometer-thick layers. Due to the powdery characteristics of this nanomaterial, its handling during the refining/packaging process generates significant emissions of GO particles into the air, which can pose a health risk to workers if not properly controlled.

The filtration cabin represents the primary engineering measure for controlling occupational exposure in the process. The intake air enters the cabin from the manufacturing room through the open front section of the cabin, is driven by a 40 kW centrifugal fan to remove GO particles emitted by the process, then is filtered in two stages (cartridges + package) and finally returns to the manufacturing area again. This protective measure is complemented by the operator's use of appropriate PPEs.

In this context, AVANZARE's main need was to improve the dry GO refining/packaging process in order to prevent and control the risk of occupational exposure to inhaled GO, ensuring the safety, sustainability and competitiveness of the manufacturing process itself.

3. Digital Twin Solution Description

The European project SUNSHINE investigated the potential of DT technology to respond to the needs identified by AVANZARE, with the following specific objectives: 1) Online monitoring of GO particle emissions, 2) Real-time prediction and alert of occupational exposure risk, 3) Optimization of process energy consumption, and 4) Reduction of filter cleaning frequency. The DT pilot solution (TRL 5-6) was developed by TECNALIA and tested and validated jointly with AVANZARE at its manufacturing facilities.

DT architecture was structured into four domains, according to the reference model established by the ISO 23247 series of standards (Figure 2). The first domain represents the physical world (the manufacturing process and its elements), which connects and synchronizes with the virtual world (third domain) through the communications layer (second domain). The fourth domain is a services layer where the user can find information. Figure 2 and Table 1 specify these four domains and provide the general architecture of the DT.

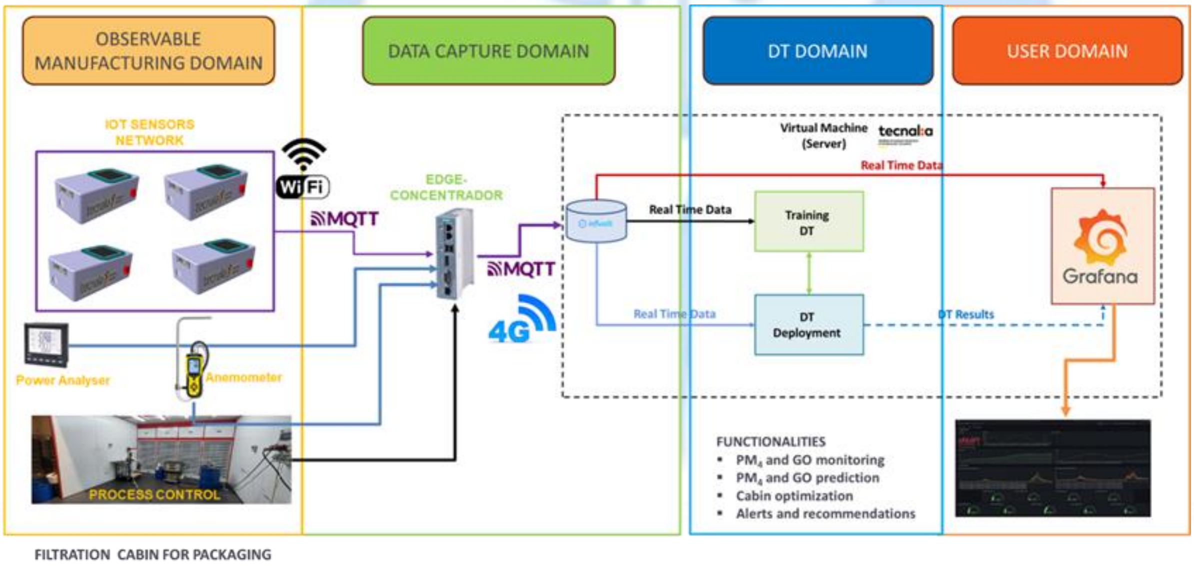

Figure 2. Building blocks and deployed architecture in AVANZARE according to ISO 23247 series.

Table 1. Architecture of the four-domain digital twin (ISO 23247) deployed in AVANZARE.

LAYER - DOMAIN (ISO 23247)	PROPOSED ARCHITECTURE FOR AVANZARE'S DIGITAL TWIN
LAYER 4 - DIGITAL TWIN USER DOMAIN	This domain is also deployed on the TECNALIA server and is accessible from anywhere within AVANZARE, via an access URL with different credential levels. The services offered by this domain are: 1) Real-time monitoring of parameters measured by sensors and process parameters of the cabin and indicators (Graphana); 2) Predictive alerts to prevent or reduce the risk of occupational inhalation exposure; 3) Optimization recommendations to modify the cabin ventilation speed and the frequency of filter cleaning (Figure 3).
LAYER 3 - DIGITAL TWIN DOMAIN	The purpose of the DT domain is to generate three results: 1) Real-time monitoring and 2) Prediction of particle concentration in the work environment, to reduce operator exposure, and 3) Optimization of the filtration cabin's energy consumption by controlling the extraction fan speed. This domain is responsible for the overall operation and management of the DT, including monitoring, digital modelling, prediction, and optimization management. The domain has two clearly differentiated operating environments (Virtual machine deployed on the TECNALIA server): one dedicated to training and generating models from historical data (Development) and another focused on the real-time execution of predictions and optimization suggestions (Production).
LAYER 2 - DATA COLLECTION AND DEVICE CONTROL DOMAIN	This domain consists of two main elements: 1) the Edge Concentrator, the computer responsible for capturing machine-level data and synchronizing it for transmission to the server database, and 2) the server hosting the database (InfluxDB) that aggregates each capture with its timestamp.
LAYER 1 – OBSERVABLE MANUFACTURING DOMAIN	This domain encompasses an industrial dry GO refining/packaging process carried out inside a filtration cabin. The elements monitored in the process are: 1) the concentration of particles (particle sensors), in order to reduce emissions and the occupational risk of inhalation exposure for operators; 2) the air velocity in the cabin filters (air velocity sensors), to improve system control; and 3) the energy consumption of the cabin (power analyser), to optimize the exhaust fan speed and activate/deactivate filter cleaning, and 4) the operating regime of the extraction cabin fan (process bus).

The DT-embedded models generated highly accurate and reliable results, underscoring the viability of this approach for real-time environmental monitoring and control. These results not only validate the performance of the developed DT but also confirm the feasibility of the optimized system to achieve an effective balance between operational efficiency and environmental and occupational safety.

Figure 3. User-Domain Mock-Up

4. Benefits and Costs

The pilot deployment of DT technology in AVANZARE has delivered the following technical and operational benefits:

- Real-time monitoring and prediction of airborne emissions and occupational inhalation exposures to GO
- Prevention and early warning of manufacturing events that could lead to occupational exposure above regulatory limit values
- Reduction of process energy consumption by automatically adjusting the extraction fan speed and cleaning cycles to the specific operational needs
- Prevention of potential operator health impacts and associated costs
- Support for regulatory compliance assurance
- Overall, a more robust, safer, sustainable, and competitively optimized manufacturing process.

The table below summarizes the main cost categories associated with the deployment and operation of the DT in the manufacturing process.

Initial Costs	Future operating costs
▪ IoT sensors and associated hardware ▪ Predictive and optimization digital models ▪ Cloud resources: simulation, data analytics, and visualization ▪ Integration with existing manufacturing systems ▪ Initial staff training	▪ Maintenance and replacement of IoT sensors ▪ Updating and maintaining the digital twin model ▪ Maintenance of software licenses and cloud service subscriptions ▪ Ongoing staff training

5. Impact on Occupational Health and Safety (OHS)

The principal OHS-related benefits—partially addressed earlier in Section 4—can be summarized as:

- Real-time hazard prediction and exposure modelling
- Early-warning of process deviations with OEL exceedance potential
- Digital traceability for regulatory compliance assurance
- Reduction of operator health risks through minimized exposure to hazardous environments and better control of emission sources.
- Lower HSE-related costs enabled by predictive analytics and fewer incident-derived losses.

Deploying a digital solution within an operator-involved manufacturing process may introduce potential adverse OHS impacts that require proactive prevention and/or mitigation. The following table summarizes these impacts along with preventive and mitigating actions that should be considered for any future commercial-scale implementation of DT in the plant.

Potential adverse OHS Impact		Recommended Prevention / Mitigation measures
1. OT/IT cybersecurity	Manipulation of process variables, data streams, or control logic with potential impact on the H&S of operators	- OT/IT network segmentation and industrial grade asset hardening (e.g. IEC 62443). - Robust access control (RBAC/MFA) and continuous security monitoring with anomaly detection.
2. Data privacy and ethical	Collection, processing or traceability of operator related personal/sensitive data; risk of undesirable surveillance.	- Privacy-by-Design implementation with data minimization and anonymization/pseudonymization. - Strict access governance and compliance with data protection frameworks (e.g. ISO 27701, GDPR).
3. Model related error	Incorrect predictions, drift, lack of calibration, algorithmic bias or misleading safety indicators.	- Formal verification & validation, periodic model re-calibration using real production data. - Systematic model performance audits and mandatory human supervision for safety critical decisions.
4. Operational complexity and cognitive overload	Increase in data density, alarms, dashboards and decision layers, elevating the risk of human error.	- Cognitive ergonomics driven design of HMI, reduction of non-essential information layers and alarm management strategy to prevent alarm fatigue (e.g. ISO 9241 series, ISO 6385, IEC 62682)
5. Operational skill degradation and DT over-reliance	Decay of manual diagnostic capability and excessive dependence on automated guidance.	- Continuous operator training using scenario-based simulations and non-DT manual diagnostic drills - Defined fallback operating procedures and operational resilience measures

6. Key Success Factors and Implementation Challenges

Among the key success factors in the implementation of the DT demonstrator (TRL 5-6), the following can be highlighted:

- Strategic leadership and commitment from AVANZARE's top management
- Adequate data infrastructure and high-quality data, supported by a technically feasible and reliable integration with the manufacturing process
- Internal capabilities and multidisciplinary collaboration
- Culture of innovation and adaptability to change
- High technical competence of the solution provider
- Progressive implementation of DT, starting with a pilot and scaling up the digital solution
- Adequate allocation of budget and resources (EC funding)

Furthermore, some of the challenges that have been identified to advance in the implementation of a definitive digital twin in the AVANZARE refining/packaging process are:

- Cybersecurity and IP protection risks
- Data-privacy, ethical and human-centric design constraints
- Operational complexity and cognitive overload
- Continuous digital training and workforce upskilling
- Need for sufficient funding to support implementation costs

7. Lessons Learned

Some lessons learned from the pilot deployment of the DT at AVANZARE include:

1. **Ensuring the quality, availability, and traceability of process data**. Data quality, stability, and reliability are critical; without robust data, a DT cannot be built or operated with confidence.
2. **Adopting a progressive DT implementation strategy based on pilot deployment and controlled scaling**. Pilot phases enable model validation, system integration, and risk reduction before extending the DT across the full manufacturing process.
3. **Considering integration and interoperability between the DT and the manufacturing process from the design stage**. An integration-oriented design allows the definition of clear functional interfaces and synchronization mechanisms, ensuring consistent and stable interaction between the DT and the physical process.
4. **Establishing multidisciplinary development teams** with hybrid technical competencies, built from internal resources and complemented by specialized external consultants. Such cross-domain expertise enables coherent DT design, reliable implementation and sustained operational performance of the digital twin
5. **Embedding regulatory and compliance requirements into the DT design**. Incorporating regulatory constraints - such as safety requirements in our case - from the design stage, ensures that the DT complies with industrial regulations without requiring later redesign.

8. Transferability and Scalability

The adoption of a progressive DT implementation strategy—based on pilot deployment followed by controlled scaling—provides a consistent approach for extending the developed DT solution to the GO manufacturing process as a whole.

Parametric DT calibration based on formulation recipes, has been identified as an approach for transferring the initially validated DT solution to other graphene-family products also manufactured by AVANZARE, thereby facilitating its implementation and minimizing associated costs.

In summary, DT technology provides a promising framework for achieving safer and more sustainable graphene-based material manufacturing processes.

9. References and Supporting Materials

The ISO 23247 series of standards on *Automation systems and integration - Digital twin framework for manufacturing* has been used as a reference for the design of the DT's high-level architecture.

10. Contact Information

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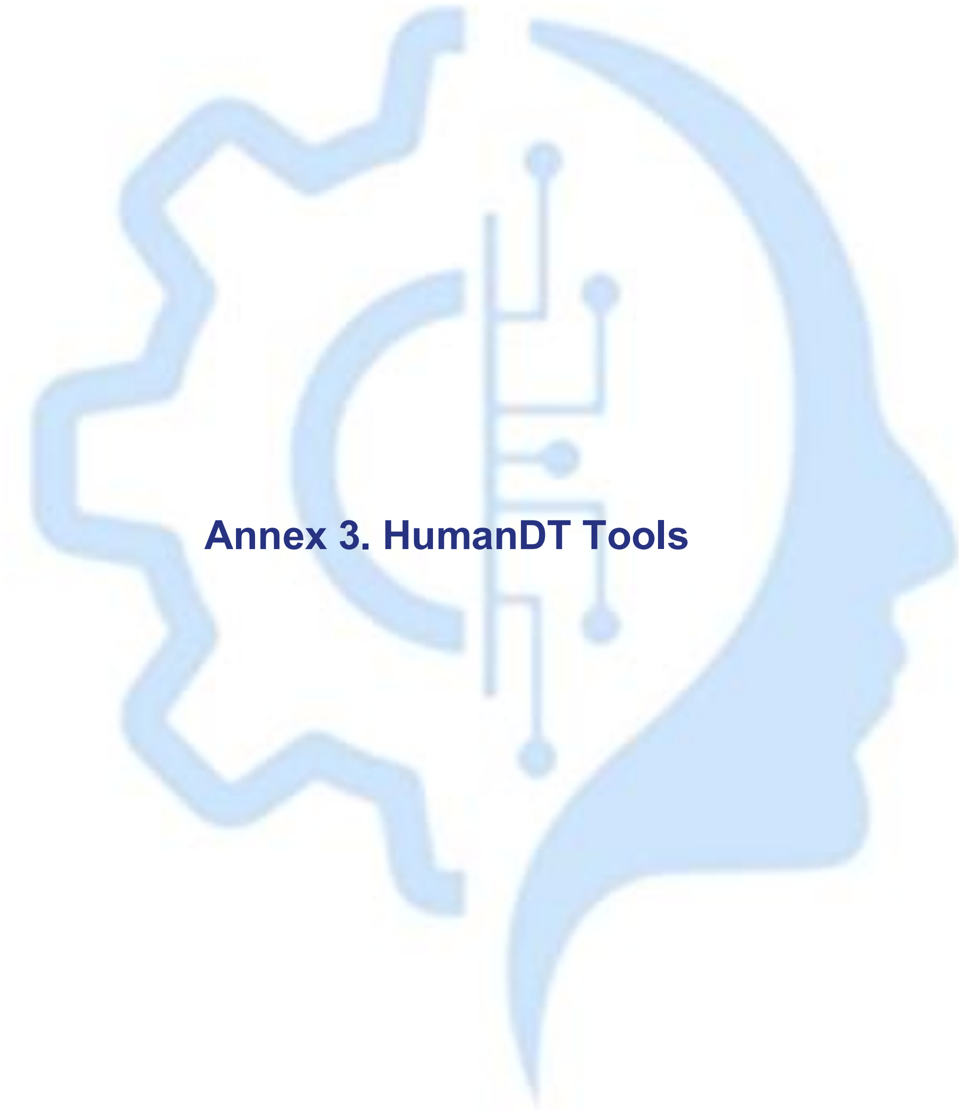


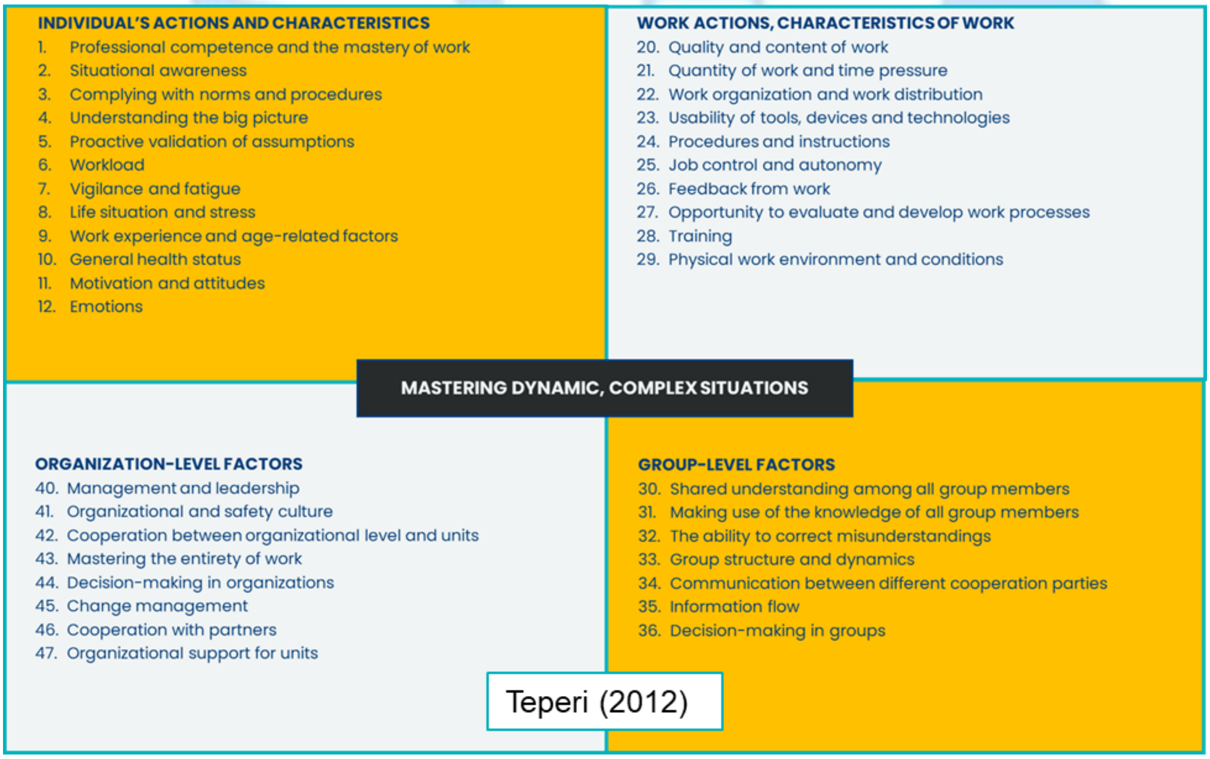
Annex 3. HumanDT Tools

1. HF Tool

The HF Tool developed by Prof. Anna-Maria Teperi aims to help practitioners recognize how human factors shape day-to-day work and overall system safety. Its core purpose is to support designers, engineers, and safety specialists in identifying how people interact with their tasks and organizational context, so that these aspects can be intentionally incorporated into system development. By doing so, the tool enables the early detection of human-factor-related vulnerabilities and reinforces safe and dependable operational conditions. It offers a clear method for interpreting how these elements influence real operational performance and where potential weaknesses or strengths may appear.

The HF Tool is typically applied at early project stages to inform human-centric design decisions by ensuring that system functions are aligned with human abilities and operational realities. It can be used in collaborative sessions—such as interviews, workshops, or multidisciplinary reviews—to capture the knowledge of frontline workers, reveal differences between planned and actual work practices, and identify human-factor risks before system deployment. When applied to the development of human-centric digital twins, the tool helps ensure that models and simulations accurately reflect real working conditions, ultimately improving usability, safety, and system robustness.

The operational procedure of the HF Tool has already been detailed in Section 2 of this Guideline (see page 39).



INDIVIDUAL'S ACTIONS AND CHARACTERISTICS

1. Professional competence and the mastery of work
2. Situational awareness
3. Complying with norms and procedures
4. Understanding the big picture
5. Proactive validation of assumptions
6. Workload
7. Vigilance and fatigue
8. Life situation and stress
9. Work experience and age-related factors
10. General health status
11. Motivation and attitudes
12. Emotions

WORK ACTIONS, CHARACTERISTICS OF WORK

20. Quality and content of work
21. Quantity of work and time pressure
22. Work organization and work distribution
23. Usability of tools, devices and technologies
24. Procedures and instructions
25. Job control and autonomy
26. Feedback from work
27. Opportunity to evaluate and develop work processes
28. Training
29. Physical work environment and conditions

MASTERING DYNAMIC, COMPLEX SITUATIONS

ORGANIZATION-LEVEL FACTORS

40. Management and leadership
41. Organizational and safety culture
42. Cooperation between organizational level and units
43. Mastering the entirety of work
44. Decision-making in organizations
45. Change management
46. Cooperation with partners
47. Organizational support for units

GROUP-LEVEL FACTORS

30. Shared understanding among all group members
31. Making use of the knowledge of all group members
32. The ability to correct misunderstandings
33. Group structure and dynamics
34. Communication between different cooperation parties
35. Information flow
36. Decision-making in groups

Teperi (2012)

Figure 1. HF Tool

2. HF Checklist

HF CHECKLIST								
Nº		**ITEM**	**SPECIFICATION**	**ASSERTIONS**	**APP.**	**IRL**	**MEASUREMENTS**	**FRL**
1. INDIVIDUAL LEVEL	1	Professional competence and the mastery of work	The knowledge, skills, and expertise required in a given job	The DT challenge users' skills, knowledge or capabilities	Y/N			
	2	Situational awareness	On-going process of perceiving, understanding, and projecting what is happening in the individual's work environment (attention, observation, memory, decision-making, and action).	The DT challenges users' attention and memory. The DT challenges users' sustaining an up-to-date understanding of what is happening in the work environment.				
	3	Complying with norms and procedures	Norms can be official instructions, such as written work guidelines, safety regulations, or industry-specific standards, or they can be unofficial practices developed within the work community.	The DT contradicts with norms and procedures mandated from user. The DT contradicts with established practices in the user's work community.				
	4	Understanding the big picture	Having a view of the system or process one is part of. This goes beyond moment-to-moment situational awareness and involves a stable, long-term grasp of how different elements interact.	The DT interferes with user's awareness of the elements in the work system or work process.				

	5	Proactive validation of assumptions	Actively preparing for what might happen, checking one's assumptions, and confirming that conditions are as expected.	The DT interferes with user's possibilities to anticipate potential future events				
	6	Workload	Managing over- and underload regarding work demands.	The DT causes over- or underload of work demands.				
	7	Vigilance and fatigue	The ability to maintain attention and performance over time.	The DT challenges user's maintaining of vigilance or causes fatigue.				
	8	Life situation and stress	The individual's life situation outside of work and it's effects on work performance	The DT sets requirements that are difficult to meet in a state of reduced cognitive capability, e.g. when the user is in a challenging life situation.				
	9	Work experience and age-related factors	Aging affects perception, learning and cognitive processes. Expertise and judgement and understanding of workflows are improved with experience.	The DT challenges users with limited working experience.				
	10	General health status	The individual's physical and mental condition in relation to the demands of the work task.	The DT sets requirements for user's health or working ability.				
	11	Motivation and attitudes	Motivation and attitudes are key drivers of work engagement and safety. Motivation arises from meaningful goals, feedback, and alignment with personal values. Attitudes can be positive or negative.	The DT has qualities or functions that are demoralizing for the user.				

	12	Emotions	Emotions influence decision-making, attention, and social interactions. Irritability and impatience can narrow attention and impair decision-making. Positive mood can support concentration and flexibility.	The DT conveys information that effects users' emotional state and simultaneously requires actions.				
2. WORK LEVEL	20	Quality and content of work	Meaningfulness, variation and demands of the tasks.	The DT affects the quality, content or demands of user's work.				
	21	Quantity of work and time pressure	Workload and the amount of tasks or activities required within a given timeframe.	The DT creates time pressure to users.				
	22	Work organization and work distribution	The clarity of roles, responsibilities, and task allocation. Clear job descriptions and well-defined responsibilities support job satisfaction and motivation.	The DT causes changes in job organization, work distribution or job descriptions.				
	23	Usability of tools, devices and technologies	Well-designed tools support safety and efficiency, while poor design or malfunctioning equipment can increase risks and hinder performance.	Usability and functionality of technology, devices or software are important elements in the DT design.				
	24	Procedures and instructions	Work instructions are the formal procedures and guidelines that ensure safety, quality, and efficiency. While clear instructions reduce risks and standardize practices, excessive bureaucracy or overly rigid rules can create blind spots and hinder adaptability.	DT design causes changes to work procedures and -instructions.				

	25	Job control and autonomy	Influence over one’s own work means the degree to which employees can control their tasks, methods, schedules and work conditions.	DT design sets restrictions to users in influencing their work and working conditions.				
	26	Feedback on work	Opportunity to develop work processes refers to employees’ ability to analyse, improve, and innovate in their own work. Involving staff in process improvement increases ownership, learning, and adaptability.	DT design may impair user's gaining feedback from their work or their professional appreciation.				
	27	Opportunity to evaluate and develop work processes	Employees’ opportunities to analyse, improve, and innovate in their own work. Involving staff in process improvement increases ownership, learning, and adaptability.	the DT design impairs users' opportunities to evaluate and develop one's work processes.				
	28	Training	Training is a systematic way to develop knowledge, skills, and attitudes necessary for safe and efficient work. Effective training addresses real needs, is tailored to the audience, and is evaluated for impact.	The DT design or the work-tasks renewed by the design require training.				
	29	Physical working environment and conditions	Physical work environment includes the ergonomic, hygienic, and environmental conditions in which work is performed—such as ventilation, lighting, temperature, noise, and layout. A well-designed environment supports safety, comfort, and productivity.	The DT does not sufficiently consider the users' physical work environment				

3. GROUP LEVEL	30	Shared understanding among all group members	every member of a group or team has a consistent and accurate understanding of what is happening and what needs to be done. It is built through clear communication, common terminology, and effective use of information systems.	The DT design does not support forming shared understanding of the on-going situation among relevant users .				
	31	Making use of the knowledge of all group members	In complex work, no single person can master everything, so it is important to utilize the diverse expertise of the team. Teams that are aware of each member's strengths and areas of expertise can solve problems more effectively and anticipate needs, even under pressure.	The DT design does not support utilizing the knowledge of all necessary parties.				
	32	The ability to correct misunderstandings	Communication is deemed to have flaws, so corrections are routinely needed. The ability to recognize and correct misunderstandings is a key factor in safe and profitable work.	The DT design does not allow redirecting or correcting actions when				
	33	Group structure and dynamics	Composition, structure and social relationships within a group.	The DT design possibly hinders teamwork.				
	34	Communication between different cooperation parties	Communication between different cooperation parties is vital for both operational success and safety.	DT does not enable cooperation with all relevant parties.				

	35	Information flow	Effective information flow is critical for maintaining shared situational awareness and continuity of operations. For example, in production environments, shift handovers must allow enough time for outgoing and incoming staff to exchange all relevant information.	The DT design does not convey all necessary information. The DT design potentially impairs information flow from one shift to another.				
	36	Decision-making in groups	Decision-making in groups involves evaluating options, assessing risks, and making choices collectively.	The DT design does not support joined decision-making.				
4. ORGANIZATION LEVEL	40	Management and leadership	Management is about planning, organizing, and coordinating resources to achieve specific goals efficiently, while leadership focuses on inspiring, guiding, and motivating people toward a shared vision.	The DT does not sufficiently include relevant information to support management.				
	41	Organizational and safety culture	The shared values, beliefs, and behaviours that shape how work is done with regard to operations and safety.	The DT does not fit to organizations typical ways of doing things.				
	42	Cooperation between different organizational levels and units	Effective collaboration requires clear communication, mutual trust, and shared processes.	An organizational level or unit is not properly considered in the DT design.				
	43	Mastering the entirety of work	Employees and units should understand not only their own roles but also how their work fits into the broader organizational system.	The DT does not support users in forming an overall picture of production.				
	44	Decision-making in organizations	Decisions about staffing, equipment, and investments have long-term impacts and may introduce hidden risks or benefits.	The DT design is not aligned with recent managerial decisions.				

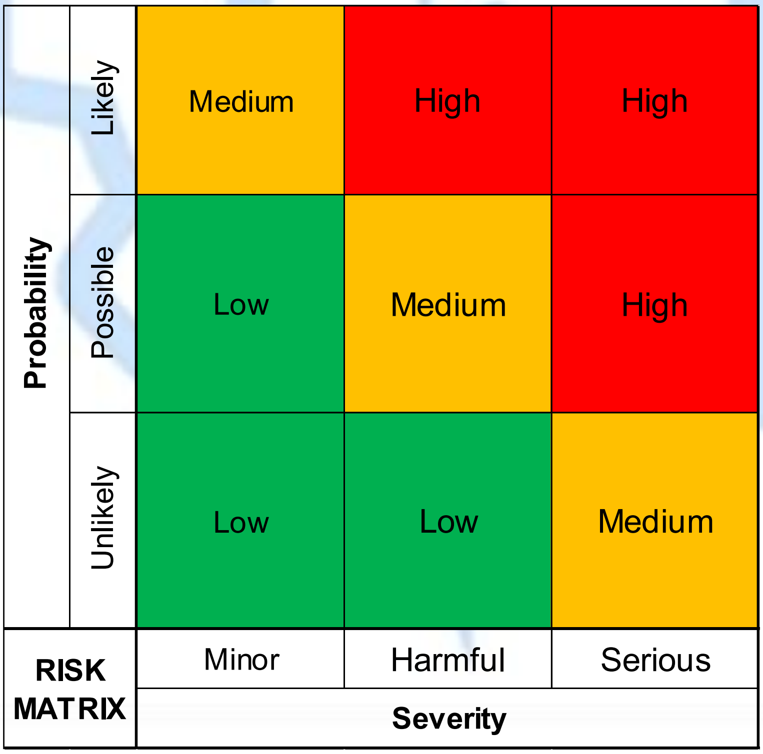
	45	Change management	How organizations plan, implement, and adapt to changes.	The change management required by the implementation of the DT design is not considered.				
	46	Cooperation with partners	Collaboration organization's external partners, such as subcontractors, suppliers, or authorities.					
	47	Organizational support for units	The support provided to operations from other organizational functions	The required from the DT from company's internal units is not considered				

3. Risk Tool

The risk matrix is a semi-quantitative technique that uses two parameters—Probability (P) and Severity (S)—to generate a risk level (EN 31010). The cells of the matrix are typically color-coded to represent the different risk levels resulting from the combinations of P and S. Each risk level is associated with a decision rule.

The 3 × 3 risk matrix proposed by the Guideline uses three Probability levels (Unlikely, Possible, Likely) and three Severity levels (Minor, Harmful, Serious), producing nine possible combinations, which are grouped into three risk categories: Low, Medium, and High, coloured in green, orange, and red, respectively, to facilitate classification. The decision criterion applied by the matrix is: High risks shall be mitigated without delay, as they require immediate risk-reduction actions to achieve an acceptable residual risk level; Medium risks shall be addressed through the implementation of appropriate and proportionate risk-reduction measures, and Low risks are deemed tolerable under normal operating conditions and may be subject to periodic monitoring to verify that their status remains unchanged.

The Risk matrix tool is easy to use and enables a quick classification of risks, making it widely used as a screening tool to rapidly establish priorities. However, it presents a significant degree of subjectivity if it is not applied by experienced evaluators.



Probability	Likely	Medium	High	High
	Possible	Low	Medium	High
	Unlikely	Low	Low	Medium
RISK MATRIX		Minor	Harmful	Serious
		Severity		

Figure 2. Risk Tool

4. Compendium of Technical Strategies for HF Risk Management in the Design of Manufacturing DT

COMPENDIUM OF TECHNICAL STRATEGIES FOR MANAGING HUMAN-FACTOR RISKS						
IMPLEMENTED STRATEGY			DESCRIPTION	DIGITAL TWIN APPLICATION	DT APPLICATION EXAMPLE	RELATED STANDARDS
1. SAFE DESIGN (HCbD)	1	Error-tolerant interfaces	Design the DT interfaces and functions to prevent human errors and ensure that the system automatically transitions to a safe state in the event of failure. An error-tolerant interface blocks unsafe actions, prevents critical failures, and reduces operational risks, equipment damage, and avoidable accidents.	DT validates all inputs before applying them, blocks incorrect values, and maintains safe states to prevent actions that could compromise operations.	When an operator enters a value outside the allowed range, the DT blocks it, displays the permitted limits, and maintains a safe state. It also allows the change to be undone within the first seconds if not confirmed.	EN 61508-1 EN 61508-2 EN 61508-3 EN ISO 13849-1 EN IEC 62061 EN ISO 9241-110
	2	Cognitive HMI ergonomics	Design interfaces that optimise comprehension, minimise cognitive load, and enable fast and accurate decision-making. Considering cognitive load ensures clarity and efficiency; ignoring it generates confusion, incorrect decisions, delays, and a higher likelihood of operational errors.	The DT interface presents information clearly and visually structured, enabling fast understanding without cognitive overload.	The panel organizes information into functional blocks that reduce operational ambiguity. Tables are simplified, and a search tool is added to locate data without increasing visual load.	EN ISO 9241-11 EN ISO 6385 ISO 9241-110

	3	Functional resilience and controlled degradation	Design the DT to maintain operational continuity in the event of technical failures, loss of connectivity, or human error. The system must preserve its essential functions, prioritise safety, and operate in a safe degraded state until normal conditions are restored. Not doing so leads to interruptions, data loss, and risks to personnel and equipment.	DT preserves essential functions during sensor, network, or module failures, displaying only reliable data to avoid decisions based on incomplete information.	If a sensor fails, the DT switches to a safe mode and shows the last valid reading. If the cloud connection is lost, it continues operating locally without interrupting essential supervision.	EN ISO 22301 EN 61508 NIST SP 800-34
	4	Human–robot interaction	Ensure by design that humans and robots—especially cobots in shared workspaces—can work together safely, in a controlled and efficient manner, guaranteeing that automation respects human limits. Proper interaction minimises accidents and unexpected stops; ignoring it reduces workforce trust and increases operational risk.	The DT includes visualizations and alerts on robot movements and risk zones, enabling safe interaction with automated systems.	The DT displays the robot's motion zone and alerts when an operator enters it. The robot automatically reduces speed when a person approaches.	EN ISO 10218-1 EN ISO 10218-2 ISO/TS 15066 EN ISO 13855 EN ISO 12100
	5	Logical interlocks and dual validation	Integrate mandatory logical conditions and multiple validations into the control system design to prevent hazardous actions unless all prerequisites have been verified. These interlocks prevent severe errors and ensure that critical actions are executed in a controlled manner. Not applying them increases the risk of accidental changes, process failures, safety incidents, and unauthorised interventions.	The DT requires additional confirmation for high-impact actions, reducing the likelihood of unintended stops or configuration changes.	The DT requires double confirmation before stopping a production line. A remote stop requires validation by two independent roles.	EN 61508 EN ISO 13849 -1 NIST SP 800-53 EN IEC 62443

	6	Contextual assistance and explainability	Provide relevant contextual information exactly when the operator needs it, and ensure that DT decisions (calculations, recommendations, predictions, alerts) are interpretable and explainable. Robust information design prevents misinterpretations and reduces human error.	The DT provides clear explanations for its recommendations, improving user understanding and trust.	When the DT recommends an action, it shows the data used to justify it. If it suggests reducing speed, it displays the trend that triggered the recommendation.	EN IEC/IEEE 82079-1 EN ISO 20607
	7	Safety signage	Incorporate standardised signage, colours, pictograms, and codes that enable rapid, consistent, and unambiguous interpretation by personnel. Appropriate signalling avoids interpretation errors and improves reaction time to critical states.	The DT applies standardized colours and symbols to indicate states and alarms, minimizing misinterpretation under pressure.	Operational states follow a standard coding: green (normal), yellow (warning), red (critical). Critical alarms flash red for immediate prioritization.	EN ISO 7010 EN ISO 3864
	8	Human-centric design (HCD)	Integrate a detailed understanding of the user (capabilities, limitations, context, risks, expectations, and real working conditions) throughout the entire DT lifecycle, ensuring that the system adapts to the human. HCD reduces unnecessary complexity, improves safety and acceptance, and prevents confusing interfaces, user rejection, and errors.	The DT is designed and validated with real users, incorporating their needs and reducing complexity to deliver an intuitive and safe tool.	After operators reported low text readability, the DT increases contrast. An operational flow is also optimized from six to three steps after field testing.	EN ISO 9241-210 EN ISO 6385 EN ISO 9241-110

	9	Human-role and autonomy level	Define the required level of human supervision during critical operations: 1) Human-in-the-loop (mandatory human action), 2) Human-on-the-loop (continuous human supervision with operational automation), 3) Human-over-the-loop (strategic supervision). Proper allocation prevents hazardous unexpected automatisms, unsupervised decisions, and loss of trust.	The DT communicates the active autonomy level and clarifies when operator intervention is required for critical decisions.	The DT indicates when a recommendation requires operator validation before execution. In supervised automatic mode, it allows the action to be stopped immediately.	EN ISO 13849-1 EN 61508 ISO/IEC 22989 NIST AI RMF 1.0
2. PROTECTION	10	Secure architecture and least-privilege access	Design the DT under the principle of least privilege, ensuring that each actor—human or system—accesses only the information required for their tasks. This limits errors, unauthorised access, and operational failures. Ignoring it facilitates security breaches, unauthorised modifications, and risks to production.	The DT assigns role-based permissions and restricts sensitive actions, ensuring no unauthorized user can execute changes or access critical data.	The DT allows operators to view process data but prevents PLC parameter changes without approval. Analysts may view KPIs but cannot export sensitive data or modify recipes without formal authorization.	EN IEC 62443 EN ISO/IEC 27001 EN ISO/IEC 27002 NIST SP 800-207 NIST SP 800-53 NIST SP 800-82 EN 61508 EN ISO 13849-1 EN IEC 62061
	11	Alarm system lifecycle	Ensure that system alarms are useful, prioritised, and properly configured, enabling fast and safe decision-making. Poor alarm configuration leads to overload, loss of attention, delayed responses, and high operational risk.	The DT classifies, prioritizes, and groups alarms to show only relevant notifications and support rapid operator response.	The DT groups repetitive alarms into a single notification to prevent saturation. During scheduled maintenance, it temporarily suppresses known alarms to reduce noise.	EN IEC 62682

	12	Privacy and data protection	Ensure that personal data managed by the DT is protected from the outset by applying minimisation, anonymisation, or pseudonymisation by default, and by implementing controls that prevent re-identification. This preserves privacy, regulatory compliance, and workforce trust.	The DT anonymizes personal data and controls access to sensitive information, ensuring regulatory compliance and user protection.	Performance data is displayed aggregated by shift, without personal identifiers. Historical data used for predictive models is pseudonymized and deleted after the defined retention period.	GDPR EN ISO/IEC 27701 ISO 31700-1 EN ISO/IEC 27001 EN ISO/IEC 27002
	13	Robust access control, auditability and segregation of duties	Ensure robust authentication, complete activity logging, and separation of critical tasks across roles to avoid errors, misuse, or unauthorised changes. Not applying these measures generates severe failures, loss of traceability, and compliance risks.	The DT logs all actions, enforces strong authentication, and separates critical functions to prevent unauthorized operations and support traceability.	Each action is logged with user, timestamp, and reason. The person who develops a change cannot deploy it, ensuring separation of duties.	EN ISO/IEC 27001 EN ISO/IEC 27002 EN IEC 62443 NIST SP 800-53
	14	OT–IT encryption and system hardening	Protect DT information and systems through encryption, secure communications, hardened devices, and configurations that remove unnecessary or vulnerable services. These measures prevent interception, data manipulation, and attacks that compromise industrial processes.	The DT secures industrial communications through encryption and hardened configurations that prevent external access or process manipulation.	Communications between the DT and the OT network are encrypted. Certificates rotate automatically and insecure protocols are disabled.	EN IEC 62443 EN ISO/IEC 27001 EN ISO/IEC 27002 NIST SP 800-125 NIST SP 800-52

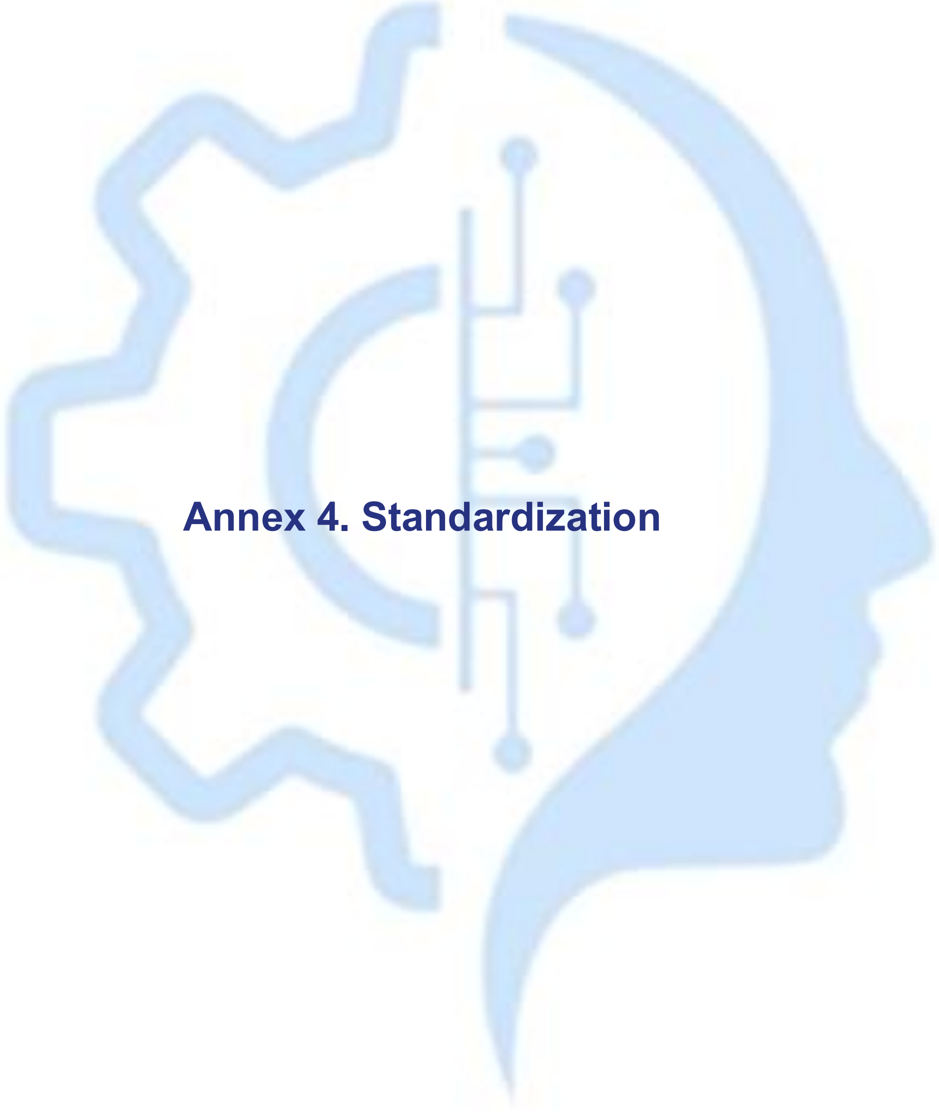
	15	Psychophysiological operator monitoring	Detect when an operator exceeds physical or cognitive limits to prevent errors, slowdowns, and risks. Monitoring anticipates overload-related failures and enables task redistribution. Ignoring it increases the probability of incidents and reduces operational performance.	The DT detects operator overload patterns and proposes task redistribution to maintain safety and performance.	The DT detects alarm overload on a specific operator and recommends workload redistribution. If an operator handles critical alarms for too long, it suggests a preventive break.	EN ISO 10075 EN ISO 6385 EN IEC 62682 EN ISO 45001
	16	Secure backups, versioning and rollback	Ensure operational continuity through reliable backups, version control, and safe rollback mechanisms in case of failure, human error, or cyberincident. This prevents data loss, downtime, and irreversible errors.	The DT stores historical configuration versions and allows rapid restoration in case of errors or failed updates.	After a failure, the DT restores the previous configuration without losing history. Backups are validated weekly in a test environment to ensure integrity.	EN ISO/IEC 27001 EN ISO/IEC 27002 EN IEC 62443-3-3 NIST SP 800-34 EN ISO 22301
	17	Physical and organizational protection measures	Prevent access to hazardous areas using technical and organisational protective measures. Integration with the DT enables monitoring and control of hazardous zones, increasing operator safety.	The DT monitors safety conditions in robotic cells and blocks automatic actions when human presence or open safeguards are detected.	If a protected door in the manufacturing cell is opened, the DT blocks automated actions. After closure, it requests verification before re-enabling automation.	EN ISO 10218-1 EN ISO 102018-2 ISO/TS 15066 EN ISO 14120 EN ISO 13857
	18	Data governance and ethical principles	Apply policies, roles, and controls that ensure integrity, quality, traceability, privacy, and fairness across the data lifecycle. Including principles such as minimisation, algorithmic non-discrimination, and worker protection prevents bias, misuse, and unsafe or unfair decisions.	The DT controls data usage, showing data sources and rules to ensure fair, transparent, and bias-free decision-making.	Operating times are displayed in aggregated form to avoid individual attribution. The DT shows data lineage before allowing its use in decision-making.	EN ISO/IEC 38505-1 GDPR EN ISO/IEC 27018 IEEE 7000 IEE 7003 IEEE 7010

	19	Ergonomic analysis of workload	Systematically assess the physical, cognitive, and emotional demands of tasks. Balancing workload reduces errors, fatigue, and operational stress; ignoring it increases incidents and degrades work quality.	The DT detects spikes in physical or cognitive load and recommends rebalancing tasks to prevent saturation and reduce errors.	The DT detects that an operator is handling too many alarms and redistributes workloads. The scheduler balances tasks to maintain reasonable shift loads.	ISO 10075 ISO 11228 ISO 6385
	20	Human-impact change	Ensure that any DT change that affects operator work is evaluated, communicated, and validated beforehand to avoid risks, confusion, and poor adaptation.	The DT notifies users in advance of any updates affecting screens or information flows and guides transition to avoid confusion.	Before updating a screen, the DT notifies users of upcoming changes and presents before/after previews to ease the transition.	EN ISO/IEC 20000-1 EN ISO 9241 EN ISO 12100
	21	Standardized technical documentation	Ensure that manuals, procedures, and operating instructions comply with international standards for safe-use information. Poor documentation causes failures, misuse, and avoidable human errors.	The DT integrates manuals and procedures accessible from each screen, ensuring immediate access to validated instructions.	The DT provides standardized instructions accessible with one click. A QR code on the machine opens the corresponding procedure directly.	EN IEC/IEEE 82079-1 EN ISO 20607
	22	Technical shift handover	Systematise the transfer of critical operational information between shifts: process status, alarms, active risks, decisions taken, pending tasks, anomalies, and any deviation that may affect safety or performance. A structured handover ensures continuity and prevents loss of safety-critical information.	The DT automatically summarizes the previous shift's activity and requires review by the incoming operator to avoid loss of critical information.	The incoming operator receives an automatic incident summary. The handover includes a digital checklist requiring electronic signature.	EN ISO 11064 EN IEC 62832

	23	Usability metrics and continuous feedback	Establish quantitative and qualitative indicators to measure human-system interaction (efficiency, effectiveness, cognitive load, friction). These metrics support continuous DT improvement.	The DT analyses user navigation patterns and identifies usability issues, enabling evidence-based improvements to screens and workflows.	A difficult-to-locate chart is moved to the main screen. The redesign is validated through A/B testing and the most efficient version is adopted.	EN ISO 9241-11 ISO/IEC 25062 EN ISO 6385
	24	Comprehensive risk management	Ensure that technical and human risks are analysed and controlled so that decisions are based on evidence rather than intuition or production pressure. Ignoring risks exposes the system to vulnerabilities that can lead to severe failures and accidents.	The DT combines technical and human data to display real-time risks and support informed decisions before failures occur.	The DT detects increased micro-stoppages and signals an emerging risk. It uses a bow-tie visualization to highlight causes and active barriers.	EN ISO 31000 EN ISO 12100 EN IEC 61508
	25	Progressive change deployment	Introduce new functionalities or processes through controlled pilot implementations, evaluating human, technical, and organisational impact before full deployment.	The DT introduces new functions gradually through pilot groups, gathering operational feedback before full deployment.	A new DT feature is tested with a pilot team and refined before deployment. It is activated via feature flags and can be disabled if it generates confusion.	ISO 10018
	26	Roles and responsibilities	Clearly define who is Responsible, who Approves, who must be Consulted, and who must be Informed for each task, avoiding ambiguity, omissions, and coordination failures.	The DT identifies who performs, approves, and supervises each action, reducing errors caused by unclear responsibilities.	When an anomaly occurs, the DT automatically displays the responsible person, approver, and notifier. Each workflow clearly includes the off-shift escalation path.	EN ISO 9001

	27	Safety culture	Promote an organisational environment where people feel psychologically safe reporting deviations, risks, or concerns without fear of retaliation. A proactive safety culture enables early risk detection and prevents major incidents.	The DT enables quick, non-punitive reporting of risks or anomalies and provides follow-up on corrective actions.	When an operator reports an inconsistent reading, the DT assigns the issue to maintenance. Near-miss events are logged without identifying individuals.	EN ISO 45001 .
3. INFORMATION AND TRAINING	28	Competence-based training	Provide training oriented to real operational skills, ensuring that each operator performs only the tasks for which they are qualified.	The DT verifies that each user has the required training before allowing access to critical or advanced functions.	The DT blocks access to advanced functions until it verifies the operator’s valid training. If certification has expired, advanced permissions are automatically revoked.	EN ISO 10015 EN ISO 10018
	29	Digital twin simulation training	Use the DT as a safe environment to practise procedures, understand processes, anticipate failures, and train responses without exposing operators to real-world risk.	The DT offers simulated scenarios for practicing operational and failure procedures, reducing errors in real conditions.	A technician practices responding to a complex alarm using the DT simulator without affecting production. A monthly power-failure drill is executed and logged for evaluation.	EN ISO/IEC/IEEE 15288 IEEE 1730
	30	Cybersecurity awareness and training	Train workers in threats, vulnerabilities, and best practices. Cybersecurity training reduces human errors exploited by attackers.	The DT includes contextual reminders and training to reinforce safe behaviours and prevent risky actions due to lack of knowledge.	The DT blocks a suspicious file and displays a security reminder. It also detects unauthorized USB devices and guides the user through the validation process.	EN ISO/IEC 27001 EN ISO/IEC 27002 NIST SP 800-53 NIST SP 800-82 ENISA guidelines.

	31	Usability and alarm lifecycle training	Train operators to interpret interfaces, prioritise alarms, understand alarm semantics, distinguish severity levels, and make decisions under pressure without cognitive overload.	The DT provides practical exercises to train users in correct alarm interpretation and prioritization.	The DT provides simulations to train alarm prioritization. During a critical alarm, it displays a step-by-step quick-response guide.	IEC 62682 EN ISO 9241-11 EN ISO 9241-110
	32	Technical refresher and competence assessment	Periodically update knowledge and verify competencies using quantitative and qualitative indicators to maintain proficiency and reduce errors in critical situations.	The DT detects when a user needs knowledge refreshers and proposes updated training before performing critical tasks.	If a user has not used a function for months, the DT proposes refresher training. Before critical tasks, it requests a short update micro-lesson.	EN ISO 10015



Annex 4. Standardization

Standardization is essential for the safe and effective adoption of DT technology and HCDT approach. Standardization bodies (ISO, IEC, CEN, CENELEC, etc) are developing frameworks that unify terminology, architectures, and interoperability requirements, reducing fragmentation and ensuring scalable and secure ecosystems. A DT is a complex digital system. Outlined below is a set of standards, organized into several key areas, that are potentially applicable to the specification, design, validation, and deployment of HC manufacturing DT.

The ISO 23247 and ISO 9241-210/110 standards form the formal conceptual foundation for designing DT in HC manufacturing environments. Together, they establish the architectural, ergonomic, and human–system interaction principles needed to ensure that DT are not only technically interoperable but also usable, safe, and consistently aligned with human capabilities and needs throughout their entire lifecycle.

1. Digital Twin for manufacturing
ISO 23247-1:2021 Automation systems and integration — Digital twin framework for manufacturing — Part 1: Overview and general principles
ISO 23247-2:2021 Automation systems and integration — Digital twin framework for manufacturing — Part 2: Reference architecture
ISO 23247-3:2021 Automation systems and integration — Digital twin framework for manufacturing — Part 3: Digital representation of manufacturing elements
ISO 23247-4:2021 Automation systems and integration — Digital twin framework for manufacturing — Part 4: Information exchange
ISO/FDIS 23247-5 Automation systems and integration — Digital twin framework for manufacturing — Part 5: Digital thread for digital twin (Under development)
ISO/DIS 23247-6 Automation systems and integration — Digital twin framework for manufacturing — Part 6: Digital twin composition (Under development)
ISO/TR 23247-100:2025 Automation systems and integration — Digital twin framework for manufacturing — Part 100: Use case on management of semiconductor ingot growth process
ISO/DTR 23247-101 Automation systems and integration — Digital twin framework for manufacturing — Part 101: Use case on management of robotic multilayer and multipass gas-shielded metal arc welding processes (under development)
ISO/IEC 20924:2024 Internet of Things (IoT) and digital twin — Vocabulary
ISO/IEC 30173:2023 Digital twin — Concepts and terminology
ISO/IEC 30188 Digital Twin — Reference architecture

2. HCD, HF and ergonomics
EN 16710-2:2016 Ergonomics methods - Part 2: A methodology for work analysis to support design
EN ISO 6385:2016 – Ergonomic principles in the design of work systems
EN ISO 9241 11 – Ergonomics of human system interaction — Part 11: Usability: Definitions and concepts
EN ISO 9241-110:2020 Ergonomics of human-system interaction — Part 110: Interaction principles
EN ISO 9241-210:2019 Ergonomics of human-system interaction — Part 210: Human-centred design for interactive systems
EN ISO 10075-1:2017 Ergonomic principles related to mental workload - Part 1: General issues and concepts, terms and definitions
EN ISO 11064-1:2000 Ergonomic design of control centres - Part 1: Principles for the design of control centres
EN ISO 26800:2011 Ergonomics — General approach, principles and concepts
IEEE 7000-2021 IEEE Standard Model Process for Addressing Ethical Concerns during System Design
IEEE 7010-2020 IEEE Recommended Practice for Assessing the Impact of Autonomous and Intelligent Systems on Human Well-Being
ISO 6385:2016 Ergonomics principles in the design of work systems
ISO 11228-1:2021 Ergonomics — Manual handling — Part 1: Lifting, lowering and carrying
ISO 27500:2016 The human-centred organization — Rationale and general principles
ISO 27501:2019 The human-centred organization — Guidance for managers
ISO 31700-1:2023 Consumer protection — Privacy by design for consumer goods and services — Part 1: High-level requirements
ISO/TR 22100-3:2016 Safety of machinery — Relationship with ISO 12100 — Part 3: Implementation of ergonomic principles in safety standards

3. Safety

EN IEC 62061:2021 – Safety of machinery - Functional safety of safety-related control systems
EN 61508-1:2010 – Functional safety of electrical/electronic/programmable electronic safety-related systems -- Part 1: General requirements
EN 61508-2:2010 –Functional safety of electrical/electronic/programmable electronic safety-related systems -- Part 2: Requirements for electrical/electronic/programmable electronic safety-related systems
EN 61508-3:2010 – Functional safety of electrical/electronic/programmable electronic safety-related systems -- Part 3: Software requirements
EN IEC/IEEE 82079-1:2020 Preparation of information for use (instructions for use) of products - Part 1: Principles and general requirements
EN ISO 3864-1:2011 – Graphical symbols — Safety colours and safety signs — Part 1: Design principles for safety signs and safety markings
EN ISO 7010:2020 Graphical symbols - Safety colours and safety signs - Registered safety signs
EN ISO 10218-1:2011 – Robotics — Safety requirements — Part 1: Industrial robots
EN ISO 10218-2:2025– Robotics - Safety requirements - Part 2: Industrial robot applications and robot cells
EN ISO 12100:2010 Safety of machinery — General principles for design — Risk assessment and risk reduction
EN ISO 13849-1:2023 – Safety of machinery — Safety related parts of control systems — Part 1: General principles for design
EN ISO 13855:2025 Safety of machinery - Positioning of safeguards with respect to the approach of the human body
EN ISO 13857:2019 Safety of machinery - Safety distances to prevent hazard zones being reached by upper and lower limbs
EN ISO 14120:2015 Safety of machinery - Guards - General requirements for the design and construction of fixed and movable guards
EN ISO 20607:2019 Safety of machinery - Instruction handbook - General drafting principles
ISO/IEC TR 24028: 2020 Information technology — Artificial intelligence — Overview of trustworthiness in artificial intelligence
ISO/TS 15066:2016 – Robots and robotic devices — Collaborative robots

4. Information security
IEC TS 62443-1-1:2009 Industrial communication networks - Network and system security - Part 1-1: Terminology, concepts and models
IEEE 1730-2022 IEEE Recommended Practice for Distributed Simulation Engineering and Execution Process (DSEEP)
IEEE 7003-2024 IEEE Standard for Algorithmic Bias Considerations
EN IEC 62682:2023 Management of alarm systems for the process industries
EN IEC 62832-1:2020 Industrial-process measurement, control and automation - Digital factory framework - Part 1: General principles
EN ISO/IEC 22989:2023 – Information technology — Artificial intelligence — Concepts and terminology
EN ISO/IEC 27001:2023 – Information security, cybersecurity and privacy protection — Information security management systems — Requirements
EN ISO/IEC 27002:2022 – Information security, cybersecurity and privacy protection — Information security controls
EN ISO/IEC 27018:2020 – Information technology - Security techniques - Code of practice for protection of personally identifiable information (PII) in public clouds acting as PII processors
EN ISO/IEC 27701:2021 – Security techniques — Extension to ISO/IEC 27001 and ISO/IEC 27002 for privacy information management — Requirements and guidelines
EN ISO/IEC 29100:2020 Information technology - Security techniques - Privacy framework
NIST SP 800-52 Rev. 2: 2019 Guidelines for the Selection, Configuration, and Use of Transport Layer Security (TLS) Implementations
NIST SP 800-53 Rev. 5:2020 Security and Privacy Controls for Information Systems and Organizations.
NIST SP 800-82 Rev. 3:2023 Guide to Operational Technology (OT) Security
NIST SP 800-125:2011 Guide to Security for Full Virtualization Technologies
NIST SP 800-207:2020 Zero Trust Architecture
ANSI/ISA-18.2-2016 Management of Alarm Systems for the Process Industries

5. Risk management

ISO 31000:2018 – Risk management — Guidelines
EN 31010:2010 Risk management — Risk assessment techniques
EN ISO 22301:2019 – Security and resilience — Business continuity management systems — Requirements
NIST SP 800-34 Rev. 1:2010 Contingency Planning Guide for Federal Information Systems
EN ISO 9001:2015/A1:2024 Quality management systems - Requirements
ISO 10018:2020 Quality management. Guidance for people engagement
ISO/IEC/IEE 15288:2023 Systems and software engineering — System life cycle processes
ISO/IEC 20000-1:2018 Information technology — Service management — Part 1: Service management system requirements
EN ISO 45001:2023 – Occupational health and safety management systems — Requirements with guidance for use

6. Other
EC (2016) Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (Text with EEA relevance)
ENISA Guidelines (https://www.enisa.europa.eu/publications)