The road to advanced manufacturing in the medical device industry

Siemens Digital Industries Software

Medical Device Innovation Consortium

October 1, 2021

AUTHORS

Gary A. Gray
Director Digital Enterprise Consulting
Siemens Digital Industries Software

Joaquin Atoche Rejon
Digital Enterprise Solution Architect Fellow
Siemens Digital Industries Software

AUTHOR NOTE This paper was authored by Siemens Digital Industries Software at the request of the Medical Device Innovation Consortium (MDIC). Both parties have joint legal rights to publish this material with acknowledgments.

MDIC
MEDICAL DEVICE INNOVATION CONSORTIUM

TABLE OF CONTENTS

MDIC
MEDICAL DEVICE INNOVATION CONSORTIUM

ABSTRACT

Every company is looking for a competitive advantage. It is a way to stand out from their competitors and get to market faster than anyone else and with the best quality, features, and price. Advanced manufacturing can provide that advantage. Through digital transformation, companies can make significant improvements that enhance product quality, design and manufacturing connectedness, manufacturing capacity, agility, and throughput.

For the medical device industry, the timing has never been more critical. Focused attention on the medical device industry caused by the pandemic in 2020 has brought the topic of advanced manufacturing into specific focus. This attention creates opportunities for medical device companies to step into the spotlight and demonstrate their leadership and adaptability.

This paper will walk the reader through advanced manufacturing and the related areas where change is required and organize the topic into digital threads that define interconnected information flows. The current state of the medical device industry will be reviewed and compared to other industries, leveraging experiences and lessons learned. Afterward, a flexible path will be defined that companies can follow regardless of where they are in their advanced manufacturing journey. The journey is challenging but not impossible, and it starts now.

Keywords: advanced manufacturing, medical devices, medical device manufacturing, digitalization roadmap, digital transformation, digital threads, digital twin.

EXECUTIVE SUMMARY

The medical device industry is in a unique position today. The industry has seen increased attention due to COVID-19 and the impacts of the pandemic, and the issues it presented for companies to meet the new demand. These circumstances have raised many questions about the state of the industry. Medical device companies that are leading the digital transformation to advanced manufacturing technologies moved to a remote work environment and barely slowed down as the pandemic raged. Those behind and still reliant on paper-based or disconnected processes have seen production slow, employees become less productive, and have been slower to introduce new products to the market. While other situations may have caused similar issues, none have gained more people's attention than what transpired in 2020.

With this unique position comes opportunity – the opportunity to finally make a case for embracing advanced manufacturing technologies. Technology partners are eager to help the industry modernize and become an agile force in the future, capable of adapting to any unexpected disruption that may come along. It's also an opportunity to improve product quality, reduce costs, speed up new product introduction, and not only meet regulatory standards, but exceed them.

All of this is possible. This paper will take you on a journey to advanced manufacturing and lay out the benefits, the roadblocks and how to navigate around them. With the attention and focus on the medical device industry, there has never been a better time than now. Regardless of where you are on the journey, there is a path to advanced manufacturing, and it starts here.

The goal of this paper

Our goal is to illustrate how a digitalization roadmap can guide a medical device company in its journey to digitally transform its product design and manufacturing practices to leverage advanced manufacturing technologies. The diversity of medical device products is the primary reason there is no single benchmark or reference case study that one could point to and say, "this is where the medical device industry is" on the journey to advanced manufacturing. There is no one-size-fits-all solution strategy for advanced manufacturing. This paper seeks to provide concepts and ideas for any organization that wishes to begin a journey to incorporate advanced manufacturing technologies or complement efforts that have already been started.

Advanced manufacturing can include technical solutions such as robotics, additive manufacturing (AM), or a smart manufacturing process that utilize a wide array of physical and virtual sensors to collect data for real-time quality control. Advanced manufacturing can also include improved design and manufacturing practices, such as generative design or continuous manufacturing. The common denominator across the advanced manufacturing landscape is the digital connectivity and the real-time collection and use of data that is foundational to the strategy appropriate to an organization's specific journey. Utilizing the methods detailed in this document, which are based on real-world case studies and experience, will result in drastic improvements in new product introduction (NPI) process integration, manufacturing automation, efficient orchestration of manufacturing operations with built-in compliance, end-to-end traceability (trusted traceability), process and product quality, and more while leveraging enterprise-ready solutions that are cost-effective and scalable. This paper also addresses some of the obstacles and roadblocks found along the way and provide guidance on avoiding or overcoming them.

WHAT IS ADVANCED MANUFACTURING?

The key to success in any organization is by combining the right people, processes, and technologies. In this paper, the term "advanced manufacturing" focuses mainly on the best practice processes and proven technologies available in the market today that could positively impact medical device companies, their partners, suppliers, and ultimately the patients that receive healthcare diagnoses and treatments utilizing medical devices. Advanced manufacturing is not a specific destination that all medical device companies need to reach. Instead, it is a journey of incorporating tools and concepts that promote manufacturing maturity, which enables the company to successfully react to the trends (outlined below) while allowing a high degree of manufacturing process efficiency and flexibility, providing support during market fluctuations and disruptions. Companies have unique needs and will have different starting points on the journey to advanced manufacturing, but professional guidance and assistance are available. The tools and concepts discussed in this paper are not only for large corporations. Small and medium-sized companies can benefit significantly by adopting these principles from the onset. What's important is increasing the level of process and product quality while reducing adverse events. Therefore, manufacturers can reduce their production costs and achieve higher margins while providing superior products with improved safety expected by patients, health care providers, and regulators.

It is essential to understand that for a company to adopt advanced manufacturing technologies, it cannot be a quality or manufacturing-specific effort. It happens with seamless integration with other departments or businesses in the organization that also need to contribute. Advanced manufacturing does not occur in isolation from the rest of the company. The road to advanced manufacturing starts with innovation in research and development (R&D) and product design and engineering by utilizing technologies to enable a two-way flow of information (closed loop) between product development and manufacturing. The synergy created by the seamless flow of information can provide significant business benefits throughout the organization, including improved management visibility, enabling improved decision-making and input. Providing a common framework for communication creates opportunities for synergies in other areas like training and supplier integration.

For example, design engineering must rethink how they design products to realize all of additive manufacturing's (often referred to as 3D printing) benefits; products must be designed, optimized, and analyzed to support the characteristics that enable the 3D printing process. Merely changing the manufacturing process for existing parts from casting or forging to 3D printing is not an effective use of the technology. Products must be designed or redesigned for 3D printing to realize the full potential of the technology and avoid potential risks of the process. Another example is the inclusion of product and manufacturing information (PMI) directly on the 3D computer-aided design (CAD) models (instead of annotations on 2D drawings), which provides superior manufacturing technology for design transfer communication and collaboration with all the relevant parameters, specifications, and standards to produce quality parts. The more connected product design is to manufacturing, the faster and more accurately manufacturing can identify issues, make required changes, improve and optimize production processes, and produce higher quality products.

The above example illustrates how advanced manufacturing begins early in the design phase. Functional departments and processes must connect to establish a foundation for advanced manufacturing across the product lifecycle. The ability to better integrate the transfer of the design into manufacturing is critical for bringing products to market faster. Elevating the maturity of product design technologies and practices and integrating design and manufacturing systems enables the utilization of more advanced manufacturing methodologies.

Technology alone is not a complete solution. For companies to integrate processes and technologies, the people must be adequately considered. The people aspects of the advanced manufacturing journey have two distinct elements. One is the physical interaction between the person and the product in the form of operations executed in manufacturing. The other focuses on how people experience and adapt to technological and organizational changes.

As manufacturing becomes more autonomous, fewer people are on the manufacturing floor; however, the risks can be more significant as they interact with machines, automation, and the output of the technologies. When people do not know how the machines move, where to stand, and, more importantly, where not to stand, job-related injuries and personal safety are at risk. To not effectively use the power and benefits of the technologies to optimize production and minimize error, layering on additional human processing where it doesn't add value can introduce the errors the technology was intended to remove. The virtual representation of the production digital twin, including the factory layout, equipment, and people, can be utilized to plan efficient equipment operation and worker safety by understanding the manual operations and ergonomics crucial to efficient factory flow, plant layout, and work cell design.

When introducing new technology, companies should understand the relationship between people and the changes caused by the technology. Managing this change across an organization will be a focus later when discussing barriers to adoption when engaged in digital transformation efforts within the organization. Companies must always consider both aspects of people involvement when developing a strategic roadmap and planning digital transformation initiatives.

MEDICAL DEVICE INDUSTRY DRIVERS

The medical device industry represents a large and diverse group of companies with a complex range of product types, diverse markets, production rates, and manufacturing technologies. On top of industry complexity, there are accelerated market technology innovations like smart connected devices, wearable technology (WT), software as a medical device (SaMD), the Internet of Medical Things (IoMT), Medical Device-as-a-Service (MDaaS), and cloud-based artificial intelligence (AI) for patient monitoring (connected care). In addition, the medical device industry's multiple business trends are all putting increased pressure on manufacturing operations' current approaches. Key trends include:

- Accelerated product innovation, including an increased number of NPIs
- Mass customization (shrinking lot sizes, personalized medical devices)
- Regulatory complexity (designing products in compliance with global regulatory agencies such as the FDA in the United States, MDR in the European Union, and NMPA in China)
- Real-time and big-data analytics (the generation of big data, managing digitalization and metrics, not documents, and the need for digital models to capture real-world performance data)
- Market consolidation, expansion, and integration (including reliance on partnerships) means companies need to reimagine their existing manufacturing strategies to address these technology innovations and industry business trends to prepare for the future consolidation or simultaneous expansion and integration

ADVANCED MANUFACTURING ENABLING TECHNOLOGY

Regardless of company size or product complexity, every manufacturer can benefit from the technologies and strategies described in this paper. This section will address some of the terminology and technologies referenced as part of the digital transformation efforts critical to the current and future success of advanced manufacturing technology implementations in any industry. Below are some existing technologies that are critical to current and future success with advanced manufacturing technology implementations.

Digital twin

Yes, there is more than one digital twin, but they all use the same underlying data, which is managed in a central database, so everyone and everything stays in sync. The digital twin is a digital model of assets utilized for design, production, and performance, including the common threads of information that enable improvement in the different product lifecycle areas from design to the final physical product and field service. This paper focuses on three kinds of digital twin, the product digital twin, the production digital twin, and the performance digital twin and how they enable other advanced manufacturing technologies.

Product digital twin

It starts with the product digital twin developed in design engineering. This digital twin has many purposes, from integrated associative design, simulations, assembly, integration, and regulatory verification and certification. Product design, production planning, production engineering, production execution, and service will utilize the configurable product digital twin. It is the baseline digital data supporting other digital twins and their usage. The product digital twin describes the geometry, materials, components, and behavior of the product and is produced by and directly supports functional areas such as:

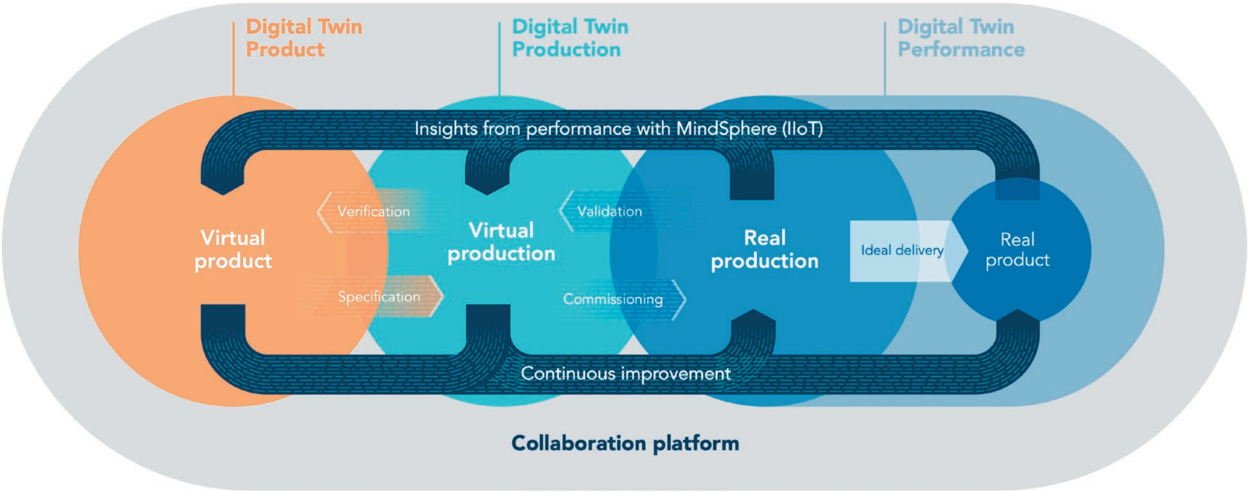
Product design

- Concept and systems engineering
- Portfolio management and program execution
- Product design and engineering (including design transfer to manufacturing)
- Configuration management and core engineering
- Quality management
- Manufacturing engineering
- Supply chain and procurement

Production digital twin

Next, the production digital twin encompasses production planning, production engineering, and production execution. The production digital twin is critical to implementing factory automation, virtual

Figure 1.



commissioning, and other advanced manufacturing technologies. In many cases, the product digital twin is used in conjunction with the production digital twin to communicate and verify manufacturing requirements. The use of both product and production digital twins together is one of the closed-loop quality digital thread enablers, providing information back upstream to the design process. The production digital twin produced by and directly supports functional areas across the lifecycle such as:

Production planning

- Configuration management and core engineering
- Portfolio management and program execution
- Quality management
- Supply chain and procurement
- Image analysis, fabrication and surgical planning
- Manufacturing process planning
- Factory line and robotics planning

Production engineering

- Supply chain and procurement
- Plant planning, commissioning and construction
- Quality management
- Production engineering
- Portfolio management and program execution

Production execution

- Supply chain and procurement
- Material inventory and logistics control
- Production equipment management and maintenance
- Production operations and execution
- Quality management
- Portfolio management and program execution

Performance digital twin

Finally, the performance digital twin or the Industrial Internet of Things (IIoT) allows for product performance monitoring, predictive maintenance, and predictive end-of-life. The performance digital twin, connected to the product and production digital twin, will support functions such as:

- Service and operations planning
- Supply chain and procurement
- Shop floor execution
- Service and operations maintenance and execution
- Quality management
- Product performance
- Customer feedback

Each digital twin builds on and provides feedback to the other digital twin. The digital twin reduces the time and cost of developing and manufacturing products by enabling more robust designs and reducing product costs. The design improvements enable efficient manufacturing processes and technologies while also reducing maintenance, downtime, and cost to the consumer through increased quality and safety for patients and healthcare providers.

DIGITAL THREADS

A digital thread is an interconnected flow of data across multiple solutions and product lifecycle phases that enable seamless end-to-end processes. They share common data models to facilitate communication and collaboration while providing consistent traceability. The flow of information across organizations creates multiple digital threads. The path to advanced manufacturing is defined by enabling the right technologies and optimizing the flow of information across the digital threads.

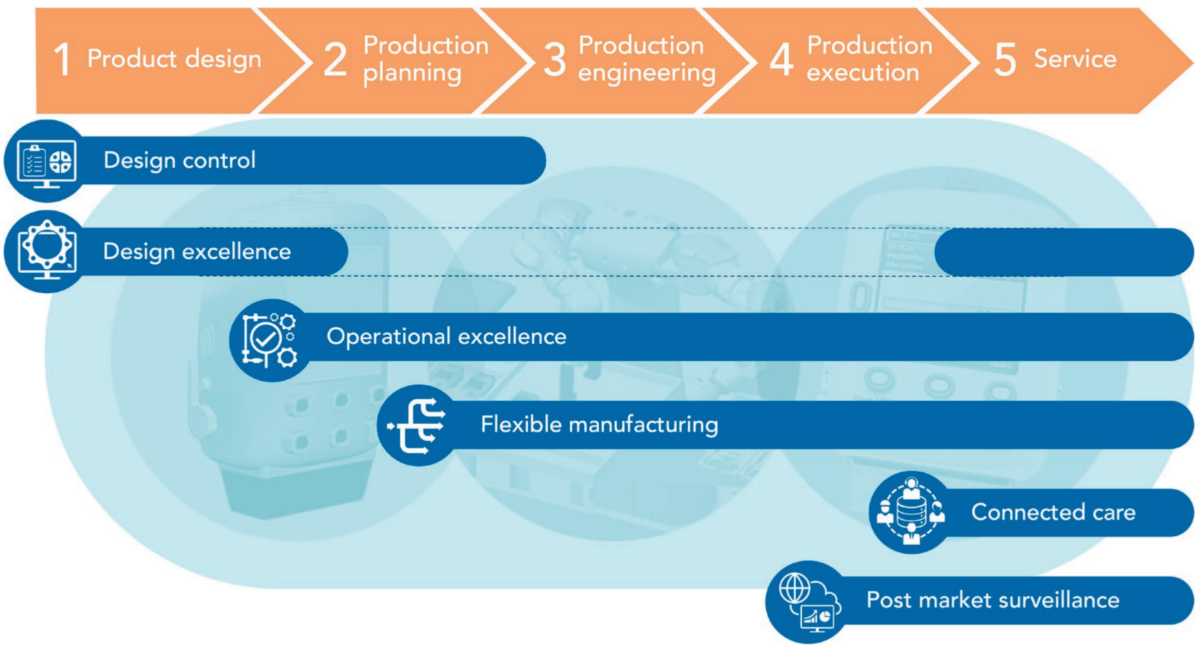
A digital thread is a framework that includes integrated process flows utilizing connected data that bridges typically siloed functions through the product lifecycle. Digital threads enable a just-in- time (JIT) methodology for the digital world, providing the right information to the right place at the right time.[1] This eliminates the current "throw it over the wall" approach that is the source of inaccuracies, missing information, and disconnected systems and data. The digital threads described in this paper connect and span product design, production planning, production engineering, production execution, and services.

Design control

The medical device industry is facing a changing landscape. As products are distributed worldwide, country-specific regulatory demands, in-country manufacturing, and supply chains increase complexity. These complexities require a significantly more comprehensive approach to developing the quality practices and procedures that ensure device quality and compliance known as design controls. As a result, companies face a dilemma: how to build comprehensive product innovation programs while avoiding slowdowns.

To establish the traceability and consistency of design information needed to meet regulatory demand and control costs, companies must move away from a document-centric model of information to a data-centric one. Creating granular traceability of design evolution will be the catalyst for reduced time-to-market, better risk management, and superior design quality. In addition, transparency and traceability of contextualized design control data enable

Figure 2.



regulators to easily navigate the entire history of the design control implementation.

Empowering mechanical, electrical and software teams to author and manage design control information as linked data elements instead of static documents that lack version control becomes the foundation for more effective multidisciplinary collaboration. The appropriate domain-specific design controls are readily apparent to the teams that use them. Managing complexity in context across the organization by automatically generating design documentation and real-time information sharing empowers teams to work swiftly and with more confidence. As a result, it facilitates faster, higher quality, and more predictable product development.

Design excellence

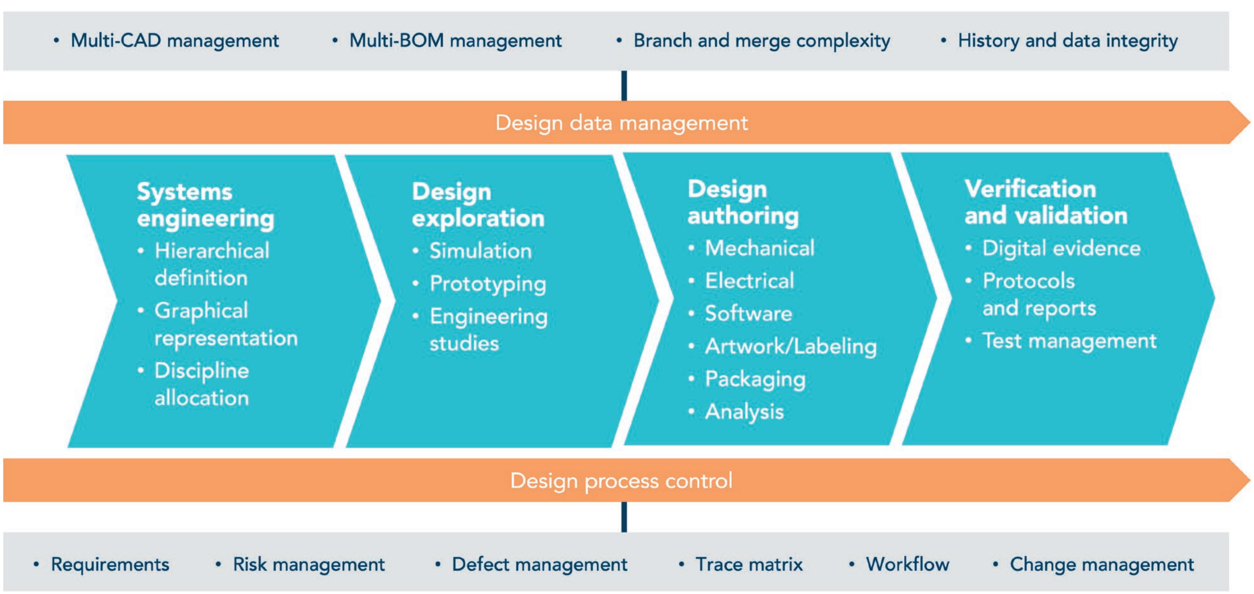
Design excellence encompasses all product design areas integrating them into a cohesive set of tools, processes, and data required to create interdisciplinary designs. Maximizing the re-use of assets and ensuring a seamless and comprehensive validation against production requirements is a primary concern. To gain a competitive edge and drive optimal product functionality, companies must orchestrate their tools and processes in a single, overarching architecture. This effort entails a culture shift that will enable functional areas to relate to one another and work collaboratively across disciplines toward a single goal instead of being stuck in silos and chasing disparate goals.

The ability of current tools to exchange data directly eliminates the administrative burden and associated opportunities for mistakes and miscommunications that create rework and lost time-to-market, or worse, producing a faulty product. Eliminating waste in development, optimizing performance, and resolving quality issues earlier in the product lifecycle are critical tasks even in a nonadvanced manufacturing scenario; however, these objectives have become easier to accomplish with the tools available today. And these tools are much more accessible to a broader range of companies, not just large corporations.

Key technology areas in design excellence include the following:

- **Model-based systems engineering (MBSE)** – Integrates requirements, reliability, availability, maintainability, and safety (RAMS), failure mode and effects analysis (xFMEA), and system modeling directly on the 3D models of the product

Figure 3.



- **Multi-disciplinary design authoring** – Mechanical, electrical, software, artwork/labeling, packaging, analysis. Integrated data management, improved collaboration, able to create a complete virtual representation of the product
- **Design exploration** – Simulation, optimization, prototyping, engineering studies (design of experiments). Design exploration takes the virtual product representation to the next level, facilitating evaluation of characteristics and performance and helping optimize the design selection decision-making
- **Verification and validation** – Digital evidence, protocols and reports, test management. Use the design process selection and optimization outcome to further improve validations of assemblies and entire products based on virtualization digital evidence while reducing physical prototypes

Program complexity is the common symptom for many root causes that lead to challenges with medical device design. The design excellence digital thread integrates all aspects of design in a common environment capable of managing the complex relationships between the design disciplines. Furthermore, working in this environment provides opportunities to improve quality and safety, improving the ability to meet regulatory compliance.

Operational excellence

To accelerate new product introduction, it is critical to integrate design data into manufacturing. Utilizing a digital product design transfer to manufacturing will result in a faster time-to-market. It allows virtual process and production design and optimization of the manufacturing resource planning and manufacturing engineering processes, utilizing the digital product and plant twin data without interfering with current production.

Utilizing the holistic digital twin of production to integrate the plant, line, and equipment allows you to utilize virtual commissioning and production optimization while providing real-time visibility into production assets and processes without physically reconfiguring resources. Optimizing manufacturing and warehouse operations enables the user to define safe and optimized human positioning and human/robotics safety and maximize throughput while creating visibility across the supply chain. Optimization accelerates time-to-market and allows adjustments to fluctuating demands with rapid production scaling.

Operational excellence requires a bidirectional flow of information using the comprehensive digital twin of production to ensure compliance and design intent with continuous feedback loops for quality and efficiency improvements. Digital threads provide data tracing for compliance and safety while improving supplier collaboration related to product data, design changes, and quality controls.

Flexible manufacturing

Flexible manufacturing aims to minimize, or eliminate if possible, the disruptions in discrete manufacturing, thereby transforming it into a continuous flow process. The personalization of medical device products is driving many manufacturers to a one-piece flow (continuous flow) manufacturing strategy. One-piece flow allows manufacturers to respond to predicted or unpredicted changes with minimal or no disruption to the production of devices.

Flexible manufacturing incorporates operation intelligence across all aspects of manufacturing execution. Combining manufacturing simulation, execution intelligence, and automation of equipment and lines transforms manufacturing processes into agile, automated operations that provide versatility and adaptability to product and customer demand changes. Flexible manufacturing also requires efforts to improve practices for control, management, and optimization of production orders, materials, and shop floor equipment resources, and the respective integrations to enterprise resource planning (ERP), and supply logistics, quality management systems, and shop floor equipment.

Flexible manufacturing enables practices to gather and analyze information from processes, execution results, equipment, and customer feedback and turn it into key performance indicators (KPIs) to maintain continuous manufacturing optimization benchmarks.

You can possibly benchmark against the following issues because so you can have visibility into improvements of the following:

- **Planning** – Evaluating production schedule and capacity to optimize material and resources to ensure seamless operations
- **Execution** – Improving the utilization and availability of people and equipment while optimizing logistics
- **Intelligence and analytics** – Turning different sources of information into actionable insights for management to predictably respond to trends and disruptions and provide real-world data to engineering to create and simulate more reliable designs
- **Tracking** – You can also measure many other precise KPIs for operation control, preventive service, maintenance, and more

Connected care

To achieve accelerated progress in the connected care space, companies need to shift their thinking to leverage prebuilt modern technology platforms while still trusting and building on their existing expertise. They need to accept that privacy and regulatory guidance will evolve to enable agile and adaptable processes for product development. Companies can harness device and clinical data streams to intelligently adapt therapies and connect more healthcare and digital solution experts remotely, increasing productivity and effectiveness of patient outcomes as a result. This paves the way for more individualized, patient-specific diagnoses and treatments developed collaboratively with medical technology companies and healthcare providers.

With established secure connectivity through multiple channels intelligently linked in manufacturing, distribution networks, electronic medical records (EMRs), and other healthcare provider systems, companies can possess the visibility to change course to meet demand nimbly. The capability to do this in an environment equipped to handle cybersecurity requirements enables companies to pivot to new solutions while agilely mitigating privacy risks.

Real-time visibility and connectivity enable companies to connect to healthcare providers, medical devices, and patients personally. The resulting level of oversight and communication will underpin more individualized care across the spectrum of healthcare workers and device and diagnostic solutions. This unprecedented personalization will encourage and empower patients to take an active role in their care journey, which can improve their health outcomes.

Post-market surveillance

Being closely tied to quality and post-market surveillance provides visibility and intelligence into the product's performance after the sale. A total shift in mindset is needed for organizations to move from reactive to proactive analysis of big data feeds to address issues earlier or even before they occur. Creating the infrastructure for post-market surveillance needs to start with the underlying data infrastructure for capturing, preprocessing, and aggregating data required to drive proactive risk management using more contextualized analytics and artificial intelligence.

The IoT management platforms can enable data capture from various sources such as the supply chain, production equipment and systems, distribution networks, and clinical use. As a result, medical device manufacturers can establish a two-way relationship with consumers through a digital connection that drives innovation: capture and access IoT data for full traceability throughout the product's life. Analytics and insights throughout the product lifecycle drive continuous improvement with the use of KPIs throughout the lifecycle. Data captured and analyzed across the product life cycle and especially during manufacturing plays a significant role as the source of intelligence for improving quality of design, the efficiency of planning and execution, and ultimately optimizing the use of resources, increasing quality, and driving down the overall cost of the product.

Weaving AI into the product lifecycle needs to be done so that it focuses on risk. It can be difficult for an individual quality expert to make sense of a mass of data. AI can monitor for anomalies that may seem insignificant and then automate the process of highlighting issues for a human to investigate. For example, a slight change in the performance of a component may correlate these early warning signs with subsequent quality or safety issues that need to be addressed before creating problems.

When a problem is discovered, designers can use simulation to model the problem, correct the problem, and then use the second simulation round to validate it worked as intended. This allows them to close a corrective and preventative action (CAPA) report more quickly and with less work. AI algorithms can then be set up to monitor for a new change and see if any problems remain. The monitoring can also help companies ensure that the controls they put into place work as intended.

Closed-loop quality

Closed-loop quality allows departments and organizations to validate that quality and safety requirements are being met or exceeded by making regulatory, customer, and patient demands visible throughout the entire product life cycle through a model-based approach. A model-based approach makes it easier to improve product quality, performance, and cost through more streamlined workflows across teams. It also helps to generate any regulatory documentation dynamically. It can automate a response to any audit or traceability requests when required, as all product data and documentation are linked to the model. The requirements are continuously updated to reflect changes in scientific, regulatory, and market trends. Integrating the quality of the product and process through design, manufacturing, distribution, and use/service and back allows for more effective quality planning, improved quality results on execution, and enables gathering and sending more detailed non-conformance feedback to all product life cycle areas.

The closed-loop quality digital thread allows quality assurance, audits and compliance, and training and qualification teams to more effectively facilitate continuous improvement support of engineering and manufacturing processes. Another critical aspect of the closed-loop for quality is the tracking and integrating direct customer experience into product design and performance and manufacturing process improvements. A comprehensive digital twin can create the infrastructure for automating the flow of all data related to product design, manufacturing, compliance, and quality processes using models. It also makes it possible to automatically generate regulatory compliant records as a byproduct of more efficient design and manufacturing processes.

CURRENT ADOPTION OF ADVANCED MANUFACTURING TECHNIQUES

As we stated in the beginning, not all companies are in the same place to implement advanced manufacturing. Some may not have even started, preferring to operate in traditional, paper-based business processes. However, the tools to implement all these concepts are available, and many companies have adapted them to varying degrees.

One significant consideration in this space is the position that the regulator will take regarding these techniques. Companies are often cautious of implementing innovation in a regulated area, owing to the perception that the costs of meeting the regulatory burden may be higher than they are willing to bear. However, the FDA is actively working to clarify what those barriers are to lower the perceived risk of implementation. Simply put, many of the concepts of advanced manufacturing actively support the execution of a robust quality system. As such, it is in both the regulator's and industry's best interests to support these ideas.

Suppose the regulator supports and encourages the implementation of digital tools that are available to the industry. In that case, it then becomes an exercise of planning and weighing options- things to consider for initiating activities in any or all the outlined advanced manufacturing concepts. We list some of the critical things to consider when deciding when and how to implement advanced manufacturing ideas.

CURRENT STATE OF THE MEDICAL DEVICE INDUSTRY

The Medical device industry has a tradition of producing reliable, safe, innovative products, consistent revenue growth, and excellent profitability. That same culture that has provided success in the past has also been conservative and cautious when it comes to change and has been relatively slow compared to other consumer-oriented industries to adopt digital technology. The medical device industry realities described below, along with other factors we'll explore, are forcing companies to evolve product development and manufacturing practices with technology that may seem impossible to keep up with, or at the least a daunting endeavor from where they are today.

Problems and challenges

In the last few years, studies carried out by different consulting firms like McKinsey & Company,[2] KPMG, MDIC, and the FDA point to accelerated investment in strategic business areas and new technologies being deployed. Examples of these investments include the use of additive manufacturing in orthopedics and many other products. However, the same articles also point to several problems and challenges medical device companies are facing today.

Continuous increase in costs and adverse effects from quality issues

Recent data shows that serious medical device events (Class I recalls) have kept pace with industry growth between 2014 and 2018 based on an analysis of FDA data.[3] The medical device industry, like other industries, faces constant pressure to reduce the cost of their products while material cost increases. Reducing cost and improving quality can be competing requirements if there is no proper strategy in place that also addresses return-on-investment (ROI) as a critical aspect. Implementing advanced manufacturing technologies that can improve quality can also have a positive ROI and help reduce costs.

Problems arising from accelerated technology introduction

There is no question that technology is advancing faster than most companies can adopt it. But moving to advanced manufacturing is not about trying to keep up with technology on a daily basis. It's about having the right strategy to position the organization to take advantage of technology as it's ready to be implemented. Additive manufacturing is still a maturing technology. Some companies have decided to invest in equipment. In contrast, others take a different approach, embracing design for additive manufacturing and outsourcing the production of parts while the technology evolves. Smaller companies may never have the volumes to justify the need to purchase additive machines, but they can still benefit from the technology.

Limited validation

Validation has long been a priority in design. Companies have been trying to eliminate physical prototypes for years. But validation goes beyond the product itself. The ability to virtually validate the production machines, equipment, and lines before physically operating them is a game-changer for manufacturing. No longer should manufacturers stop production lines, update the code in the programmable logic controllers (PLCs), human machine interfaces (HMIs), etc., and then test it before making adjustments and repeating the process. Virtual commissioning can validate that the equipment will run as expected, and if errors are encountered, changes are made before applying to the physical equipment. This reduces changeover downtime significantly.

The shift toward increased software in the product

Software is a rapid growth area in medical devices. Human beings are complex organisms, and medical devices have to perform just as well for a 100-pound patient as they do for a 300-pound patient. The needs of both these patients can be quite different from one another, but software can help a device perform as expected for both without requiring a unique device for each patient. The software helps in monitoring the patient and the device itself and making adjustments as needed without caregiver intervention. The integration of software with the electromechanical operation of devices makes managing the software and its relationships to the mechanical and electrical components even more critical and challenging without current technology. Knowing the correct software build that pairs with the correct revision of mechanical and electrical components and tracking their use can help identify problems before they occur. The connectedness of data across disciplines helps the company improve product quality and speed up the design of future products through the analysis of real-world performance data.

Change is inevitable

A constant in every industry, and especially the medical device industry, is change. The conservative nature of medical device companies creates a cautious attitude toward certain changes. But change does not have to be feared or resisted. Technological advances in the medical field drive changes in medical device products, which companies embrace. Medical device manufacturers should also embrace advances in the field of manufacturing technology and digitalization. The benefits of advances in the medical field coupled with advanced manufacturing capabilities are a powerful justification for change. Having a technology partner is a significant benefit to reduce risk when implementing changes in manufacturing and related areas.

There are still companies within the medical device industry struggling to get away from older business practices. They continue to face challenges to implement solutions that have already been successful in other industries like automotive, aerospace and defense, and high-tech electronics. Table 1 below shows some of the realities the medical device industry

Table 1.

28% of medical device manufacturer respondents believe their digital manufacturing transformation strategy is mature or very mature

Wilson Research

66% of all medical device companies still use paper documents during production

Axendia

90% of respondents believe digital manufacturing transformation will lessen the burden of regulatory compliance

Wilson Research

89% of medical device firms believe digital manufacturing transformation is essential/critical to address regulatory compliance

Wilson Research

79% of medical device respondents believe accelerated product innovation is a top trend impacting products

Wilson Research

Up to **18%** of lost revenue is the cost of poor quality for medical device manufacturers

McKinsey & Company [2]

Results based on Wilson Research surveys conducted in 2020 and 2021,[4] [5] except where noted.

is struggling with today and how they also believe advanced manufacturing can help.

The pressure to adopt new practices to cope with market pressures while maintaining or accelerating business targets pushes the industry to a crossroads. As a result, executives need to approach their product development, manufacturing, distribution, and product use in new ways and embrace existing solutions proven through use from other industries to enable the necessary transformations required to reach or maintain a competitive leadership position. Simultaneously, evolving technologies are maturing rapidly, requiring an eye on the horizon for how the new technology will fit into their current direction.

The lessons of natural disasters, pandemics, climate change, and other disruptions

What can be learned from history? There have been numerous events that have caused disruptions in the way we live and work. These disruptions will not stop. There will always be events beyond our control that will create unexpected disruptions to the way we live and work. These disruptions often cause:

- Rapid changes in demand
- Disruption of supply chains from the availability of raw materials to purchased materials and component products
- Difficulty to re-align manufacturing capabilities – automotive companies making respirators
- Disruption of product delivery logistics
- Disruption of the regulatory process (creating a need for emergency authorizations outside the normal approval processes)
- Limitation on access to maintenance, service, and support

While preventing these disruptions is likely beyond our control, how our operations are equipped to deal with them is not. Advanced manufacturing technologies can enable manufacturers to be better prepared when unexpected disruptions occur, either because of natural disasters or sudden changes in demand due to unforeseen industry disruptions. What history has taught us is these disruptions will continue; the question is, how well will your company be prepared to respond?

SURVEY RESULTS AND ANALYSIS

Multiple surveys were conducted to gather information on the current state of advanced manufacturing in the medical device industry and other industries for comparison. The following results were compiled from these surveys of company employees. The comparative industries represented are aerospace and defense, automotive, high-tech electronics, and others like consumer product goods, energy, mining and utilities that were compiled together in a group called other.

Results

Table 2 presents some of the results from the survey on the topic of digital manufacturing transformation maturity. The medical device industry results are provided alongside aerospace and defense, auto, electronics, and other industries for comparison. This illustrates the need for more action on the part of medical device companies and highlights that advances in other industries can prove beneficial to the strategy and implementation in the medical device industry. In many categories, automotive leads other industries, which is an indicator of how automotive companies could start and ramp up the production of ventilators during the pandemic.

Table 2. Partial results, Wilson Research survey on manufacturing transformation maturity.[4]

Topic	Industry				
	Medical %	**A&D %**	**Auto %**	**Electronics %**	**Other %**
Maturity of digital manufacturing transformation strategy					
Reactive	29	14	20	40	–
Developing	43	57	10	20	43
Mature	21	29	40	20	57
Very mature	7	–	30	20	–
Maturity of digital manufacturing simulation and analysis					
Reactive (ad hoc)	12.5	–	–	–	–
Repeatable (siloed)	62.5	25	29	100	50
Integrated	12.5	50	29	–	50
Collaborative (re-use)	12.5	25	43	–	–
Adaptive (predictive)	–	–	–	–	–
Maturity of digital manufacturing production equipment automation					
Reactive (ad hoc)	57	25	12	–	–
Repeatable (siloed)	29	–	37	–	50

Topic	Industry				
Continued	Medical %	A&D %	Auto %	Electronics %	Other %
Integrated	14	75	13	100	–
Collaborative (re-use)	–	–	13	–	50
Adaptive (predictive)	–	–	25	–	–
Maturity of digital manufacturing AI					
Reactive (ad hoc)	75	25	43	–	100
Repeatable (siloed)	12.5	50	14	–	–
Integrated	12.5	–	43	–	–
Collaborative (re-use)	–	25	–	100	–
Adaptive (predictive)	––	–	–	–	–

Other results show that 50 percent of medical device respondents indicated their organizations weren't even thinking about plant simulation yet, while 21 percent indicated it was in their three-to-five-year plan. In the other industries, 42 percent of aerospace and defense respondents indicated they had started or were fully engaged in implementing plant simulation.[5]

The medical device industry was behind the aerospace and defense, auto, and electronics industry in implementing manufacturing execution software (MES), augmented and virtual reality (AR and VR), low-code development (ahead of aerospace and defense), and MBSE. But it wasn't all bad news for the medical device industry. The industry leads adoption in areas of additive manufacturing, ERP/product lifecycle management (PLM) integration, and social collaboration.

Analysis

The data shows that accelerated product innovation is the top trend impacting medical device companies today. This is followed by regulatory complexity, technology innovation, increased number of NPIs, and shrinking lot sizes and personalization in descending order of times referenced. These trends are complicated by the top business challenges of cost reduction, improving efficiency, and meeting regulatory compliance, all with nearly the same number of references. Quality and organizational culture follow close behind and are still significant business challenges.

In most manufacturing maturity categories, the medical device industry was behind the A aerospace and defense, auto, and electronics industries[4] (see appendices C and D for complete results). Furthermore, in many of these areas, respondents from the medical device industry felt they did not have the appropriate in-house expertise to form a strategy and implement these advanced manufacturing technologies properly. These results illustrate the need for businesses to partner with a technology provider to help guide them, but 46 percent of respondents indicated they had not partnered with a technology provider.

The survey data and information from industry literature support the conclusion that the medical device industry has been slow to adopt advanced manufacturing technologies. But in doing so, they now have the unique ability to leverage what has been learned in other industries while taking advantage of more mature solutions available in the market today. The message from this is now is the time to start defining your company's strategy and planning to tackle this journey toward advanced manufacturing.

THE PATH FORWARD

The journey to advanced manufacturing is a complex challenge for every organization. It needs to be addressed with the proper technology partners and with a sound enterprise strategy. It must be flexible and inclusive of culture changes and must embrace product and technology evolution. Most importantly, it is a continuous cycle that will evolve as technology changes. Every device manufacturer finds itself in a different starting position in its journey, and sometimes the differences are also reflected at lower organization levels. Most companies' executives already recognize their challenges. The question is where to start? How do we move forward?

How do companies move forward?

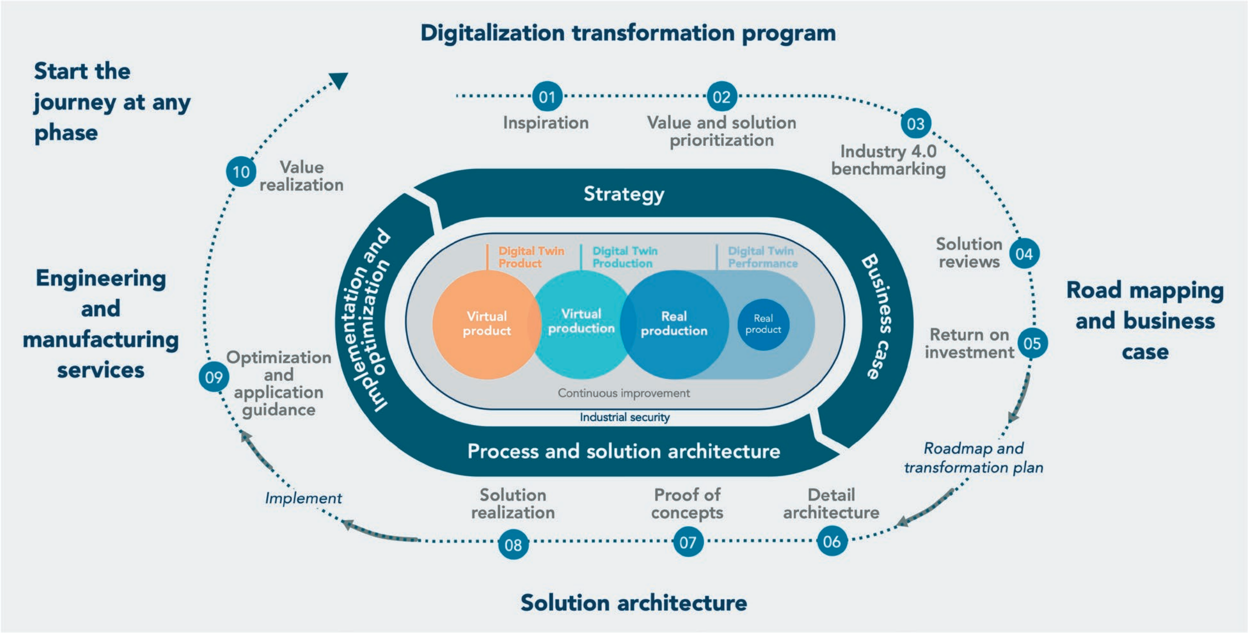
Moving forward toward advanced manufacturing for medical devices requires rethinking the overall strategy and tool landscape around the product development and manufacturing processes and the existing practices for product development, quality, and regulatory compliance. The right direction is toward a quality-centric enterprise strategy that prioritizes the integrated flow of information across all digital threads, supported by a culture focused on digitalization and enablement of virtualization technologies that accelerate product improvement before it reaches physical production. Working with a technology partner is recommended to maximize the benefits. It allows companies to focus on what they do best while leveraging the technology partner's expertise in providing phased strategic implementation plans that focus on the technology available today for the near term and considers the future direction of technology.

Developing the right strategy

The first step toward advanced manufacturing starts with a transformation strategy that analyzes the organization's key value drivers. Organizations must define a transformation landscape encompassing all the existing digital solutions focusing on a set of transformation scenarios that target perfecting the digital threads while optimizing value and prioritizing capabilities that provide immediate benefit and enable downstream processes. The strategy needs to be supported by a set of metrics that will allow benchmarking the future results as they progress and a valuation model that reflects the expected ROI.

The strategy should produce clearly defined initiatives that propose changes to the organization,

Figure 4.



technology, and the digital solution landscape. Some of those initiatives can be executed quickly and will enable more complex parts of the strategy. However, it should also include initiatives that are focused on reducing the risks introduced by innovative technologies, like knowledge gaps, changes to the existing engineering and manufacturing practices, and existing infrastructure.

Finding the right technology partner

The digital transformation requires changes in many areas of engineering, manufacturing, and information technology (IT) solutions. The right approach to developing the right strategy, choosing the right solutions, and enabling the digital landscape transformation starts by selecting the right technology partner focusing on an integrated digital transformation. Developing the proper digitalization transformation roadmap is best accomplished by engaging with an experienced technology partner with a mature end-to-end digitalization vision and a robust solution portfolio that aligns with the company's goals and ensures the roadmap is aligned with the business objectives.

Executing the strategy

The digital transformation strategy's execution needs to follow a value-oriented approach based on priorities that need to be revised in short cycles to ensure that business, product, and technology changes are continuously evaluated and future needs anticipated. Implementing such changes following Agile methodologies helps managers adapt to the business and culture changes driving the transformation. Agile methods also help control the resources and the cost associated with the transformation and focus on value delivery.

Potential barriers

The barriers perceived in previous years in the medical devices industry[6] continue to exist today in many companies despite market and technology changes.

Operating systems

- Disconnected solution islands, lack of integration
- Outdated software issues
- Manual feedback loops

Management infrastructure

- Lack of metrics, product, production, performance analytics, and proper metrics
- Lack of integrated customer feedback

Mindset and behaviors

- No culture supporting closed-loop-quality
- No culture to drive change
- Lack of collaboration within and between organizational structures
- No focus on enabling manufacturing
- Not utilizing current technology and best practices processes

Business

- Organizational structure and culture too rigid
- Conflicting priorities
- No clarity of regulatory expectations
- Financial viability for investment

How to overcome barriers

As technology and the complexity of processes and solutions are continuously changing, it is critical to have a technology partner with a long-term vision and integrated solution infrastructure that aligns with the company's direction. A suitable suite of solutions and subject matter support is critical to overcoming the data flow and integration issues that limit digital transformation evolution. It also ensures continuous technology alignment and improvement while improving ROI and reducing risk during implementation.

Executives must be onboard with the adoption of new technology and take a lead role. It is their responsibility to define an enterprise manufacturing digitalization strategy. The core of the digitalization transformation is the digital strategy that establishes the value goals and ROI targets. It identifies the specific digital threads and process scenarios that need to be optimized to achieve the efficiency and quality required. The executives also set the tone for the culture necessary to embrace the changes in technology and the organization.

It is essential to have a plan to implement new technology. There are many dependencies in a comprehensive digitalization strategy, and knowing the best order to execute is critical to success. Companies should implement the strategy incrementally using a phased approach, focusing on added value and transformation goals. The value should always be a key metric when developing a strategy. Focusing on the technologies that can provide the highest value to the overall strategy will help create synergy for the rest of the strategy.

Although there should be a phased approach for technology solutions, planning should be comprehensive. Define and strategize the complete digitalization landscape in the beginning. Move away from isolated projects that focus on one specific issue. Focus on establishing integrated digital threads that provide connectedness and measurable value. Aligning to digital threads will lead to improved collaboration between disciplines and across departments. This will speed up changes and improve overall quality due to increased visibility.

Technology is not the only thing that will undergo change during a digital transformation. People in the organization react differently to change. Leaders must enable and support organizational change. Empower teams and provide training on the technology to align the organization's capabilities to overcome the transformation's challenges. Connecting change to what the employees care about will help them embrace the change and accelerate the pace.

Companies can accelerate the introduction of technology by enabling targeted proof-of-concept initiatives to expose users to new tools, accelerate the learning curve, and evaluate the technologies before introducing new standard processes. One way for companies to leverage the knowledge and experience from other organizations, regardless of industry, is to partner with a technology provider with expertise in these transformations and understand the challenges and how to overcome them.

Emerging manufacturing technologies

Technology is advancing at an ever-increasing rate. Focusing on adopting new emerging technologies across the design and manufacturing environments is crucial to continued success for the organization. Such technologies can provide a significant impact on the product lifecycle as well as on the business's bottom line. As technology develops, the integration with and between the digital threads strengthens, providing more opportunities for more streamlined processes and fewer errors. Some of the critical technologies that are transforming the present and the future are listed below.

Additive and subtractive manufacturing

Additive and subtractive manufacturing have evolved continuously since the mid-1980s. Many forms of material deposition exist to date with many industrial applications. Machines that enable additive manufacturing are also continually evolving. Our research shows this is the most common advanced manufacturing technology being adopted by medical device companies today. How it's being implemented and connected to the rest of the organization to take full advantage of the benefits AM provides is critical. Additive manufacturing is not simply a new way to manufacture existing parts. It is a revolutionary technology that completely changes the way engineers can design parts and assemblies. It allows for assemblies consisting of multiple components to be printed as a single part, eliminating assembly time and opportunity for error or failure. Additive manufacturing can also impact plant layouts. Placing the additive machine close to where the parts are needed for final assembly enables a new JIT (and place) manufacturing era.

Artificial intelligence (AI)

Artificial intelligence is becoming an essential tool for manufacturing by providing the analysis capabilities to allow the production systems to operate faster and with improved quality. The applications include physical verification and evaluation of production system performance. AI is and will continue to be a significant driver of the autonomous manufacturing evolution.

AI and machine learning (ML) are also factoring heavily into medical devices today and will continue to make inroads in the future. The FDA has already approved at least 64 AI/ML algorithms for use.[7] As more medical device companies embrace AI and ML technology, more approved algorithms will be required to provide new advanced medical devices that are capable of being used to diagnose and treat medical conditions. Since these algorithms are patentable technology, competing medical device companies cannot use existing ones. The studies investigating and incorporating these technologies have increased from 596 in 2010 to 12,422 in 2019. The FDA has recommended a total product lifecycle (TPLC) regulatory approach to this technology to evaluate software as a medical device (SaMD).

Autonomous mobile robotics (AMRs)

Robotics is now disruptively changing the world of manufacturing. The proportion of tasks performed by robots is estimated to increase from 10 percent today to 25 percent in 2025. Advances in AMR technology will lead to the next chapter of the global manufacturing industrial revolution. While a dynamic and flexible manufacturing environment presents specific challenges for AMRs today,[8] methodologies are evolving due to research in autonomous vehicles that can address these issues and make them a reality even in the most dynamic manufacturing environments.

Blockchain

The concept of cyber manufacturing (CM) is a likely future reality. Product customization and market trends push organizations to work closely with partners and consumers in an inherently trustless network.[9] Blockchain technology provides distributed databases and a digital protocol for transactions between business partners – with no intermediaries such as banks or payment systems. A blockchain record transacts in a linear, chronological order that is always open and traceable. Blockchain has the potential to provide solutions for medical device security and traceability, from product development to device support in healthcare and patient environments.

Connectivity and edge devices

The IoT seamlessly connects the physical world and digital world, which enables new business opportunities and enormous optimization potential for all industry processes. The core IoT technology provides the technical basis for the IIoT, shaping the evolution toward autonomous, interacting smart things in the manufacturing and shop floor production environments. There are currently more than 30 million IoT devices in the world, and that number continues to increase rapidly.[10]

Edge devices are a physical component, similar to a router, that transmits data taken from a sensor or other equipment from a local network to the cloud (sometimes called a data lake). The edge device can sort and translate the data if needed to match the cloud's needs. Edge devices are required because local devices and the cloud often communicate with different protocols. When implementing edge devices, caution is necessary as they are often left vulnerable to attack. Security should be a primary consideration for edge devices and their connectivity.

Cybersecurity

In the digital age, cybersecurity is a prerequisite for organizations to safeguard critical infrastructure and products. Cybersecurity will play an increasing role in protecting the safety of equipment and people in the medical device industry. IoT and edge devices are a fast-paced growth area, and cybersecurity has not been a critical concern in these areas.[10] Organizations will need to focus cybersecurity efforts on these technologies to keep data secure and protected.

Workflow-based medical device simulation and validation

Leading-edge medical device manufacturers have expanded use of simulation to extend medical device simulation's potential by leveraging the use of multi-physics and computing capabilities to design standard models for in silico testing and eventual evaluation of results in clinical trials. Models can generate a library of patient profiles and morphologies for accurately evaluating the devices in a virtual population, extending the applicability and quality of the design.[11]

CONCLUSION

The time is now. The importance of the journey to advanced manufacturing has never been greater for the medical device industry. The pace of technology innovation will not slow down and wait for companies to catch up. The need for rapid innovation of medical devices has never been more apparent. The need for flexible manufacturing and agile processes that can adapt to the ever-changing demand is evident. The data that can be leveraged to improve quality, design, manufacturing operations, and patient care can finally be harvested with the technology available today.

The stakes couldn't be higher. The survival of businesses is on the line. Firms that start this journey will be better suited to survive far into the future; those that don't will fade away. There is no better time than now to start the journey to advanced manufacturing.

The benefits couldn't be more paramount. Patients need superior products with improved quality, safety, and reliability that empower them to have an active role in their care. Advanced manufacturing can help companies meet patient needs with accelerated new product introduction, personalized medical devices, improved health monitoring, diagnoses, and treatment. Advanced Manufacturing will ensure the right products at the right time to the right patients with higher quality and enhanced reliability, providing safer devices for better patient outcomes.

APPENDIX A: REVIEW OF LITERATURE AND CASE STUDIES

To better comprehend the impact of technologies in the digital threads and the possible benefits for medical device manufacturers, we reviewed existing industry literature and more than 150 case studies of successful applications of technology in the automotive, aerospace and defense, high tech electronics, and medical devices industries.

The automotive, aerospace and defense, and high-tech electronics industries face current challenges, including the shift towards electrification and autonomous vehicles, smart and mobile devices, and the race for commercial space travel. These challenges have been met with great success by companies like Samsung (IoT, Robotics, AI)[12] and SpaceX (3D Printing)[13] due to their ability to quickly adopt new technologies and introduce new products from R&D to manufacturing with high efficiency and quality. Their challenges are like those of the medical devices industry. The companies' future results require the highest quality products that align with many regulations globally and force them to rethink how they will meet the external demands placed on their internal operations. Evaluating how these industries have improved their operations by using defined digital threads provides medical device manufacturers with a roadmap to define their advanced manufacturing path within the digital threads unique to medical device companies.

Design control

An integrated backbone that supports product strategy and governance and enables integrated data flows during the product lifecycle is critical for optimized digital threads. Automotive, aerospace, and electronics manufacturers using technologies to promote advanced manufacturing rely on having an integrated PLM backbone that supports collaboration and executing the digital thread's engineering activities. Data accuracy and accessibility for interdisciplinary teams enable shorter design cycles and better designs. Teams can use technologies to improve design, performance, quality and efficiency to flow the product definition to manufacturing faster.

Automotive manufacturers have long relied on integrated PLM solutions to handle integrated data and knowledge management (for example, Toyota, Ford, GM, VW). The practice is also well established in aerospace (Boeing, Airbus) and other industries. Examples of medical device manufacturers include integrated DNA Technologies (Faster ISO 9001 and ISO 1345 certification), Siemens Healthcare (80 percent requirements re-use, higher quality), Wright Medical Technology (NPIs in record times).

Many medical device manufacturers still work in complex and outdated system landscapes. Sometimes paper-based procedures are used to achieve the same data management facing continuous data integration challenges, limited collaboration and efficiency, lack of flexibility, and difficulties in optimizing production processes and controlling quality outcomes. The lack of a proper PLM backbone is commonly cited as one of the most critical issues affecting medical device manufacturers.

Design excellence

Product engineering needs to define and design the product to accelerate the time it takes to reach manufacturing without sacrificing quality or performance. Key technologies used in this digital thread include:

- Model-based systems engineering
- Generative computer-aided system (CAx) design
- Software design and management
- Design for manufacturing
- Design for service
- Design for test
- Simulation, including design optimization

The different industries' approaches concerning these technologies have driven their ability to respond to new product challenges and new technology disruptions. The automotive, aerospace, and high-tech electronics industries, for example, have spent significant resources to standardize their CAx practices across design teams and suppliers to reduce the necessary design cycle time and improve on other factors that facilitate the work of manufacturing. Implementation of new additive manufacturing technologies in both industries is successful with the support of generative design. Generative design allows design engineers to create optimized models for 3D printing, reducing the number of individual components and simplifying fabrication. In recent years, MBSE has also become critical for both industries to accurately define the functions expected from the product, improve their verification, increase technical knowledge reuse, and shorten new programs' cycle time. In addition to the design activities, design for manufacturing has been critical to bridging the divide between engineering and manufacturing, thus ensuring the product's manufacturability, accelerating the time to production and improving product quality, thereby reducing quality issues and lowering the cost of the final product. Design for service in automotive and aerospace is another critical technology that enables manufacturers to facilitate field support of their products, maintain product performance, and fulfill customer needs. The high-tech electronics industry has also added design for testing by implementing elements of the design precisely engineered to facilitate product validation, field testing and monitoring.

The rapid expansion of software used in products is another design area in which companies quickly evolved and adapted to new technologies. Aerospace, automotive and electronic products depend heavily on software components to operate. Software design and management are critical elements of design excellence typically integrated into their organizational structure and design practices.

A common technology across all industries is the use of product design simulation. Simulation allows manufacturers to perform functional verification and validation and ensure the product's manufacturability, reducing the need for costly and time-consuming prototypes. Simulation areas include structural analysis, acoustics and vibration, system dynamics, thermal and flow analysis, stress analysis, controls development and many others. Design exploration technology is used in conjunction with simulation to automate the evaluation of different design alternatives.

The proof of success in using these technologies is in the reduced time and resources that automotive, aerospace and defense and high-tech electronics companies spend on NPI for manufacturing compared to the previous decades, and even a few years back, while improving efficiencies and quality. Certification in aerospace is a time-consuming and expensive regulatory process. TLG Aerospace replaces costly wind tunnel tests by using computational fluid dynamics (CFD) analysis. Automated test correlation for verification allows Honda Jet to reduce the amount of physical testing from requirements to verification by correlating the physical to the analytical simulation models.

Some of the leading medical device manufactures are also implementing advanced product design technologies. Some examples of medical device success stories include the use of design exploration and 3D computer-aided engineering (CAE) by BD to improve syringe mechanisms, Hitachi's use of thermal analysis to improve ultrasound probes, Thoratec's use of design exploration for heart pump design studies and generative design and 3D printing for customer-specific protheses in orthopedics.

Operational excellence

Manufacturers have significant investments in existing facilities (Brownfields) that need to be continuously adapted to support new products. Also, new products sometimes require the development of specialized facilities. The technologies used to improve manufacturing processes and facilities include process and line/plant simulation, robotics and human safety analysis and virtual commissioning of equipment and lines.

Automotive and electronic manufacturers with large production volumes use process simulation to evaluate the fabrication process and identify process activity improvements to optimize design, time, materials and tooling/equipment. Examples of these technologies include computer-aided system virtual design reviews for assembly (VDRA), computer-aided manufacturing (CAM) simulations (part fabrication simulation), manufacturing process design (process, human analysis and robotics) and process flow simulations to calculate operation timings, resource consumptions, etc. Some of the leading companies also use production line and plant simulations to evaluate the line capabilities, define equipment location and capacity, evaluate material logistics, production throughput, eliminate bottlenecks and ensure operator and robot safety. Companies use the digital twin of the product and equipment lines to simulate the line and evaluate its operation. This reduces downtime of the physical line and allows for testing and optimization virtually. Virtual commissioning is another technology that is becoming more widely used to support greenfield and brownfield production line changes. Changes are made and virtually simulated to test the operation of the line before implementing the change, allowing for corrections and adjustments to minimize downtime during the transition.

Examples of process and line optimization in the automotive industry include Mahindra's (25 percent reduction in greenfield setup time and a 28 percent improvement in work time) and Volvo (savings up to 50 percent engineering costs). Examples in the medical devices industry include Siemens Magnet Technology (optimized material flows, greater flexibility, low waste), MEDIN (faster NPI, larger market footprint), Bausch+Stroebel (30 percent savings in engineering, flexible, customer-oriented facilities).

These technologies enable manufacturers to integrate new products into production faster, improve operation efficiency and reduce manufacturing execution times and costs. However, the medical devices industry's evolution has been slower than in other industries, and many technology efforts are still fragmented.

Flexible manufacturing

As soon as the product and the production line have aligned with the production process's needs, the product is ready to move into the manufacturing execution environment. This digital thread focuses on the technologies needed to plan and manage the physical product's fabrication. Critical technologies include the manufacturing execution system (MES) backbone, shop floor automation, robotic equipment and other fabrication technologies.

Automotive, aerospace and electronics manufacturers use MES as the backbone technology that glues engineering (PLM) with the supply chain and the shop floor.

Manufacturing execution enables optimal resource use, control of costs, planning and scheduling production activities, a clear view of the supply and delivery chains, and orchestrates scheduling activities and resources on the shop floor. The integration of the shop floor allows continuous monitoring and further optimization of the operations. In addition, it provides a closed-loop for manufacturing to feedback issues found during execution back into engineering and process and production optimization. Industry results show increased efficiency and flexibility for new product introduction and enable higher manufacturing planning flexibility, consistent execution, more efficient material logistics, cost reduction and improved quality.

Automotive companies like Ford and GM have highly integrated and automated facilities, yet they are so flexible they can handle single product order configurations and adapt resources and their supply chain to support turbulent market conditions as observed during the medical ventilator production crisis in March 2020.

Some of the leading medical device manufacturers implementing technologies for flexible manufacturing include Boston Scientific (cardiovascular-paperless manufacturing across facilities worldwide, 54 percent less CAPAs, 25 percent fewer nonconformances, $40M overall cost savings), Fresenius (diagnostic devices – 100 percent elimination of first and second manufacturing device history record (DHR) reviews, 82 percent reduction in final DHR review, $1.6M in inventory reduction), and ConforMIS (orthopedics – integrated execution and quality management helps reduce 65 percent of quality reviews and 20 percent shorter lead time, 100 percent elimination of paper cost).

Connected care

Quality is a critical topic for automotive, aerospace, and electronics due to the possible impact on consumer brand perception and economic effect on the companies when problems are found after the products have been made operational. Examples of significant issues that have impacted these industries include:

- Safety recalls for Toyota due to faulty brakes and airbags[14]
- Faulty design in the flight control system of the Boeing 737 MAX that cost the lives of more than 346 passengers in two accidents[15]
- Battery recall for Samsung that severely impacted the market of the Samsung Galaxy Note 7 phone series worldwide[16]

In the medical device industry, quality can have an even more significant impact on companies due to the direct effect on the consumers' health. McKinsey's[2] research points to a staggering 10 percent average drop in share price in addition to penalties and the long-term impact on the company's reputation. Examples of adverse events include recalls at Medtronic (lead-to-ICD wires – Oct 2007) and Boston Scientific (defibrillators – March 2010), significantly impacting the companies' shareholder value. Most importantly, the upward trend in the medical industry's adverse quality issues continue to accelerate with increased software-related issues.

The closed-loop quality thread intersects all other digital threads. Quality starts early in the design and continues during verification planning, product performance analysis, and physical testing. It impacts the manufacturing process's design and is critical to selecting materials and suppliers, fabrication technology, and equipment. The quality results from manufacturing execution and those obtained from service providers and customers are crucial to continuously improving all other digital threads.

The automotive, aerospace, and high-tech electronics manufacturers have implemented methodologies like CAPA, APQP, and FMEA to define and document product quality, physical verification, plan and control audits, document nonconformances, customer feedback, and warranty issues. Quality information is sent back to PLM and supplier quality management systems to close the quality improvement cycle. The degree of success depends on having the right systems integration supporting the engineering and manufacturing processes. Most importantly, the closed-loop quality digital thread depends on the organizations' commitment to quality throughout the product life cycle. A study from Aberdeen Group[17] found a 6 percent higher OEE, with almost 10 percent more successful NPIs, 3 percent more products in compliance with regulations, mandates, SOPs, and over 50 percent lower failure costs on companies having a QMS solution fully integrated with PLM. The digital twin paradigm brings a higher potential to closed-loop quality by enabling virtual verification to reduce manufacturing defects, reduce the cost of traceability with integrated factory automation, and use IoT and AI supporting analysis of execution quality and equipment data to improve manufacturing operations.

The medical devices industry needs to invest in enabling a closed-loop quality digital thread that accelerates the introduction of the highest quality products to the market and brings the most benefit to the patient's health. A vital requirement of digital transformation is to move away from a culture centered on documentation management to a culture that focuses on digital excellence. The risks are too high for medical device manufacturers to maintain the status quo as products become more complex. The pace of introducing new products to the market and incorporating the latest technologies puts intense pressure on engineering and manufacturing teams, increasing the risk of a potentially severe impact on quality and safety, directly impacting the customer's health.

Post-market surveillance

Consumer trends focusing on product quality, energy consumption (green technologies), and mobile support and monitoring of devices in different industries drive manufacturers to deploy technologies that enable the gathering and analyzing of data both in the manufacturing environment and after products have been delivered to the customers.

This digital thread focuses on technologies that support gathering information and analytics to improve different product lifecycle areas, including manufacturing and post-manufacturing. The key technologies include:

- Industrial IoT (data and analytics gathered from manufacturing equipment and line sensors to optimize equipment operations)
- Data collected from production execution to evaluate manufacturing performance (performance analytics)
- Data gathered from customer feedback concerning quality and product performance (consumer feedback)
- Data captured from product performance and service in the field (IoT)
- Data gathered along the digital threads to certify conformance to regulations, product safety, and quality assurance (trusted traceability)

Industrial IoT is one of the critical technology solutions deployed by the automotive and high-tech electronic industries to provide real-time analytics supporting automation technology (SCADA). In highly automated environments, the IIoT analytics enable faster response time to manufacturing operation events and support the planning and implementation of preventive maintenance, thus improving operation and reducing the risk of bottlenecks or downtimes.

In high-tech electronics, data provided from field devices help manufacturers understand device behavior and performance (usage patterns and issues), allowing them to plan upgrades and support capabilities. For example, automotive is implementing similar technology for autonomous driving connected mobility, and aerospace already implements the technology in a lot of aircraft equipment and system monitoring devices.

Medical device manufacturers are also challenged by similar trends in manufacturing and health care settings like hospitals where devices are mobile (wearable, shareable) and difficult to service due to the wide variation in technologies, platforms, and limited industry standards. To improve manufacturing operations and quality, medical device manufacturers need to embrace technology to gather and analyze manufacturing execution data and field service data and provide metrics and KPIs that facilitate strategic decision making.

MDIC
MEDICAL DEVICE INNOVATION CONSORTIUM

APPENDIX B: GLOSSARY OF TERMS AND ABBREVIATIONS

Design for manufacturing and assembly (DFMA)	DFMA is an engineering methodology that simplifies a product's design to improve ease of manufacture and assembly efficiency.
Digital enterprise	A digital enterprise is a company where all business processes are driven by digital technology and big data.
Digital manufacturing	Digital manufacturing uses an integrated, computer-based system comprised of simulation, 3D visualization, analytics, and collaboration tools to simultaneously create product and manufacturing process definitions.
Digital thread	The digital thread represents a connected data flow and integrated process view of the product data throughout its lifecycle across traditionally siloed functions. In addition, the digital thread helps document and trace the data transformation as it moves across different processes and operations.
Digital transformation	Digital transformation is the process of digitalizing business processes and information to pursue a more agile and efficient business model.
Digital twin	A digital twin is an exact, virtual representation of a product or process that includes design specifications and engineering models describing its geometry, materials, components, and behavior. It also consists of the as-built and operational data unique to the specific physical asset that it represents. The digital twin is used to communicate this information to all other functional areas within an organization and its partners while virtually validating its physical counterpart's performance.
Digitalization	Digitalization is the analysis and application of digital data insights to improve products, processes, and operations.
Generative design	Generative design is an engineering approach that uses algorithms to discover every possible iteration of a solution.
Industrial Internet of Things (IIOT)	Industrial Internet of Things (IIoT) is the application of an IoT framework to devices and machines within manufacturing. The IIoT is part of a larger concept known as the Internet of Things (IoT). The IoT is a network of intelligent computers, devices, and objects that collect and share vast amounts of data. The collected data is sent to a central cloud-based service aggregated with other data and then shared with end users in a helpful way.
Industry 4.0	Industry 4.0 is a concept that describes the use of digitalization and networked technology to create the fourth industrial revolution.
MDIC	Medical Device Innovation Consortium
Model-based systems engineering (MBSE)	Model-based systems engineering helps companies develop the complex products their customers demand. Model-based systems engineering focuses on creating and exploiting domain models as the primary means of information exchange between engineers.
NPI	New product introduction
PMI	Product and manufacturing Information
Flexible manufacturing	Combine manufacturing simulation, execution, and automation to transform fast or flexible processes into agile and automated operations.

APPENDIX C: ADVANCED MANUFACTURING TECHNOLOGY ADOPTION STUDY 2021

A1. What is your role in the decision process of adopting new technologies?

	Total	Medical device industry	A&D industry	Auto industry	Electronics industry	Other industry	MDEC
All respondants	68	14	10	13	7	10	4
No answer	3	0	0	0	0	0	0
Those answering	65 100%	14 100%	10 100%	13 100%	7 100%	10 100%	4 100%
I make recommendations regarding purchase decisions	27 41.5	8 57.1	6 60.0	3 23.1	3 42.9	4 40.0	3 75.0
I have some influence over purchasing decisions	23 35.4	7 50.0	2 20.0	7 53.8	3 42.9	3 30.0	2 50.0
I make purchase decisions	19 29.2	6 42.9	3 30.0	4 30.8	3 42.9	2 20.0	2 50.0
I am a user of software tools, but do not participate in purchase decisions	16 24.6	0 0.0	2 20.0	6 46.2	1 14.3	2 20.0	0 0.0
Other (specify)	3 4.6	0 0.0	0 0.0	0 0.0	0 0.0	1 10.0	1 25.0

Note: Multiple response

A2. Which most closely describes your job responsibilities?

	Total	Medical device industry	A&D industry	Auto industry	Electronics industry	Other industry	MDEC
All respondants	68	14	10	13	7	10	4
No answer	8	0	0	0	0	0	0
Those answering	60 100%	14 100%	10 100%	13 100%	7 100%	10 100%	4 100%
C-suite	4 6.7	1 7.1	1 10.0	0 0.0	2 28.6	0 0.0	1 25.0
Engineering management	8 13.3	2 14.3	1 10.0	3 23.1	1 14.3	1 10.0	0 0.0
Manufacturing management	1 1.7	1 1.7	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0
Quality management	2 3.3	1 1.7	0 0.0	1 7.7	0 0.0	0 0.0	0 0.0
Senior management	3 5.0	2 14.3	0 0.0	0 0.0	1 14.3	0 0.0	2 50.0
Design engineer	10 16.7	3 21.4	1 10.0	0 0.0	2 28.6	2 20.0	0 0.0
Electronics engineer	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0
Hardware engineer	1 1.7	0 0.0	0 0.0	0 0.0	0 0.0	1 10.0	0 0.0
Mechanical engineer	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0
Manufacturing engineer	1 1.7	0 0.0	1 10.0	0 0.0	0 0.0	0 0.0	0 0.0
Simulation engineer	1 1.7	0 0.0	1 10.0	0 0.0	0 0.0	0 0.0	0 0.0
Software engineer	2 3.3	0 0.0	1 10.0	1 7.7	0 0.0	0 0.0	0 0.0
Project manager	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0
Quality	1 1.7	0 0.0	0 0.0	1 7.7	0 0.0	0 0.0	0 0.0
Research and development	7 11.7	0 0.0	1 10.0	2 15.4	1 14.3	3 30.0	0 0.0
Other engineer (specify)	3 5.0	0 0.0	1 10.0	2 15.4	0 0.0	0 0.0	0 0.0
Software tools support	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0

Continued	Total	Medical device industry	A&D industry	Auto industry	Electronics industry	Other industry	MDEC
All respondants	**68**	**14**	**10**	**13**	**7**	**10**	**4**
No answer	**8**	**0**	**0**	**0**	**0**	**0**	**0**
Those answering	**60** **100%**	**14** **100%**	**10** **100%**	**13** **100%**	**7** **100%**	**10** **100%**	**4** **100%**
IT	3 5.0	1 7.1	0 0.0	0 0.0	0 0.0	2 20.0	0 0.0
Sales, marketing	3 5.0	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0	1 25.0
Engineering services/consulting	8 13.3	3 21.4	2 20.0	3 23.1	0 0.0	0 0.0	0 0.0
Industry analyst	1 1.7	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0
Education	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0
Other (specify)	1 1.7	0 0.0	0 0.0	0 0.0	0 0.0	1 10.0	0 0.0

Note: Single response

A3. What is your organization's primary business activity or industry?

	Total	Medical device industry	A&D industry	Auto industry	Electronics industry	Other industry	MDEC
All respondants	**68**	**14**	**10**	**13**	**7**	**10**	**4**
No answer	**14**	**0**	**0**	**0**	**0**	**0**	**1**
Those answering	**54** **100%**	**14** **100%**	**10** **100%**	**13** **100%**	**7** **100%**	**10** **100%**	**3** **100%**
Aerospace and defense	10 18.5	0 0.0	10 100.0	0 0.0	0 0.0	0 0.0	0 0.0
Automotive and transportation	13 24.1	0 0.0	0 0.0	13 100.0	0 0.0	0 0.0	0 0.0
Electronics and semiconductors	7 13.0	0 0.0	0 0.0	0 0.0	7 100.0	0 0.0	0 0.0
Medical devices	14 25.9	14 100.0	0 0.0	0 0.0	0 0.0	0 0.0	3 100.0
Other (specify)	10 18.5	0 0.0	0 0.0	0 0.0	0 0.0	10 100.0	0 0.0

Note: Single response

A4. In which medical device sector do you primarily work?

	Total	Medical device industry	A&D industry	Auto industry	Electronics industry	Other industry	MDEC
All respondants	68	14	10	13	7	10	4
No answer	54	0	10	13	7	10	1
Those answering	14 100%	14 100%	0 100%	0 100%	0 100%	0 100%	3 100%
Electro-medical equipment	6 42.9	6 42.9	0	0	0	0	2 66.7
Irradiation apparatuses	0 0.0	0 0.0	0	0	0	0	0 0.0
Surgical and medical instruments	3 21.4	3 21.4	0	0	0	0	0 0.0
Surgical appliances and supplies	1 7.1	1 7.1	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0
Dental equipment and supplies	1 7.1	1 7.1	0	0	0	0	0 0.0
Other (specify)	3 21.4	3 21.4	0	0	0	0	1 33.3

Note: Single response

A5. Which of the following categories best reflects your company's annual revenue?

	Total	Medical device industry	A&D industry	Auto industry	Electronics industry	Other industry	MDEC
All respondants	68	14	10	13	7	10	4
No answer	17	0	0	2	0	1	1
Those answering	51 100%	14 100%	10 100%	11 100%	7 100%	9 100%	3 100%
Less than $1 million	5 9.8	4 28.6	1 10.0	0 0.0	0 0.0	0 0.0	0 0.0
$1 million–$4.9 million	5 9.8	2 14.3	0 0.0	0 0.0	2 28.6	1 11.1	0 0.0
$5 million–$99.9 million	3 5.9	1 7.1	0 0.0	1 9.1	1 14.3	0 0.0	0 0.0
$100 million–$999 million	9 17.6	1 7.1	0 0.0	5 45.5	2 28.6	1 11.1	0 0.0
$1 billion–$4.9 billion	11 21.6	4 28.6	3 30.0	1 9.1	1 14.3	2 22.2	2 66.7
$5 billion or more	18 35.3	2 14.3	6 60.0	4 36.4	1 14.3	5 55.6	1 33.3

Note: Ranged response

B1. How would you describe the maturity level that most closely applies to your company's digital manufacturing transformation strategy?

	Total	Medical device industry	A&D industry	Auto industry	Electronics industry	Other industry	MDEC
All respondants	**68**	**14**	**10**	**13**	**7**	**10**	**4**
No answer	**25**	**0**	**3**	**3**	**2**	**3**	**1**
Those answering	**43** **100%**	**14** **100%**	**7** **100%**	**10** **100%**	**5** **100%**	**7** **100%**	**3** **100%**
Not mature: Evolving vision, reactive	9 20.9	4 28.6	1 14.3	2 20.0	2 40.0	0 0.0	0 0.0
Developing: Disconnected initiatives Focus on vision, infrastructure, product improvement	15 34.9	6 42.9	4 57.1	1 10.0	1 20.0	3 42.9	1 33.3
Mature, but not fully evolved: Focus on knowledge, value, customer	14 32.6	3 21.4	2 28.6	4 40.0	1 20.0	4 57.1	1 33.3
Very mature: Focus on new technology, intelligence, customer orientation	5 11.6	1 7.1	0 0.0	3 30.0	1 20.0	0 0.0	1 33.3

Note: Single response

B2. What are the top 3 market and technology trends impacting your product(s)?

	Total	Medical device industry	A&D industry	Auto industry	Electronics industry	Other industry	MDEC
All respondants	**68**	**14**	**10**	**13**	**7**	**10**	**4**
No answer	**24**	**0**	**2**	**3**	**2**	**3**	**1**
Those answering	**44** **100%**	**14** **100%**	**8** **100%**	**10** **100%**	**5** **100%**	**7** **100%**	**3** **100%**
Accelerated product innovation	35 79.5	11 78.6	7 87.5	9 90.0	4 80.0	4 57.1	3 100.0
Technology innovation	31 70.5	7 50.0	5 62.5	8 80.0	5 100.0	6 85.7	2 66.7
Regulatory complexity	19 43.2	8 57.1	2 25.0	3 30.0	2 40.0	4 57.1	2 66.7
Increased number of new product introductions	12 27.3	4 28.6	0 0.0	4 40.0	1 20.0	3 42.9	0 0.0
Shrinking lot sizes and personalization	8 18.2	4 28.6	0 0.0	2 20.0	1 20.0	1 14.3	0 0.0
Big data analytics	6 13.6	2 14.3	1 12.5	1 10.0	1 20.0	1 14.3	1 33.3
Other (specify)	4 9.1	1 7.1	3 37.5	0 0.0	0 0.0	0 0.0	1 33.3

Note: Multiple response

B3. What are the top 3 business challenges that are driving your company's digitalization efforts?

	Total	Medical device industry	A&D industry	Auto industry	Electronics industry	Other industry	MDEC
All respondants	68	14	10	13	7	10	4
No answer	25	0	3	3	2	3	1
Those answering	43 100%	14 100%	7 100%	10 100%	5 100%	7 100%	3 100%
Improving efficiency	28 65.1	9 64.3	2 28.6	8 80.0	3 60.0	6 85.7	3 100.0
Cost reduction	26 60.5	7 50.0	3 42.9	6 60.0	4 80.0	6 85.7	1 33.3
Innovation	15 34.9	3 21.4	3 42.9	4 40.0	2 40.0	3 42.9	1 33.3
Regulatory and compliance	13 30.2	6 42.9	2 28.6	1 10.0	2 40.0	2 28.6	0 0.0
Quality	10 23.3	3 21.4	3 42.9	1 10.0	1 20.0	2 28.6	0 0.0
Culture	9 20.9	5 35.7	1 14.3	2 20.0	0 0.0	1 14.3	2 66.7
IT infrastructure	8 18.6	1 7.1	1 14.3	3 30.0	2 40.0	1 14.3	1 33.3
Business practices	5 11.6	3 21.4	1 14.3	0 0.0	1 20.0	0 0.0	1 33.3
Other (specify)	3 7.0	0 0.0	2 28.6	1 10.0	0 0.0	0 0.0	0 0.0

Note: Multiple response

B4. Is your company partnering with a technology provider to plan and manage your digital manufacturing transformation?

	Total	Medical device industry	A&D industry	Auto industry	Electronics industry	Other industry	MDEC
All respondants	68	14	10	13	7	10	4
No answer	25	0	3	3	2	3	1
Those answering	43 100%	14 100%	7 100%	10 100%	5 100%	7 100%	3 100%
Yes	22 51.2	8 57.1	2 28.6	6 60.0	2 40.0	4 57.1	2 66.7
No	21 48.8	6 42.9	5 71.4	4 40.0	3 60.0	3 42.9	1 33.3

Note: Single response

C1. How critical is your digital manufacturing transformation success to address your regulatory compliance needs?

	Total	Medical device industry	A&D industry	Auto industry	Electronics industry	Other industry	MDEC
All respondants	68	14	10	13	7	10	4
No answer	39	5	5	5	5	5	1
Those answering	29 100%	9 100%	5 100%	8 100%	2 100%	5 100%	3 100%
Not important =1	2 6.9	1 11.1	1 20.0	0 0.0	0 0.0	0 0.0	0 0.0
=2	3 10.3	0 0.0	0 0.0	3 37.5	0 0.0	0 0.0	0 0.0
=3	10 34.5	3 33.3	0 0.0	1 12.5	2 100.0	4 80.0	1 33.3
=4	11 37.9	3 33.3	3 60.0	4 50.0	0 0.0	1 20.0	2 66.7
Critical = 5	3 10.3	2 22.2	1 20.0	0 0.0	0 0.0	0 0.0	0 0.0

Note: Ranged response

MDIC
MEDICAL DEVICE INNOVATION CONSORTIUM

C2. Do you think that your digital manufacturing transformation will lessen the burden of your regulatory compliance needs?

	Total	Medical device industry	A&D industry	Auto industry	Electronics industry	Other industry	MDEC
All respondants	68	14	10	13	7	10	4
No answer	37	4	4	5	5	5	1
Those answering	31 100%	10 100%	6 100%	8 100%	2 100%	5 100%	3 100%
Yes	22 71.0	9 90.0	5 83.3	6 75.0	1 50.0	1 20.0	3 100.0
No	9 29.0	1 10.0	1 16.7	2 25.0	1 50.0	4 80.0	0 0.0

Note: Single response

C3. Would you consider having direct collaboration with regulator teams to improve/ accelerate your compliance activities?

	Total	Medical device industry	A&D industry	Auto industry	Electronics industry	Other industry	MDEC
All respondants	68	14	10	13	7	10	4
No answer	37	4	5	4	5	5	1
Those answering	31 100%	10 100%	5 100%	9 100%	2 100%	5 100%	3 100%
Direct collaboration	9 29.0	3 30.0	2 40.0	3 33.3	0 0.0	1 20.0	2 66.7
Integrated collaboration	7 22.6	3 30.0	1 20.0	0 0.0	2 100.0	1 20.0	1 33.3
No direct collaboration	6 19.4	1 10.0	1 20.0	4 44.4	0 0.0	0 0.0	0 0.0
Not sure	9 29.0	3 30.0	1 20.0	2 22.2	0 0.0	3 60.0	0 0.0

Note: Single response

C4. Select the statement you agree with in terms of your current regulatory compliance goals

	Total	Medical device industry	A&D industry	Auto industry	Electronics industry	Other industry	MDEC
All respondants	68	14	10	13	7	10	4
No answer	38	4	6	4	5	5	1
Those answering	30 100%	10 100%	4 100%	9 100%	2 100%	5 100%	3 100%
Struggle to meet	8 26.7	3 30.0	1 25.0	1 11.1	2 100.0	1 20.0	0 0.0
Consistently meets the first time	16 53.3	6 60.0	2 50.0	5 55.6	0 0.0	3 60.0	3 100.0
Exceeds	4 13.3	1 10.0	1 25.0	1 11.1	0 0.0	1 20.0	0 0.0
Far exceeds	2 6.7	0 0.0	0 0.0	2 22.2	0 0.0	0 0.0	0 0.0

Note: Single response

C5. Do you think your digital manufacturing transformation makes some regulatory requirements obsolete?

	Total	Medical device industry	A&D industry	Auto industry	Electronics industry	Other industry	MDEC
All respondants	68	14	10	13	7	10	4
No answer	37	4	5	4	5	5	1
Those answering	31 100%	10 100%	5 100%	9 100%	2 100%	5 100%	3 100%
Yes	13 41.9	6 60.0	2 40.0	1 11.1	2 100.0	2 40.0	3 100.0
No	18 58.1	4 40.0	3 60.0	8 88.9	0 0.0	3 60.0	0 0.0

Note: Single response

D1a. How would you describe your company's maturity level today concerning advanced manufacturing in the following areas? – Systems engineering

	Total	Medical device industry	A&D industry	Auto industry	Electronics industry	Other industry	MDEC
All respondants	68	14	10	13	7	10	4
No answer	45	6	6	5	6	8	1
Those answering	23 100%	8 100%	4 100%	8 100%	1 100%	2 100%	3 100%
Reactive (ad hoc)	2 8.7	1 12.5	0 0.0	0 0.0	1 100.0	0 0.0	0 0.0
Repeatable (siloed)	10 43.5	4 50.0	2 50.0	3 37.5	0 0.0	1 50.0	1 33.3
Integrated	4 17.4	1 12.5	1 25.0	1 12.5	0 0.0	1 50.0	1 33.3
Collaborative (re-use)	3 13.0	1 12.5	0 0.0	2 25.0	0 0.0	0 0.0	1 33.3
Adaptive (predictive)	4 17.4	1 12.5	1 25.0	2 25.0	0 0.0	0.0	0 0.0

Note: Ranged response

D1b. How would you describe your company's maturity level today concerning advanced manufacturing in the following areas? – Product configuration and change control

	Total	Medical device industry	A&D industry	Auto industry	Electronics industry	Other industry	MDEC
All respondants	68	14	10	13	7	10	4
No answer	46	6	6	6	6	8	1
Those answering	22 100%	8 100%	4 100%	7 100%	1 100%	2 100%	3 100%
Reactive (ad hoc)	2 9.1	0 0.0	0 0.0	1 14.3	1 100.0	0 0.0	0 0.0
Repeatable (siloed)	9 40.9	5 62.5	2 50.0	2 28.6	0 0.0	0 0.0	1 33.3
Integrated	2 9.1	1 12.5	0 0.0	1 14.3	0 0.0	0 0.0	1 33.3
Collaborative (re-use)	8 36.4	2 25.0	1 25.0	3 42.9	0 0.0	2 100.0	1 33.3
Adaptive (predictive)	1 4.5	0 0.0	1 25.0	0 0.0	0 0.0	0 0.0	0 0.0

Note: Ranged response

D1c. How would you describe your company's maturity level today concerning advanced manufacturing in the following areas? – Generative/additive design

	Total	Medical device industry	A&D industry	Auto industry	Electronics industry	Other industry	MDEC
All respondants	68	14	10	13	7	10	4
No answer	47	7	6	6	6	8	1
Those answering	21 100%	7 100%	4 100%	7 100%	1 100%	2 100%	3 100%
Reactive (ad hoc)	3 14.3	2 28.6	0 0.0	0 0.0	0 0.0	1 50.0	1 33.3
Repeatable (siloed)	7 33.3	2 28.6	1 25.0	3 42.9	1 100.0	0 0.0	0 0.0
Integrated	6 28.6	2 28.6	2 50.0	1 14.3	0 0.0	1 50.0	2 66.7
Collaborative (re-use)	4 19.0	0 0.0	1 25.0	3 42.9	0 0.0	0 0.0	0 0.0
Adaptive (predictive)	1 4.8	1 14.3	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0

Note: Ranged response

D1d. How would you describe your company's maturity level today concerning advanced manufacturing in the following areas? – Product design

	Total	Medical device industry	A&D industry	Auto industry	Electronics industry	Other industry	MDEC
All respondants	68	14	10	13	7	10	4
No answer	46	6	6	6	6	8	1
Those answering	22 100%	8 100%	4 100%	7 100%	1 100%	2 100%	3 100%
Reactive (ad hoc)	1 4.5	0 0.0	0 0.0	1 14.3	0 0.0	0 0.0	0 0.0
Repeatable (siloed)	7 31.8	4 50.0	1 25.0	0 0.0	1 100.0	1 50.0	1 33.3
Integrated	6 27.3	1 12.5	2 50.0	3 42.9	0 0.0	0 0.0	0 0.0
Collaborative (re-use)	7 31.8	3 37.5	0 0.0	3 42.9	0 0.0	1 50.0	2 66.7
Adaptive (predictive)	1 4.5	0 0.0	1 25.0	0 0.0	0 0.0	0 0.0	0 0.0

Note: Ranged response

D1e. How would you describe your company's maturity level today concerning advanced manufacturing in the following areas? – Software management

	Total	Medical device industry	A&D industry	Auto industry	Electronics industry	Other industry	MDEC
All respondants	68	14	10	13	7	10	4
No answer	46	6	6	6	6	8	1
Those answering	22 100%	8 100%	4 100%	7 100%	1 100%	2 100%	3 100%
Reactive (ad hoc)	2 9.1	1 12.5	1 25.0	0 0.0	0 0.0	0 0.0	1 33.3
Repeatable (siloed)	7 31.8	4 50.0	1 25.0	1 14.3	1 100.0	0 0.0	0 0.0
Integrated	6 27.3	1 12.5	1 25.0	3 42.9	0 0.0	1 50.0	1 33.3
Collaborative (re-use)	7 31.8	2 25.0	1 25.0	3 42.9	0 0.0	1 50.0	1 33.3
Adaptive (predictive)	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0

Note: Ranged response

D1f. How would you describe your company's maturity level today concerning advanced manufacturing in the following areas? – Design for manufacturing simulation and analysis

	Total	Medical device industry	A&D industry	Auto industry	Electronics industry	Other industry	MDEC
All respondants	68	14	10	13	7	10	4
No answer	46	6	6	6	6	8	1
Those answering	22 100%	8 100%	4 100%	7 100%	1 100%	2 100%	3 100%
Reactive (ad hoc)	1 4.5	1 12.5	0 0.0	0 0.0	0 0.0	0 0.0	1 33.3
Repeatable (siloed)	10 45.5	5 62.5	1 25.0	2 28.6	1 100.0	1 50.0	1 33.3
Integrated	6 27.3	1 12.5	2 50.0	2 28.6	0 0.0	1 50.0	1 33.3
Collaborative (re-use)	5 22.7	1 12.5	1 25.0	3 42.9	0 0.0	0 0.0	0 0.0
Adaptive (predictive)	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0

Note: Ranged response

D1g. How would you describe your company's maturity level today concerning advanced manufacturing in the following areas? – Manufacturing performance engineering (simulation)

	Total	Medical device industry	A&D industry	Auto industry	Electronics industry	Other industry	MDEC
All respondants	68	14	10	13	7	10	4
No answer	46	6	6	6	6	8	1
Those answering	22 100%	8 100%	4 100%	7 100%	1 100%	2 100%	3 100%
Reactive (ad hoc)	3 13.6	1 12.5	1 25.0	1 14.3	0 0.0	0 0.0	1 33.3
Repeatable (siloed)	6 27.3	4 50.0	0 0.0	1 14.3	1 100.0	0 0.0	1 33.3
Integrated	7 31.8	1 12.5	3 75.0	2 28.6	0 0.0	1 50.0	0 0.0
Collaborative (re-use)	5 22.7	1 12.5	0 0.0	3 42.9	0 0.0	1 50.0	1 33.3
Adaptive (predictive)	1 4.5	1 12.5	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0

Note: Ranged response

D1h. How would you describe your company's maturity level today concerning advanced manufacturing in the following areas? – Integrated digital process planning and manufacturing transfer

	Total	Medical device industry	A&D industry	Auto industry	Electronics industry	Other industry	MDEC
All respondants	68	14	10	13	7	10	4
No answer	46	6	6	6	6	8	1
Those answering	22 100%	8 100%	4 100%	7 100%	1 100%	2 100%	3 100%
Reactive (ad hoc)	3 13.6	1 12.5	1 25.0	1 14.3	0 0.0	0 0.0	0 0.0
Repeatable (siloed)	5 22.7	2 25.0	0 0.0	1 14.3	1 100.0	1 50.0	0 0.0
Integrated	7 31.8	2 25.0	3 75.0	2 28.6	0 0.0	0 0.0	2 66.7
Collaborative (re-use)	5 22.7	1 12.5	0 0.0	3 42.9	0 0.0	1 50.0	1 33.3
Adaptive (predictive)	2 9.1	2 25.0	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0

Note: Ranged response

MDIC
MEDICAL DEVICE INNOVATION CONSORTIUM

D1i. How would you describe your company's maturity level today concerning advanced manufacturing in the following areas? – Manufacturing process and production simulation

	Total	Medical device industry	A&D industry	Auto industry	Electronics industry	Other industry	MDEC
All respondants	68	14	10	13	7	10	4
No answer	46	6	6	6	6	8	1
Those answering	22 100%	8 100%	4 100%	7 100%	1 100%	2 100%	3 100%
Reactive (ad hoc)	4 18.2	2 25.0	1 25.0	1 14.3	0 0.0	0 0.0	1 33.3
Repeatable (siloed)	4 18.2	3 37.5	0 0.0	0 0.0	1 100.0	0 0.0	1 33.3
Integrated	7 31.8	0 0.0	3 75.0	3 42.9	0 0.0	1 50.0	0 0.0
Collaborative (re-use)	5 22.7	1 12.5	0 0.0	3 42.9	0 0.0	1 50.0	1 33.3
Adaptive (predictive)	2 9.1	2 25.0	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0

Note: Ranged response

D1j. How would you describe your company's maturity level today concerning advanced manufacturing in the following areas? – Robotics, workspace, and human simulation

	Total	Medical device industry	A&D industry	Auto industry	Electronics industry	Other industry	MDEC
All respondants	68	14	10	13	7	10	4
No answer	46	6	6	6	6	8	1
Those answering	22 100%	8 100%	4 100%	7 100%	1 100%	2 100%	3 100%
Reactive (ad hoc)	6 27.3	3 37.5	2 50.0	1 14.3	0 0.0	0 0.0	1 33.3
Repeatable (siloed)	6 27.3	3 37.5	0 0.0	1 14.3	1 100.0	1 50.0	1 33.3
Integrated	6 27.3	0 0.0	2 50.0	3 42.9	0 0.0	1 50.0	0 0.0
Collaborative (re-use)	4 18.2	2 25.0	0 0.0	2 28.6	0 0.0	0 0.0	1 33.3
Adaptive (predictive)	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0

Note: Ranged response

D1k. How would you describe your company's maturity level today concerning advanced manufacturing in the following areas? – Integrated manufacturing planning and advanced scheduling

	Total	Medical device industry	A&D industry	Auto industry	Electronics industry	Other industry	MDEC
All respondants	68	14	10	13	7	10	4
No answer	46	6	6	6	6	8	1
Those answering	22 100%	8 100%	4 100%	7 100%	1 100%	2 100%	3 100%
Reactive (ad hoc)	3 13.6	2 25.0	1 25.0	0 0.0	0 0.0	0 0.0	0 0.0
Repeatable (siloed)	8 36.4	2 25.0	1 25.0	3 42.9	1 100.0	1 50.0	1 33.3
Integrated	7 31.8	3 37.5	1 25.0	2 28.6	0 0.0	1 50.0	2 66.7
Collaborative (re-use)	3 13.6	1 12.5	1 25.0	1 14.3	0 0.0	0 0.0	0 0.0
Adaptive (predictive)	1 4.5	0 0.0	0 0.0	1 14.3	0 0.0	0 0.0	0 0.0

Note: Ranged response

D1l. How would you describe your company's maturity level today concerning advanced manufacturing in the following areas? – Execution integrated quality management system

	Total	Medical device industry	A&D industry	Auto industry	Electronics industry	Other industry	MDEC
All respondants	68	14	10	13	7	10	4
No answer	46	6	6	6	6	8	1
Those answering	22 100%	8 100%	4 100%	7 100%	1 100%	2 100%	3 100%
Reactive (ad hoc)	3 13.6	1 12.5	2 50.0	0 0.0	0 0.0	0 0.0	0 0.0
Repeatable (siloed)	6 27.3	3 37.5	1 25.0	1 14.3	1 100.0	0 0.0	1 33.3
Integrated	10 45.5	2 25.0	1 25.0	5 71.4	0 0.0	2 100.0	1 33.3
Collaborative (re-use)	2 9.1	2 25.0	0 0.0	0 0.0	0 0.0	0 0.0	1 33.3
Adaptive (predictive)	1 4.5	0 0.0	0 0.0	1 14.3	0 0.0	0 0.0	0 0.0

Note: Ranged response

MDIC MEDICAL DEVICE INNOVATION CONSORTIUM

D1m. How would you describe your company's maturity level today concerning advanced manufacturing in the following areas? – Production equipment automation

	Total	Medical device industry	A&D industry	Auto industry	Electronics industry	Other industry	MDEC
All respondants	68	14	10	13	7	10	4
No answer	46	7	6	5	6	8	2
Those answering	22 100%	7 100%	4 100%	8 100%	1 100%	2 100%	2 100%
Reactive (ad hoc)	6 27.3	4 57.1	1 25.0	1 12.5	0 0.0	0 0.0	1 50.0
Repeatable (siloed)	6 27.3	2 28.6	0 0.0	3 37.5	0 0.0	1 50.0	1 50.0
Integrated	6 27.3	1 14.3	3 75.0	1 12.5	1 100.0	0 0.0	0 0.0
Collaborative (re-use)	2 9.1	0 0.0	0 0.0	1 12.5	0 0.0	1 50.0	0 0.0
Adaptive (predictive)	2 9.1	0 0.0	0 0.0	2 25.0	0 0.0	0 0.0	0 0.0

Note: Ranged response

D1n. How would you describe your company's maturity level today concerning advanced manufacturing in the following areas? – Production line automation

	Total	Medical device industry	A&D industry	Auto industry	Electronics industry	Other industry	MDEC
All respondants	68	14	10	13	7	10	4
No answer	46	6	6	6	6	8	1
Those answering	22 100%	8 100%	4 100%	7 100%	1 100%	2 100%	3 100%
Reactive (ad hoc)	7 31.8	4 50.0	1 25.0	2 28.6	0 0.0	0 0.0	1 33.3
Repeatable (siloed)	4 18.2	2 25.0	0 0.0	1 14.3	0 0.0	1 50.0	1 33.3
Integrated	7 31.8	1 12.5	3 75.0	2 28.6	0 0.0	1 50.0	0 0.0
Collaborative (re-use)	3 13.6	1 12.5	0 0.0	1 14.3	1 100.0	0 0.0	1 33.3
Adaptive (predictive)	1 4.5	0 0.0	0 0.0	1 14.3	0 0.0	0 0.0	0 0.0

Note: Ranged response

D1o. How would you describe your company's maturity level today concerning advanced manufacturing in the following areas? – Additive manufacturing (material removal and deposition)

	Total	Medical device industry	A&D industry	Auto industry	Electronics industry	Other industry	MDEC
All respondants	68	14	10	13	7	10	4
No answer	45	6	6	5	6	8	1
Those answering	23 100%	8 100%	4 100%	8 100%	1 100%	2 100%	3 100%
Reactive (ad hoc)	8 34.8	6 75.0	0 0.0	2 25.0	0 0.0	0 0.0	2 66.7
Repeatable (siloed)	7 30.4	0 0.0	0 0.0	5 62.5	0 0.0	2 100.0	0 0.0
Integrated	4 17.4	1 12.5	3 75.0	0 0.0	0 0.0	0 0.0	1 33.3
Collaborative (re-use)	4 17.4	1 12.5	1 25.0	1 12.5	1 100.0	0 0.0	0 0.0
Adaptive (predictive)	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0

Note: Ranged response

D1p. How would you describe your company's maturity level today concerning advanced manufacturing in the following areas? – Artificial intelligence in the shop floor

	Total	Medical device industry	A&D industry	Auto industry	Electronics industry	Other industry	MDEC
All respondants	68	14	10	13	7	10	4
No answer	46	6	6	6	6	8	1
Those answering	22 100%	8 100%	4 100%	7 100%	1 100%	2 100%	3 100%
Reactive (ad hoc)	12 54.5	6 75.0	1 25.0	3 42.9	0 0.0	2 100.0	2 66.7
Repeatable (siloed)	4 18.2	1 12.5	2 50.0	1 14.3	0 0.0	0 0.0	1 33.3
Integrated	4 18.2	1 12.5	0 0.0	3 42.9	0 0.0	0 0.0	0 0.0
Collaborative (re-use)	2 9.1	0 0.0	1 25.0	0 0.0	1 100.0	0 0.0	0 0.0
Adaptive (predictive)	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0

Note: Ranged response

D1q. How would you describe your company's maturity level today concerning advanced manufacturing in the following areas? – Virtual commissioning of equipment and line

	Total	Medical device industry	A&D industry	Auto industry	Electronics industry	Other industry	MDEC
All respondants	68	14	10	13	7	10	4
No answer	47	6	7	6	6	8	1
Those answering	21 100%	8 100%	3 100%	7 100%	1 100%	2 100%	3 100%
Reactive (ad hoc)	13 61.9	6 75.0	2 66.7	4 57.1	0 0.0	1 50.0	2 66.7
Repeatable (siloed)	3 14.3	1 12.5	0 0.0	1 14.3	0 0.0	1 50.0	1 33.3
Integrated	3 14.3	1 12.5	1 33.3	1 14.3	0 0.0	0 0.0	0 0.0
Collaborative (re-use)	1 4.8	0 0.0	0 0.0	1 14.3	0 0.0	0 0.0	0 0.0
Adaptive (predictive)	1 4.8	0 0.0	0 0.0	0 0.0	1 100.0	0 0.0	0 0.0

Note: Ranged response

D1r. How would you describe your company's maturity level today concerning advanced manufacturing in the following areas? – Defect tracking and non-conformance management

	Total	Medical device industry	A&D industry	Auto industry	Electronics industry	Other industry	MDEC
All respondants	68	14	10	13	7	10	4
No answer	46	6	6	6	6	8	1
Those answering	22 100%	8 100%	4 100%	7 100%	1 100%	2 100%	3 100%
Reactive (ad hoc)	6 27.3	3 37.5	2 50.0	1 14.3	0 0.0	0 0.0	1 33.3
Repeatable (siloed)	7 31.8	2 25.0	2 50.0	1 14.3	0 0.0	2 100.0	0 0.0
Integrated	5 22.7	3 37.5	0 0.0	2 28.6	0 0.0	0 0.0	2 66.7
Collaborative (re-use)	1 4.5	0 0.0	0 0.0	1 14.3	0 0.0	0 0.0	0 0.0
Adaptive (predictive)	3 13.6	0 0.0	0 0.0	2 28.6	1 100.0	0 0.0	0 0.0

Note: Ranged response

D1s. How would you describe your company's maturity level today concerning advanced manufacturing in the following areas? – Advanced product traceability (birth certificate)

	Total	Medical device industry	A&D industry	Auto industry	Electronics industry	Other industry	MDEC
All respondants	68	14	10	13	7	10	4
No answer	46	6	7	5	6	8	1
Those answering	22 100%	8 100%	3 100%	8 100%	1 100%	2 100%	3 100%
Reactive (ad hoc)	5 22.7	3 37.5	1 33.3	1 12.5	0 0.0	0 0.0	1 33.3
Repeatable (siloed)	5 22.7	1 12.5	1 33.3	1 12.5	0 0.0	2 100.0	0 0.0
Integrated	4 18.2	2 25.0	1 33.3	1 12.5	0 0.0	0 0.0	1 33.3
Collaborative (re-use)	4 18.2	1 12.5	0 0.0	3 37.5	0 0.0	0 0.0	0 0.0
Adaptive (predictive)	4 18.2	1 12.5	0 0.0	2 25.0	1 100.0	0 0.0	1 33.3

Note: Ranged response

D1t. How would you describe your company's maturity level today concerning advanced manufacturing in the following areas? – Production analytics and intelligence management

	Total	Medical device industry	A&D industry	Auto industry	Electronics industry	Other industry	MDEC
All respondants	68	14	10	13	7	10	4
No answer	46	6	6	6	6	8	1
Those answering	22 100%	8 100%	4 100%	7 100%	1 100%	2 100%	3 100%
Reactive (ad hoc)	5 22.7	2 25.0	2 50.0	1 14.3	0 0.0	0 0.0	1 33.3
Repeatable (siloed)	7 31.8	3 37.5	1 25.0	1 14.3	0 0.0	2 100.0	1 33.3
Integrated	5 22.7	2 25.0	0 0.0	3 42.9	0 0.0	0 0.0	0 0.0
Collaborative (re-use)	2 9.1	1 12.5	1 25.0	0 0.0	0 0.0	0 0.0	1 33.3
Adaptive (predictive)	3 13.6	0 0.0	0 0.0	2 28.6	1 100.0	0 0.0	0 0.0

Note: Ranged response

D2a. Looking at the same technology areas, which have completed or ongoing digitalization efforts at your company, and which are areas where you need additional expertise to be successful? – Systems engineering

	Total	Medical device industry	A&D industry	Auto industry	Electronics industry	Other industry	MDEC
All respondants	68	14	10	13	7	10	4
No answer	52	8	7	8	6	9	1
Those answering	16 100%	6 100%	3 100%	5 100%	1 100%	1 100%	3 100%
Complete digitalization	4 25.0	0 0.0	1 33.3	2 40.0	1 100.0	0 0.0	0 0.0
Digitalization effort in process	9 56.3	4 66.7	1 33.3	3 60.0	0 0.0	1 100.0	2 66.7
We need additional expertise	3 18.8	2 33.3	1 33.3	0 0.0	0 0.0	1 50.0	1 33.3

Note: Single response

D2b. Looking at the same technology areas, which have completed or ongoing digitalization efforts at your company, and which are areas where you need additional expertise to be successful? – Product configuration and change control

	Total	Medical device industry	A&D industry	Auto industry	Electronics industry	Other industry	MDEC
All respondants	68	14	10	13	7	10	4
No answer	52	8	7	8	6	9	1
Those answering	16 100%	6 100%	3 100%	5 100%	1 100%	1 100%	3 100%
Complete digitalization	2 12.5	0 0.0	0 0.0	1 20.0	1 100.0	0 0.0	0 0.0
Digitalization effort in process	12 75.0	5 83.3	2 66.7	4 80.0	0 0.0	1 100.0	2 66.7
We need additional expertise	2 12.5	1 16.7	1 33.3	0 0.0	0 0.0	0 0.0	1 33.3

Note: Single response

D2c. Looking at the same technology areas, which have completed or ongoing digitalization efforts at your company, and which are areas where you need additional expertise to be successful? – Generative/additive design

	Total	Medical device industry	A&D industry	Auto industry	Electronics industry	Other industry	MDEC
All respondants	68	14	10	13	7	10	4
No answer	52	8	7	8	6	9	1
Those answering	16 100%	6 100%	3 100%	5 100%	1 100%	1 100%	3 100%
Complete digitalization	3 18.8	0 0.0	1 33.3	1 20.0	1 100.0	0 0.0	0 0.0
Digitalization effort in process	7 43.8	2 33.3	2 66.7	3 60.0	0 0.0	0 0.0	1 33.3
We need additional expertise	6 37.5	4 66.7	0 0.0	1 20.0	0 0.0	1 100.0	2 66.7

Note: Single response

D2d. Looking at the same technology areas, which have completed or ongoing digitalization efforts at your company, and which are areas where you need additional expertise to be successful? – Product design

	Total	Medical device industry	A&D industry	Auto industry	Electronics industry	Other industry	MDEC
All respondants	68	14	10	13	7	10	4
No answer	52	8	7	8	6	9	1
Those answering	16 100%	6 100%	3 100%	5 100%	1 100%	1 100%	3 100%
Complete digitalization	5 31.3	0 0.0	1 33.3	2 40.0	1 100.0	1 100.0	0 0.0
Digitalization effort in process	10 62.5	5 83.3	2 66.7	3 60.0	0 0.0	0 0.0	3 100.0
We need additional expertise	1 6.3	1 16.7	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0

Note: Single response

D2e. Looking at the same technology areas, which have completed or ongoing digitalization efforts at your company, and which are areas where you need additional expertise to be successful? – Software management

	Total	Medical device industry	A&D industry	Auto industry	Electronics industry	Other industry	MDEC
All respondants	68	14	10	13	7	10	4
No answer	52	8	7	8	6	9	1
Those answering	16 100%	6 100%	3 100%	5 100%	1 100%	1 100%	3 100%
Complete digitalization	6 37.5	1 16.7	2 66.7	1 20.0	1 100.0	1 100.0	1 33.3
Digitalization effort in process	5 31.3	3 50.0	0 0.0	2 40.0	0 0.0	0 0.0	1 33.3
We need additional expertise	5 31.3	2 33.3	1 33.3	2 40.0	0 0.0	0 0.0	1 33.3

Note: Single response

D2f. Looking at the same technology areas, which have completed or ongoing digitalization efforts at your company, and which are areas where you need additional expertise to be successful? – Design for manufacturing simulation and analysis

	Total	Medical device industry	A&D industry	Auto industry	Electronics industry	Other industry	MDEC
All respondants	68	14	10	13	7	10	4
No answer	52	8	7	8	6	9	1
Those answering	16 100%	6 100%	3 100%	5 100%	1 100%	1 100%	3 100%
Complete digitalization	3 18.8	0 0.0	1 33.3	1 20.0	1 100.0	0 0.0	0 0.0
Digitalization effort in process	7 43.8	3 50.0	2 66.7	1 20.0	0 0.0	1 100.0	1 33.3
We need additional expertise	6 37.5	3 50.0	0 0.0	3 60.0	0 0.0	0 0.0	2 66.7

Note: Single response

D2g. Looking at the same technology areas, which have completed or ongoing digitalization efforts at your company, and which are areas where you need additional expertise to be successful? – Manufacturing performance engineering (simulation)

	Total	Medical device industry	A&D industry	Auto industry	Electronics industry	Other industry	MDEC
All respondants	68	14	10	13	7	10	4
No answer	52	8	7	8	6	9	1
Those answering	16 100%	6 100%	3 100%	5 100%	1 100%	1 100%	3 100%
Complete digitalization	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0
Digitalization effort in process	10 62.5	3 50.0	1 33.3	4 80.0	1 100.0	1 100.0	1 33.3
We need additional expertise	6 37.5	3 50.0	2 66.7	1 20.0	0 0.0	0 0.0	2 66.7

Note: Single response

D2h. Looking at the same technology areas, which have completed or ongoing digitalization efforts at your company, and which are areas where you need additional expertise to be successful? – Integrated digital process planning and manufacturing transfer

	Total	Medical device industry	A&D industry	Auto industry	Electronics industry	Other industry	MDEC
All respondants	68	14	10	13	7	10	4
No answer	52	8	7	8	6	9	1
Those answering	16 100%	6 100%	3 100%	5 100%	1 100%	1 100%	3 100%
Complete digitalization	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0
Digitalization effort in process	12 75.0	4 66.7	2 66.7	4 80.0	1 100.0	1 100.0	3 100.0
We need additional expertise	4 25.0	2 33.3	1 33.3	1 20.0	0 0.0	0 0.0	0 0.0

Note: Single response

D2i. Looking at the same technology areas, which have completed or ongoing digitalization efforts at your company, and which are areas where you need additional expertise to be successful? – Manufacturing process and production simulation

	Total	Medical device industry	A&D industry	Auto industry	Electronics industry	Other industry	MDEC
All respondants	68	14	10	13	7	10	4
No answer	53	8	7	8	6	10	1
Those answering	15 100%	6 100%	3 100%	5 100%	1 100%	0 100%	3 100%
Complete digitalization	1 6.7	0 0.0	0 0.0	1 20.0	0 0.0	0	0 0.0
Digitalization effort in process	7 46.7	2 33.3	2 66.7	2 40.0	1 100.0	0	1 33.3
We need additional expertise	7 46.7	4 66.7	1 33.3	2 40.0	0 0.0	0	2 66.7

Note: Single response

D2j. Looking at the same technology areas, which have completed or ongoing digitalization efforts at your company, and which are areas where you need additional expertise to be successful? – Robotics, workspace, and human simulation

	Total	Medical device industry	A&D industry	Auto industry	Electronics industry	Other industry	MDEC
All respondants	68	14	10	13	7	10	4
No answer	52	8	7	8	6	9	1
Those answering	16 100%	6 100%	3 100%	5 100%	1 100%	1 100%	3 100%
Complete digitalization	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0
Digitalization effort in process	7 43.8	3 50.0	1 33.3	2 40.0	1 100.0	0 0.0	2 66.7
We need additional expertise	9 56.3	3 50.0	2 66.7	3 60.0	0 0.0	1 100.0	1 33.3

Note: Single response

MDIC
MEDICAL DEVICE INNOVATION CONSORTIUM

D2k. Looking at the same technology areas, which have completed or ongoing digitalization efforts at your company, and which are areas where you need additional expertise to be successful? – Integrated manufacturing planning and advanced scheduling

	Total	Medical device industry	A&D industry	Auto industry	Electronics industry	Other industry	MDEC
All respondants	68	14	10	13	7	10	4
No answer	52	8	7	8	6	9	1
Those answering	16 100%	6 100%	3 100%	5 100%	1 100%	1 100%	3 100%
Complete digitalization	1 6.3	0 0.0	1 33.3	0 0.0	0 0.0	0 0.0	0 0.0
Digitalization effort in process	10 62.5	4 66.7	1 33.3	3 60.0	1 100.0	1 100.0	3 100.0
We need additional expertise	5 31.3	2 33.3	1 33.3	2 40.0	0 0.0	0 0.0	0 0.0

Note: Single response

D2l. Looking at the same technology areas, which have completed or ongoing digitalization efforts at your company, and which are areas where you need additional expertise to be successful? – Execution integrated quality management system

	Total	Medical device industry	A&D industry	Auto industry	Electronics industry	Other industry	MDEC
All respondants	68	14	10	13	7	10	4
No answer	52	8	7	8	6	9	1
Those answering	16 100%	6 100%	3 100%	5 100%	1 100%	1 100%	3 100%
Complete digitalization	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0
Digitalization effort in process	11 68.8	3 50.0	2 66.7	4 80.0	1 100.0	1 100.0	3 100.0
We need additional expertise	5 31.3	3 50.0	1 33.3	1 20.0	0 0.0	0 0.0	0 0.0

Note: Single response

D2m. Looking at the same technology areas, which have completed or ongoing digitalization efforts at your company, and which are areas where you need additional expertise to be successful? – Production equipment automation

	Total	Medical device industry	A&D industry	Auto industry	Electronics industry	Other industry	MDEC
All respondants	68	14	10	13	7	10	4
No answer	52	8	7	8	6	9	1
Those answering	16 100%	6 100%	3 100%	5 100%	1 100%	1 100%	3 100%
Complete digitalization	1 6.3	1 16.7	0 0.0	0 0.0	0 0.0	0 0.0	1 33.3
Digitalization effort in process	9 56.3	1 16.7	2 66.7	4 80.0	1 100.0	1 100.0	1 33.3
We need additional expertise	6 37.5	4 66.7	1 33.3	1 20.0	0 0.0	0 0.0	1 33.3

Note: Single response

D2n. Looking at the same technology areas, which have completed or ongoing digitalization efforts at your company, and which are areas where you need additional expertise to be successful? – Production line automation

	Total	Medical device industry	A&D industry	Auto industry	Electronics industry	Other industry	MDEC
All respondants	68	14	10	13	7	10	4
No answer	52	8	7	8	6	9	1
Those answering	16 100%	6 100%	3 100%	5 100%	1 100%	1 100%	3 100%
Complete digitalization	4 25.0	2 33.3	0 0.0	2 40.0	0 0.0	0 0.0	2 66.7
Digitalization effort in process	6 37.5	0 0.0	2 66.7	2 40.0	1 100.0	1 100.0	0 0.0
We need additional expertise	6 37.5	4 66.7	1 33.3	1 20.0	0 0.0	0 0.0	1 33.3

Note: Single response

D2o. Looking at the same technology areas, which have completed or ongoing digitalization efforts at your company, and which are areas where you need additional expertise to be successful? – Additive manufacturing (material removal and deposition)

	Total	Medical device industry	A&D industry	Auto industry	Electronics industry	Other industry	MDEC
All respondants	68	14	10	13	7	10	4
No answer	52	8	7	8	6	9	1
Those answering	16 100%	6 100%	3 100%	5 100%	1 100%	1 100%	3 100%
Complete digitalization	2 12.5	0 0.0	0 0.0	2 40.0	0 0.0	0 0.0	0 0.0
Digitalization effort in process	5 31.3	1 16.7	1 33.3	2 40.0	1 100.0	0 0.0	1 33.3
We need additional expertise	9 56.3	5 83.3	2 66.7	1 20.0	0 0.0	1 100.0	2 66.7

Note: Single response

D2p. Looking at the same technology areas, which have completed or ongoing digitalization efforts at your company, and which are areas where you need additional expertise to be successful? – Artificial intelligence in the shop floor

	Total	Medical device industry	A&D industry	Auto industry	Electronics industry	Other industry	MDEC
All respondants	68	14	10	13	7	10	4
No answer	52	8	7	8	6	9	1
Those answering	16 100%	6 100%	3 100%	5 100%	1 100%	1 100%	3 100%
Complete digitalization	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0
Digitalization effort in process	4 25.0	1 16.7	1 33.3	1 20.0	1 100.0	0 0.0	1 33.3
We need additional expertise	12 75.0	5 83.3	2 66.7	4 80.0	0 0.0	1 100.0	2 66.7

Note: Single response

D2q. Looking at the same technology areas, which have completed or ongoing digitalization efforts at your company, and which are areas where you need additional expertise to be successful? – Virtual commissioning of equipment and line

	Total	Medical device industry	A&D industry	Auto industry	Electronics industry	Other industry	MDEC
All respondants	68	14	10	13	7	10	4
No answer	53	9	7	8	6	9	2
Those answering	15 100%	5 100%	3 100%	5 100%	1 100%	1 100%	2 100%
Complete digitalization	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0
Digitalization effort in process	3 20.0	0 0.0	0 0.0	2 40.0	1 100.0	0 0.0	0 0.0
We need additional expertise	12 80.0	5 100.0	3 100.0	3 60.0	0 0.0	1 100.0	2 100.0

Note: Single response

D2r. Looking at the same technology areas, which have completed or ongoing digitalization efforts at your company, and which are areas where you need additional expertise to be successful? – Defect tracking and non-conformance management

	Total	Medical device industry	A&D industry	Auto industry	Electronics industry	Other industry	MDEC
All respondants	68	14	10	13	7	10	4
No answer	52	8	7	8	6	9	1
Those answering	16 100%	6 100%	3 100%	5 100%	1 100%	1 100%	3 100%
Complete digitalization	3 18.8	2 33.3	0 0.0	1 20.0	0 0.0	0 0.0	2 66.7
Digitalization effort in process	9 56.3	2 33.3	2 66.7	3 60.0	1 100.0	1 100.0	0 0.0
We need additional expertise	4 25.0	2 33.3	1 33.3	1 20.0	0 0.0	0 0.0	1 33.3

Note: Single response

D2s. Looking at the same technology areas, which have completed or ongoing digitalization efforts at your company, and which are areas where you need additional expertise to be successful? – Advanced product traceability (birth certificate)

	Total	Medical device industry	A&D industry	Auto industry	Electronics industry	Other industry	MDEC
All respondants	68	14	10	13	7	10	4
No answer	52	8	7	8	6	9	1
Those answering	16 100%	6 100%	3 100%	5 100%	1 100%	1 100%	3 100%
Complete digitalization	2 12.5	1 16.7	0 0.0	1 20.0	0 0.0	0 0.0	1 33.3
Digitalization effort in process	9 56.3	2 33.3	2 66.7	3 60.0	1 100.0	1 100.0	1 33.3
We need additional expertise	5 31.3	3 50.0	1 33.3	1 20.0	0 0.0	0 0.0	1 33.3

Note: Single response

D2t. Looking at the same technology areas, which have completed or ongoing digitalization efforts at your company, and which are areas where you need additional expertise to be successful? – Production analytics and intelligence management

	Total	Medical device industry	A&D industry	Auto industry	Electronics industry	Other industry	MDEC
All respondants	68	14	10	13	7	10	4
No answer	52	8	7	8	6	9	1
Those answering	16 100%	6 100%	3 100%	5 100%	1 100%	1 100%	3 100%
Complete digitalization	2 12.5	1 16.7	0 0.0	1 20.0	0 0.0	0 0.0	1 33.3
Digitalization effort in process	9 56.3	2 33.3	2 66.7	3 60.0	1 100.0	1 100.0	1 33.3
We need additional expertise	5 31.3	3 50.0	1 33.3	1 20.0	0 0.0	0 0.0	1 33.3

Note: Single response

D3a. Finally, select at least the top 2 technology areas that have the highest potential impact on your ROI and the top 2 technology areas that are the most difficult to address for your business. – Highest potential ROI impact

	Total	Medical device industry	A&D industry	Auto industry	Electronics industry	Other industry	MDEC
All respondants	68	14	10	13	7	10	4
No answer	54	9	7	9	6	9	1
Those answering	14 100%	5 100%	3 100%	4 100%	1 100%	1 100%	3 100%
Product design	6 42.9	3 60.0	1 33.3	1 25.0	0 0.0	1 100.0	1 33.3
Systems engineering	5 35.7	0 0.0	2 66.7	2 50.0	1 100.0	0 0.0	0 0.0
Defect tracking and non-conformance management	5 35.7	1 20.0	1 33.3	3 75.0	0 0.0	0 0.0	0 0.0
Product configuration and change control	4 28.6	3 60.0	0 0.0	1 25.0	0 0.0	0 0.0	2 66.7
Advanced product traceability (birth certificate)	4 28.6	1 20.0	1 33.3	2 50.0	0 0.0	0 0.0	1 33.3
Software management	4 28.6	1 20.0	1 33.3	2 50.0	0 0.0	0 0.0	1 33.3
Execution integrated quality management system	4 28.6	2 40.0	1 33.3	1 25.0	0 0.0	0 0.0	1 33.3
Artificial intelligence in the shop floor	3 21.4	2 40.0	0 0.0	1 25.0	0 0.0	0 0.0	1 33.3
Production equipment automation	3 21.4	1 20.0	1 33.3	1 25.0	0 0.0	0 0.0	0 0.0
Production analytics and intelligence management	3 21.4	1 20.0	0 0.0	1 25.0	0 0.0	1 100.0	0 0.0
Integrated manufacturing planning and advanced scheduling	3 21.4	2 40.0	1 33.3	0 0.0	0 0.0	0 0.0	1 33.3

Continued	Total	Medical device industry	A&D industry	Auto industry	Electronics industry	Other industry	MDEC
All respondants	68	14	10	13	7	10	4
No answer	54	9	7	9	6	9	1
Those answering	14 100%	5 100%	3 100%	4 100%	1 100%	1 100%	3 100%
Manufacturing performance engineering (simulation)	3 21.4	1 20.0	1 33.3	0 0.0	0 0.0	1 100.0	1 33.3
Manufacturing process and production simulation	2 14.3	1 20.0	0 0.0	0 0.0	0 0.0	1 100.0	0 0.0
Production line automation	2 14.3	1 20.0	0 0.0	1 25.0	0 0.0	0 0.0	1 33.3
Generative/additive design	2 14.3	0 0.0	1 33.3	1 25.0	0 0.0	0 0.0	0 0.0
Integrated digital process planning and manufacturing transfer	1 7.1	1 20.0	0 0.0	0 0.0	0 0.0	0 0.0	1 33.3
Additive manufacturing (material removal and deposition)	1 7.1	0 0.0	0 0.0	0 0.0	0 0.0	1 100.0	0 0.0
Design for manufacturing simulation and analysis	1 7.1	0 0.0	1 33.3	0 0.0	0 0.0	0 0.0	0 0.0
Robotics, workspace, and human simulation	1 7.1	1 20.0	0 0.0	0 0.0	0 0.0	0 0.0	1 33.3
Virtual commissioning of equipment and line	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0

Note: Multiple response

D3b. Finally, select at least the top 2 technology areas that have the highest potential impact on your ROI and the top 2 technology areas that are the most difficult to address for your business. – Most difficult to address

	Total	Medical device industry	A&D industry	Auto industry	Electronics industry	Other industry	MDEC
All respondants	68	14	10	13	7	10	4
No answer	56	9	7	11	6	9	1
Those answering	12 100%	5 100%	3 100%	2 100%	1 100%	1 100%	3 100%
Manufacturing performance engineering (simulation)	4 33.3	2 40.0	2 66.7	0 0.0	0 0.0	0 0.0	2 66.7
Artificial intelligence in the shop floor	4 33.3	1 20.0	2 66.7	1 50.0	0 0.0	0 0.0	1 33.3
Production analytics and intelligence management	4 33.3	0 0.0	1 33.3	2 100.0	0 0.0	1 100.0	0 0.0
Robotics, workspace, and human simulation	3 25.0	1 20.0	1 33.3	0 0.0	0 0.0	1 100.0	0 0.0
Design for manufacturing simulation and analysis	3 25.0	2 40.0	1 33.3	0 0.0	0 0.0	0 0.0	0 0.0
Manufacturing process and production simulation	3 25.0	1 20.0	2 66.7	0 0.0	0 0.0	0 0.0	1 33.3
Systems engineering	3 25.0	2 40.0	1 33.3	0 0.0	0 0.0	0 0.0	1 33.3
Software management	3 25.0	1 20.0	1 33.3	1 50.0	0 0.0	0 0.0	0 0.0
Virtual commissioning of equipment and line	3 25.0	1 20.0	1 33.3	1 50.0	0 0.0	0 0.0	0 0.0
Product configuration and change control	2 16.7	0 0.0	1 33.3	1 50.0	0 0.0	0 0.0	0 0.0
Defect tracking and non-conformance management	2 16.7	1 20.0	0 0.0	1 50.0	0 0.0	0 0.0	0 0.0
Integrated manufacturing planning and advanced scheduling	2 16.7	2 40.0	0 0.0	0 0.0	0 0.0	0 0.0	1 33.3

Continued	Total	Medical device industry	A&D industry	Auto industry	Electronics industry	Other industry	MDEC
All respondants	**68**	**14**	**10**	**13**	**7**	**10**	**4**
No answer	**56**	**9**	**7**	**11**	**6**	**9**	**1**
Those answering	**12** **100%**	**5** **100%**	**3** **100%**	**2** **100%**	**1** **100%**	**1** **100%**	**3** **100%**
Production equipment automation	2 16.7	2 40.0	0 0.0	0 0.0	0 0.0	0 0.0	1 33.3
Production line automation	2 16.7	2 40.0	0 0.0	0 0.0	0 0.0	0 0.0	1 33.3
Advanced product traceability (birth certificate)	1 8.3	0 0.0	0 0.0	1 50.0	0 0.0	0 0.0	0 0.0
Product design	1 8.3	1 20.0	0 0.0	0 0.0	0 0.0	0 0.0	1 33.3
Additive manufacturing (material removal and deposition)	1 8.3	0 0.0	0 0.0	0 0.0	0 0.0	1 100.0	0 0.0
Integrated digital process planning and manufacturing transfer	1 8.3	0 0.0	1 33.3	0 0.0	0 0.0	0 0.0	0 0.0
Generative/additive design	1 8.3	0 0.0	0 0.0	0 0.0	1 100.0	0 0.0	0 0.0
Execution integrated quality management system	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0	0 0.0

Note: Multiple response

APPENDIX D: PRODUCT ENGINEERING AND MANUFACTURING MARKET STUDY 2020

Profiles: Engineering domain by industry group

Column percent count	Medical	A&D	Auto and transport	Electronics and semi	NET	Row sample size
Mechanical: CAD	44%↑ 68	35% 132	34% 224	24%↓ 96	33% 520	520
Simulation and test	15%↓ 23	29% 109	31%↑ 205	28% 112	28% 449	449
Manufacturing engineering: CAM	17% 26	18% 70	13%↓ 87	17% 68	16% 251	251
Product lifecycle management: PLM	14% 22	11%↓ 43	13% 84	20%↑ 80	14% 229	229
Manufacturing operations: MOM	10% 15	7% 27	8% 51	11%↑ 46	9% 139	139
NET	100% 154	100% 381	100% 651	100% 402	100% 1,588	1,588

Engineering domain by Medical Advanced Manufacturing Industry Group
Fiilter: Product engineering and manufacturing, sample size = 1588, total sample size = 3591, 2003 missing, 21% filtered out, 95% confidence level

Profiles: Which most closely describes your job responsibilities?

Column percent count	Medical	A&D	Auto and transport	Electronics and semi	NET
Management jobs	22% 34	19% 74	17% 112	21% 85	19% 305
Engineering jobs	40% 62	46%↑ 177	41% 264	36%↓ 145	41% 648
Supporting jobs	35% 54	29% 111	35% 230	31% 126	33% 512
Other jobs	3%↓ 4	5% 19	7% 45	11%↑ 46	7% 114
NET	100% 154	100% 381	100% 651	100% 402	100% 1,588

Job responsibilities by Medical Advanced Manufacturing Industry Group
Filter: Product engineering and manufacturing, sample size = 1588, total sample size = 3591, 2003 missing, 21% filtered out, 95% confidence level

MDIC
MEDICAL DEVICE INNOVATION CONSORTIUM

Profiles: Annual revenue by industry group

Column percent count	Medical	A&D	Auto and transport	Electronics and semi	NET
Less than $1 million	24%↑ 36	19% 71	13%↓ 83	20% 80	18% 270
$1 million–$4.9 million	15% 22	14% 51	11%↓ 65	14% 55	13% 193
$5 million–$99.9 million	28% 41	23% 86	23% 143	26% 102	24% 372
$100 million–$999 million	12% 17	14% 52	18% 108	15% 61	16% 238
$1 billion–$4.9 billion	7% 11	11% 39	13% 80	10% 40	11% 170
$5 billion or more	14% 20	18% 67	22%↑ 136	15%↓ 58	18% 281
NET	100% 147	100% 366	100% 615	100% 396	100% 1,524

Annual revenue by Medical Advanced Manufacturing Industry Group
Filter: Product engineering and manufacturing, sample size = 1524, total sample size = 3591, 2067 missing, 21% filtered out, 95% confidence level

Technology adoption in the mechanical CAD area
Percent fully engaged or started implementation by industry

Column percent count Column comparisons	Medical	A&D	Auto and transport	Electronics and semi	NET
Additive/3D manufacturing	60% 28 d	62% 53 c d	48% 64	39% 23	52% 168 –
Model-based system engineering	30% 14	52% 46 a	47% 60 a	40% 23	45% 143 –
Generative design	24% 11	40% 35	43% 57 a d	28% 16	37% 119 –
Cloud-based CAD	11% 5	26% 23 a	29% 39 a	23% 14	25% 81 –
Low-code application development	6% 3	26% 21 a	24% 31 a	16% 9	21% 64 –
AR/VR	6% 3	23% 20 a d	25% 34 a d	7% 4	19% 61 –
Column sample size	45	77	118	51	291
Column names	A	B	C	D	E

Top 2% Technology adoption CAD: Fully engaged + Started implementation by Medical Advanced Manufacturing Industry Group
Sample size = from 311 to 329, total sample size = 9901; 9590 missing, 3.8% filtered out, 95% confidence level
Column comparison symbols: a, b, c... (confidence level >= 95%), A, B, C... (confidence level >= 99.9%); No test symbol: – , Not significant symbol:

Technology adoption in the simulation and test area
Percent fully engaged or started implementation by industry

Column percent count Column comparisons	Medical	A&D	Auto and transport	Electronics and semi	NET
Model-based system engineering	46% 6	48% 30	60% 61	47% 28	53% 125 –
Additive/3D manufacturing	38% 5	47% 28	44% 42	46% 27	45% 102 –
Frontloading simulation	36% 4	29% 17	46% 41 b d	25% 14	35% 76 –
Internet of Things (IoT)	23% 3	32% 19	26% 24	42% 25 c	31% 71 –
Cloud-based simulation	31% 4	20% 12	32% 33	36% 22 b	30% 71 –
Low-code application development	45% 5	27% 15	26% 23	32% 19	29% 62 –
Generative design	38% 5	28% 17	30% 28	22% 13	28% 63 –
Column sample size	11	55	80	51	197
Column names	A	B	C	D	E

Top 2% Technology adoption STS: Fully engaged + Started implementation by Medical Advanced Manufacturing Industry Group
Sample size = from 215 to 237, total sample size = 9901; 9686 missing, 3.8% filtered out, 95% confidence level
Column comparison symbols: a, b, c... (confidence level >= 95%), A, B, C... (confidence level >= 99.9%); No test symbol: – , Not significant symbol:

Technology adoption in the manufacturing engineering area
Percent fully engaged or started implementation by industry

Column percent count Column comparisons	Medical	A&D	Auto and transport	Electronics and semi	NET
Model-based system engineering	46% 6	71% 22 c d	42% 19	31% 10	47% 57 –
Industrialize additive/3D	36% 5	50% 14 d	43% 19	25% 8	39% 46 –
Plant simulation	21% 3	42% 11	50% 21 d	24% 8	37% 43 –
Discrete event simulation	23% 3	36% 10	33% 14	26% 8	30% 35 –
Low-code application development	23% 3	32% 9	28% 12	25% 8	28% 32 –
AR/VR	7% 1	38% 10 a d	31% 13	13% 4	24% 28 –
Column sample size	13	24	39	30	106
Column names	A	B	C	D	E

Top 2% Technology adoption manufacturing engineering: Fully engaged + Started implementation by Medical Advanced Manufacturing Industry Group, Sample size = from 115 to 121, total sample size = 4565; 4450 missing, 95% confidence level
Column comparison symbols: a, b, c... (confidence level >= 95%), A, B, C... (confidence level >= 99.9%); No test symbol: – , Not significant symbol:

Technology adoption in the manufacturing operations area
Percent fully engaged or started implementation by industry

Column percent count Column comparisons	Medical	A&D	Auto and transport	Electronics and semi	NET
Manufacturing execution software	50% 3	57% 8	60% 15	56% 10	57% 36 –
Cloud-based solutions	50% 3	29% 4	58% 14	56% 10	50% 31 –
Additive/3D manufacturing	67% 4	57% 8	38% 8	35% 6	45% 26 –
Predictive maintenance	33% 2	36% 5	58% 14	33% 6	44% 27 –
Industrial Internet of Things (IIoT)	33% 2	36% 5	43% 10	29% 5	37% 22 –
AI/ML	33% 2	29% 4	30% 7	22% 4	28% 17 –
AR/VR	33% 2	21% 3	26% 6	17% 3	23% 14 –
Low-code application development	33% 2 b	0% 0	35% 8 b	22% 4	23% 14 –
Column sample size	6	13	19	16	54
Column names	A	B	C	D	E

Top 2% Technology adoption MOM: Fully engaged + Started implementation by Medical Advanced Manufacturing Industry Group
Sample size = from 58 to 63, total sample size = 9901; 9843 missing, 3.8% filtered out, 95% confidence level
Column comparison symbols: a, b, c... (confidence level >= 95%), A, B, C... (confidence level >= 99.9%); No test symbol: – , Not significant symbol:

Technology adoption in the product lifecycle management area
Percent fully engaged or started implementation by industry

Column percent count Column comparisons	Medical	A&D	Auto and transport	Electronics and semi	NET
ERP/PLM integration	75% 9	61% 14	65% 28	58% 23	63% 74 –
Cloud-based solutions	75% 9 b	38% 8	66% 31 b	66% 29 b	62% 77 –
Social collaboration	50% 6	27% 6	52% 23	56% 23 b	49% 58 –
Low-code software development	33% 4	29% 6	36% 16	51% 20	40% 46 –
Column sample size	12	20	42	37	111
Column names	A	B	C	D	E

Top 2% Technology adoption PLM 2: Fully engaged + Started implementation by Medical Advanced Manufacturing Industry Group, Sample size = from 116 to 124, total sample size = 9901; 9785 missing, 3.8% filtered out, 95% confidence level
Column comparison symbols: a, b, c... (confidence level >= 95%), A, B, C... (confidence level >= 99.9%); No test symbol: – , Not significant symbol:

MDIC
MEDICAL DEVICE INNOVATION CONSORTIUM

Additive/3D manufacturing

Column percent count Column comparisons	Medical	A&D	Auto and transport	Electronics and semi	NET
Fully engaged	29% 23 d	32% 60 d	24% 71	17% 29	25% 183 –
Started implementation	24% 19	23% 43	21% 62	21% 35	22% 159 –
Planning 1-2 years	18% 14	10% 19	16% 46	20% 33 b	15% 112 –
Planning 3-5 years	14% 11	16% 30	14% 40	13% 22	14% 103 –
Not thinking about it	16% 13	19% 36	26% 76	29% 48 a b	24% 173 –
NET	100% 80 –	100% 188 –	100% 295 –	100% 167 –	100% 730 –
Column names	A	B	C	D	E

Adoption additive/3D manufacturing duplicate-numeric by Medical Advanced Manufacturing Industry Group
Sample size = 730, total sample size = 9901; 9171 missing, 3.8% filtered out, 95% confidence level
Column comparison symbols: a, b, c... (confidence level >= 95%), A, B, C... (confidence level >= 99.9%); No test symbol: – , Not significant symbol:

Generative design

Column percent count Column comparisons	Medical	A&D	Auto and transport	Electronics and semi	NET
Fully engaged	14% 8	16% 23	19% 43	12% 14	16% 88 –
Started implementation	14% 8	20% 29	19% 42	13% 15	17% 94 –
Planning 1-2 years	15% 9	16% 23	15% 35	22% 26	17% 93 –
Planning 3-5 years	22% 13 c	16% 23	12% 26	15% 18	15% 80 –
Not thinking about it	36% 21	33% 49	35% 80	38% 44	35% 194 –
NET	100% 59 –	100% 147 –	100% 226 –	100% 117 –	100% 549 –
Column names	A	B	C	D	E

Adoption generative design duplicate-numeric by Medical Advanced Manufacturing Industry Group
Sample size = 549, total sample size = 9901; 9352 missing, 3.8% filtered out, 95% confidence level
Column comparison symbols: a, b, c... (confidence level >= 95%), A, B, C... (confidence level >= 99.9%); No test symbol: – , Not significant symbol:

Model-based system engineering

Column percent count Column comparisons	Medical	A&D	Auto and transport	Electronics and semi	NET
Fully engaged	22% 16	31% 56 d	29% 79	21% 32	27% 183 –
Started implementation	14% 10	23% 42	22% 61	19% 29	21% 142 –
Planning 1-2 years	18% 13	13% 24	14% 38	17% 26	15% 101 –
Planning 3-5 years	18% 13	14% 25	14% 37	13% 19	14% 94 –
Not thinking about it	29% 21	19% 34	22% 59	29% 44 b	23% 158 –
NET	100% 73 –	100% 181 –	100% 274 –	100% 150 –	100% 678 –
Column names	A	B	C	D	E

Adoption model-bassed system engineering duplicate-numeric by Medical Advanced Manufacturing Industry Group
Sample size = 678, total sample size = 9901; 9223 missing, 3.8% filtered out, 95% confidence level
Column comparison symbols: a, b, c... (confidence level >= 95%), A, B, C... (confidence level >= 99.9%); No test symbol: – , Not significant symbol:

Cloud-based solutions

Column percent count Column comparisons	Medical	A&D	Auto and transport	Electronics and semi	NET
Fully engaged	16% 12	12% 22	17% 52	20% 37 b	16% 123 –
Started implementation	12% 9	14% 25	21% 65 b	21% 38	18% 137 –
Planning 1-2 years	16% 12	16% 29	16% 49	16% 29	16% 119 –
Planning 3-5 years	16% 12	13% 24	15% 45	14% 26	14% 107 –
Not thinking about it	42% 321	46% 84 c d	31% 96	29% 54	35% 266 –
NET	100% 77 –	100% 184 –	100% 307 –	100% 184 –	100% 752 –
Column names	A	B	C	D	E

Adoption cloud-bassed system solutions duplicate-numeric by Medical Advanced Manufacturing Industry Group
Sample size = 752, total sample size = 9901; 9149 missing, 3.8% filtered out, 95% confidence level
Column comparison symbols: a, b, c... (confidence level >= 95%), A, B, C... (confidence level >= 99.9%); No test symbol: – , Not significant symbol:

MDIC
MEDICAL DEVICE INNOVATION CONSORTIUM

Augmented reality (AR)/virtual reality (VR)

Column percent count Column comparisons	Medical	A&D	Auto and transport	Electronics and semi	NET
Fully engaged	1% 1	9% 12 a	11% 21 a	5% 5	8% 39 –
Started implementation	7% 5	16% 21 d	16% 32 d	6% 6	13% 64 –
Planning 1-2 years	16% 11 d	8% 10	14% 27	7% 7	11% 55 –
Planning 3-5 years	18% 12	14% 18	14% 27	21% 22	16% 79 –
Not thinking about it	57% 39	52% 67	46% 92	62% 66 c	53% 264 –
NET	100% 68 –	100% 128 –	100% 199 –	100% 106 –	100% 501 –
Column names	A	B	C	D	E

Adoption cloud-bassed system solutions duplicate-numeric by Medical Advanced Manufacturing Industry Group
Sample size = 501, total sample size = 9901; 9400 missing, 3.8% filtered out, 95% confidence level
Column comparison symbols: a, b, c... (confidence level >= 95%), A, B, C... (confidence level >= 99.9%); No test symbol: – , Not significant symbol:

Low-code application development

Column percent count Column comparisons	Medical	A&D	Auto and transport	Electronics and semi	NET
Fully engaged	8% 7	11% 21	11% 35	12% 25	11% 88 –
Started implementation	11% 10	15% 30	17% 55	17% 35	16% 130 –
Planning 1-2 years	10% 9	19% 37	19% 63 a	20% 41 a	18% 150 –
Planning 3-5 years	12% 11	11% 21	9% 31	12% 25	11% 88 –
Not thinking about it	58% 52 b c d	46% 91	44% 143	38% 78	44% 364 –
NET	100% 89 –	100% 200 –	100% 327 –	100% 204 –	100% 820 –
Column names	A	B	C	D	E

Adoption cloud-bassed system solutions duplicate-numeric by Medical Advanced Manufacturing Industry Group
Sample size = 820, total sample size = 9901; 9081 missing, 3.8% filtered out, 95% confidence level
Column comparison symbols: a, b, c... (confidence level >= 95%), A, B, C... (confidence level >= 99.9%); No test symbol: – , Not significant symbol:

Internet of Things (IoT)

Column percent count Column comparisons	Medical	A&D	Auto and transport	Electronics and semi	NET
Fully engaged	11% 2	16% 2	12% 14	16% 12	14% 40 –
Started implementation	16% 3	16% 12	17% 20	23% 18	18% 53 –
Planning 1-2 years	53% 10 B c d	9% 7	21% 25 b	19% 15	20% 57 –
Planning 3-5 years	5% 1	19% 14	20% 23	17% 13	18% 51 –
Not thinking about it	16% 3	39% 29	30% 35	25% 19	30% 86 –
NET	100% 19 –	100% 74 –	100% 117 –	100% 77 –	100% 287 –
Column names	A	B	C	D	E

Adoption IoT duplicate-numeric by Medical Advanced Manufacturing Industry Group
Sample size = 287, total sample size = 9901; 9614 missing, 3.8% filtered out, 95% confidence level
Column comparison symbols: a, b, c... (confidence level >= 95%), A, B, C... (confidence level >= 99.9%); No test symbol: – , Not significant symbol:

Plant simulation

Column percent count Column comparisons	Medical	A&D	Auto and transport	Electronics and semi	NET
Fully engaged	7% 1	27% 7	24% 10	9% 3	18% 21 –
Started implementation	14% 2	15% 4	26% 11	15% 5	19% 22 –
Planning 1-2 years	7% 1	8% 2	17% 7	33% 11 b	18% 21 –
Planning 3-5 years	21% 3	12% 3	7% 3	12% 4	11% 13 –
Not thinking about it	50% 7	38% 10	26% 11	30% 10	33% 38 –
NET	100% 14 –	100% 26 –	100% 42 –	100% 33 –	100% 115 –
Column names	A	B	C	D	E

Adoption plant simulation duplicate-numeric by Medical Advanced Manufacturing Industry Group
Sample size = 115, total sample size = 9901; 9786 missing, 3.8% filtered out, 95% confidence level
Column comparison symbols: a, b, c... (confidence level >= 95%), A, B, C... (confidence level >= 99.9%); No test symbol: – , Not significant symbol:

Discrete event simulation

Column percent count Column comparisons	Medical	A&D	Auto and transport	Electronics and semi	NET
Fully engaged	8% 1	18% 5	16% 7	10% 3	14% 16 –
Started implementation	15% 2	18% 5	16% 7	16% 5	17% 19 –
Planning 1-2 years	0% 0	7% 2	28% 12 a b	29% 9 a b	20% 23 –
Planning 3-5 years	31% 4	14% 4	9% 4	13% 4	14% 16 –
Not thinking about it	46% 6	43% 12	30% 13	32% 10	36% 41 –
NET	100% 13 –	100% 28 –	100% 43 –	100% 31 –	100% 115 –
Column names	A	B	C	D	E

Adoption plant simulation duplicate-numeric by Medical Advanced Manufacturing Industry Group
Sample size = 115, total sample size = 9901; 9786 missing, 3.8% filtered out, 95% confidence level
Column comparison symbols: a, b, c... (confidence level >= 95%), A, B, C... (confidence level >= 99.9%); No test symbol: – , Not significant symbol:

Predictive maintenance

Column percent count Column comparisons	Medical	A&D	Auto and transport	Electronics and semi	NET
Fully engaged	17% 1	21% 3	29% 7	17% 3	23% 14 –
Started implementation	17% 1	14% 2	29% 7	17% 3	21% 13 –
Planning 1-2 years	50% 3	21% 3	21% 5	17% 3	23% 14 –
Planning 3-5 years	17% 1	29% 4	17% 4	28% 5	23% 14 –
Not thinking about it	0% 0	14% 2	4% 1	22% 4	11% 7 –
NET	100% 6 –	100% 14 –	100% 24 –	100% 18 –	100% 62 –
Column names	A	B	C	D	E

Stage predictive maintenance 2 by Medical Advanced Manufacturing Industry Group
Sample size = 62, total sample size = 9901; 9839 missing, 3.8% filtered out, 95% confidence level
Column comparison symbols: a, b, c... (confidence level >= 95%), A, B, C... (confidence level >= 99.9%); No test symbol: – , Not significant symbol:

MDIC MEDICAL DEVICE INNOVATION CONSORTIUM

Artificial intelligence (AI)/machine learning (ML)

Column percent count Column comparisons	Medical	A&D	Auto and transport	Electronics and semi	NET
Fully engaged	0% 0	14% 2	13% 3	11% 2	11% 7 –
Started implementation	33% 2	14% 2	17% 4	11% 2	16% 10 –
Planning 1-2 years	33% 2	7% 1	22% 5	33% 6	23% 14 –
Planning 3-5 years	0% 0	21% 3	13% 3	28% 5	18% 11 –
Not thinking about it	33% 2	43% 6	35% 8	17% 3	31% 19 –
NET	100% 6 –	100% 14 –	100% 23 –	100% 18 –	100% 61 –
Column names	A	B	C	D	E

Stage AI/ML 2 by Medical Advanced Manufacturing Industry Group
Sample size = 61, total sample size = 9901; 9840 missing, 3.8% filtered out, 95% confidence level
Column comparison symbols: a, b, c... (confidence level >= 95%), A, B, C... (confidence level >= 99.9%); No test symbol: – , Not significant symbol:

Manufacturing execution software (MES)

Column percent count Column comparisons	Medical	A&D	Auto and transport	Electronics and semi	NET
Fully engaged	17% 1	29% 4	36% 9	39% 7	33% 21 –
Started implementation	33% 2	29% 4	24% 6	17% 3	24% 15 –
Planning 1-2 years	17% 1	21% 3	20% 5	6% 1	16% 10 –
Planning 3-5 years	17% 1	7% 1	16% 4	17% 3	14% 9 –
Not thinking about it	17% 1	14% 2	4% 1	22% 4	13% 8 –
NET	100% 6 –	100% 14 –	100% 25 –	100% 18 –	100% 63 –
Column names	A	B	C	D	E

Stage predictive maintenance 2 by Medical Advanced Manufacturing Industry Group
Sample size = 63, total sample size = 9901; 9838 missing, 3.8% filtered out, 95% confidence level
Column comparison symbols: a, b, c... (confidence level >= 95%), A, B, C... (confidence level >= 99.9%); No test symbol: – , Not significant symbol:

MDIC
MEDICAL DEVICE INNOVATION CONSORTIUM

ERP/PLM integration

Column percent count Column comparisons	Medical	A&D	Auto and transport	Electronics and semi	NET
Fully engaged	50% 6	43% 10	44% 19	35% 14	42% 49 –
Started implementation	25% 3	17% 4	21% 9	23% 9	21% 25 –
Planning 1-2 years	8% 1	13% 3	14% 6	23% 9	16% 19 –
Planning 3-5 years	8% 1	17% 4	12% 5	5% 2	10% 12 –
Not thinking about it	8% 1	9% 2	9% 4	15% 6	11% 13 –
NET	100% 12 –	100% 23 –	100% 43 –	100% 40 –	100% 118 –
Column names	A	B	C	D	E

Stage predictive maintenance 2 by Medical Advanced Manufacturing Industry Group
Sample size = 118, total sample size = 9901; 9783 missing, 3.8% filtered out, 95% confidence level
Column comparison symbols: a, b, c... (confidence level >= 95%), A, B, C... (confidence level >= 99.9%); No test symbol: – , Not significant symbol:

Social collaboration

Column percent count Column comparisons	Medical	A&D	Auto and transport	Electronics and semi	NET
Fully engaged	33% 4 b	0% 0	25% 11 b	22% 9 b	20% 24 –
Started implementation	17% 2	27% 6	27% 12	34% 14	29% 34 –
Planning 1-2 years	25% 3	23% 5	20% 9	20% 8	21% 25 –
Planning 3-5 years	8% 1	23% 5	11% 5	10% 4	13% 15 –
Not thinking about it	17% 2	27% 6	16% 7	15% 6	18% 21 –
NET	100% 12 –	100% 22 –	100% 44 –	100% 41 –	100% 119 –
Column names	A	B	C	D	E

Stage predictive maintenance 2 by Medical Advanced Manufacturing Industry Group
Sample size = 119, total sample size = 9901; 9782 missing, 3.8% filtered out, 95% confidence level
Column comparison symbols: a, b, c... (confidence level >= 95%), A, B, C... (confidence level >= 99.9%); No test symbol: – , Not significant symbol:

REFERENCES

[1] C. Leiva, "Demystifying the Digital Thread and Digital Twin Concepts," Industry Week, 01 August 2016 [Online]. Available: https://www.industryweek.com/technology-and-iiot/systems-integration/article/22007865/demystifying-the-digital-thread-and-digital-twin-concepts.

[2] McKinsey & Company, "The Business Case for Medical Device Quality," October 2013. [Online]. Available: https://www.mckinsey.com/~/media/McKinsey/dotcom/client_service/Public%20Sector/Regulatory%20excellence/The_business_case_for_medical_device_quality.ashx. [Accessed November 2020].

[3] A. Sarkissian, "An exploratory analysis of U.S. FDA Class I medical device recalls: 2014-2018," Journal of Medical Engineering & Technology, vol. 42, no. 8, pp. 595-603, 20118.

[4] Wilson Research Group, LLC, "Advanced Manufacturing Technology Adoption Study," Wilson Research Group, LLC, El Dorado Hills, 2021.

[5] Wilson Research Group, LLC, "Product Engineering and Manufacturing Market Study," Wilson Research Group, LLC, El Dorado Hills, 2020.

[6] FDA, "Understanding Barriers to Medical Device Quality," United States Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), Washington, 2011.

[7] S. Benjamens, P. Dhunnoo and B. Mesko, "The state of artificial intelligence-based FDA-approved medical devices and algorithms: an online database," Nature Partner Journals, vol. 3, 11 September 2020.

[8] A. Liaqat, W. Hutabarat, D. Tiwari, L. Tinkler, D. Harra, B. Morgan, A. Taylor, T. Lu and A. Tiwari, "Autonomous mobile robots in manufacturing: Highway Coode development, simulation, and testing," The International Journal of Advanced Manufacturing Technology, vol. 104, pp. 4617-4628, 29 August 2019.

[9] A. Angrish, B. Craver, M. Hasan and B. Starly, "A Case Study for Blockchain in Manufacturing: "FabRec": A Prototype for Peer-to-Peer Network of Manufacturing Nodes," Procedia Manufacturing, vol. 26, pp. 1180-1192, 2018.

[10] Z. Lv, "Security of Internet of Things edge devices," Journal of Software: Practice and Experience, pp. 1-11, 2020.

[11] B. Stackpole, "Medical Device Simulation's Next Frontier," Digital Engineering 24/7, 6 January 2021. [Online]. Available: https://www.digitalengineering247.com/article/medical-device-simulations-next-frontier.

[12] Samsung, "The Backbone of the Smart Factory," Samsung – Smart Factory, 2020. [Online]. Available: https://www.samsung.com/global/business/networks/solutions/smart-factory/.

[13] V. Listek, "3D Printing for Interplanetary Colonization with SpaceX," 3DPrint.com, 26 September 2019. [Online]. Available: https://3dprint.com/253073/3d-printing-for-interplanetary-colonization-with-spacex/.

[14] S. Evans and A. MacKenzie, "The Toyota Recall Crisis," Motortraind – Top Gear America, 27 January 2010. [Online]. Available: https://www.motortrend.com/news/toyota-recall-crisis/.

[15] R. Zafft, "Faulty To The Max: Boeing And The FAA's 737 Debacle," Forbes, 04 January 2021. [Online]. Available: https://www.forbes.com/sites/robertzafft/2021/01/04/faulty-to-the-max-boeing-and-the-faas-737-debacle/?sh=2e09f43a2134.

[16] K. Wiggers, "Everything we know about Samsung's Galaxy Note 7 recall," Digital Trends, 17 May 2017. [Online]. Available: https://www.digitaltrends.com/android/samsung-halts-galaxy-note-7-shipments-phones-catching-fire/.

[17] Aberdeen Group, "Analyst Insight: Closed Loop Quality Management – Integrating PLM and Quality Management," September 2010. [Online]. Available: https://www.plm.automation.siemens.com/de_ch/Images/AI-SiemensClosedLoopQuality-ML-07_tcm782-117511.pdf.

Contact information

For more information, please contact
Joseph Sapiente at jsapiente@mdic.org