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Siemens Digital Industries Software

Overcoming the top six medtech challenges

Enabling smart manufacturing
with integrated MES

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Investing in integrated MES is one of the most important technology enablers for accelerating high-quality innovation in the medtech industry.

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A woman with brown hair, wearing safety glasses and a white lab coat, is looking intently at something off-camera. The background is a blurred industrial or laboratory setting with metal frames and equipment. The image is split into two main sections: a large teal section on the left and a white section on the right.

The importance of investing in MES

The list of market conditions and forces and the pressures they are exerting on medical device and diagnostic (MD&D) manufacturers is unprecedented. Consider: The Internet of Medical Things (IoMT), personalized medicine, value-based care, real-world evidence models, demographic differences across regional economies and the implications of treating chronic diseases and the new European Union Medical Device Regulations (EU MDR). The technologies and processes designed to address these challenges have multiplied to a point that even the most seasoned professional has difficulty navigating them.

To help you find a path through this complex environment, this e-book discusses the top six challenges facing medical technology (medtech) manufacturers and introduces you to the technologies and implementation strategies that are critical for meeting these challenges. Specifically, integrated manufacturing execution systems (MES) are positioned at the heart of the digital enterprise as the key to integrating the virtual world of design and engineering with the physical world of production.

Investing in integrated MES is one of the most important technology enablers for accelerating high-quality innovation in the medtech industry.

The six challenges

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1. Accelerated product innovation

With new technologies reshaping the medical device industry, how can you accelerate seamless and high-quality new product introductions (NPI)? How will you introduce new processes with existing production and facilities? How will you get the most out of your research and development (R&D) investment?

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2. Intelligent data analytics

The MD&D industry generates vast amounts of data from design to production to product utilization. How can that data be harnessed to improve product design and manufacturing processes, especially given increasingly complex technologies, global supply chains and the rise of the IoMT?

33

3. Mass customization and 3D printing

Patients are bringing a consumer mindset to healthcare, resulting in shrinking MD&D lot size and product customization to accommodate personalized medicine. How can you meet customization requirements while maintaining business profitability? In other words, how can you implement mass customization models at scale?

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4. Market consolidation and technology partnerships

In an environment of accelerating consolidation, increasing mergers and acquisitions (M&A) and growing technology partnerships, how can MD&D manufacturers consolidate disparate systems and leverage technology to support improved communication and cooperation?

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5. Restrictive regulatory environment with global differences

According to Axendia, regulatory compliance continues to constrain improvement in MD&D manufacturing efficiency and productivity¹. The United States Food and Drug Administration (US FDA) as well as the new EU MDR are driving new requirements. What technologies can give your company a competitive edge, enabling both compliance and proactive quality improvements?

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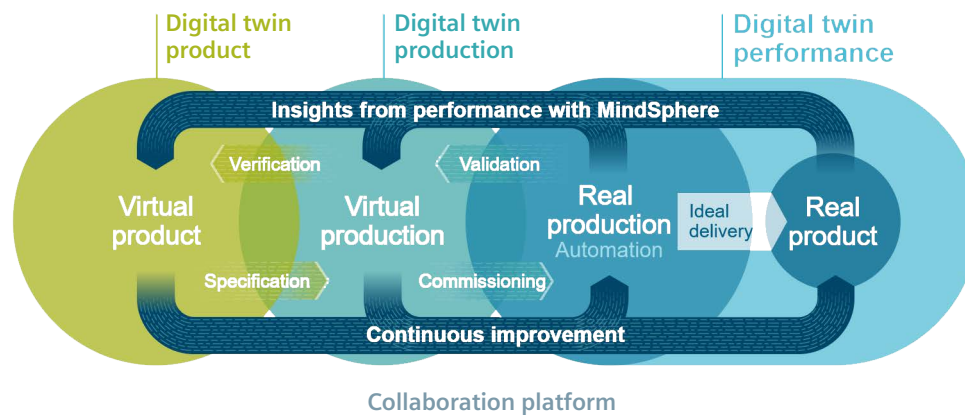
6. Value-based care and healthcare cost pressure

Acute competitive and financial pressures are emerging as healthcare institutions move toward value-based care reimbursement models, cuts in reimbursements and other changes in healthcare's financial landscape. How will your company achieve the efficiencies needed to remain competitive and profitable in this financial environment?



This e-book provides perspective on these challenges, and details how leading MD&D manufacturers are using integrated MES to enable smart manufacturing and prepare themselves for taking a leadership position.

Defining smart manufacturing and the critical role of integrated MES



Smart manufacturing is an open, end-to-end, digitalized manufacturing framework that connects all participants in the product lifecycle – from ideation in design, realization in production and utilization in the field – leveraging the intelligence being built into smart machines, parts, materials, products, buildings and supply chains. Smart manufacturing creates a holistic approach, leveraging digital design and engineering capabilities that are fully interconnected with the production environment (operators, plant managers and automation).

Smart manufacturing optimizes production of quality products using digital twins. The digital twin is an accurate virtual representation of the product, its manufacturing processes and intended use. It predicts and optimizes performance in the physical world. The greater the accuracy of the digital twin, the greater its value in predicting performance.

Smart manufacturing connects business processes with the use of digital threads. The digital thread is the chain of

information connecting all participants with the applications and information they need to design, build and support innovative products. The digital thread connects the complete value chain from ideation to realization and extends vertically through IoT connections to devices, sensors and controllers, providing performance measurements for big data and real-time strategic analysis.

The power of the digital thread and the digital twin is fueled by tools and systems that communicate with each other. Communication means the various systems and tools need to have access to, and understand the language of, the others. The real value of digitalization and business transformation occurs as a company's digital thread and digital twin capabilities mature, transforming business processes and enabling smart manufacturing.

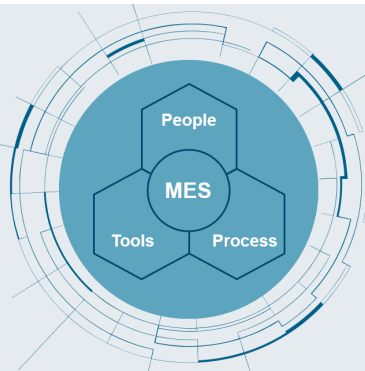
This is where the role of integrated manufacturing execution systems is critical. With smart manufacturing, we are not only making products, but also producing a huge amount of data that can further inform digital twins, and

continuously optimize production performance. MES must be used to collect data from the shop floor and IoT sources, contextualize them in a meaningful way and enrich the digital thread to communicate across the entire enterprise.

Integrating MES in smart manufacturing allows us to aggregate, analyze and transform data into actionable information that can be reported back to both product development and production planning to create an entirely closed-loop, decision-making environment for continuous optimization. Using MES ensures information from the virtual world (digital twin of product and production) can be verified, validated and commissioned for real production.

MES is the digital heart of smart manufacturing. It is the real-time software layer that links and pumps information from enterprise resource planning (ERP) and product lifecycle management (PLM) to automation, connecting the virtual world of product development and resource planning with the physical world of production. The MES receives production orders from ERP and PLM

- Implement the digital twin in real production
- Plan and orchestrate manufacturing and quality operations
- Enable continuous closed-loop improvements through as-planned and as-is data
- Bridge the gap between enterprise systems and automation
- Transform big data into IoT actionable information



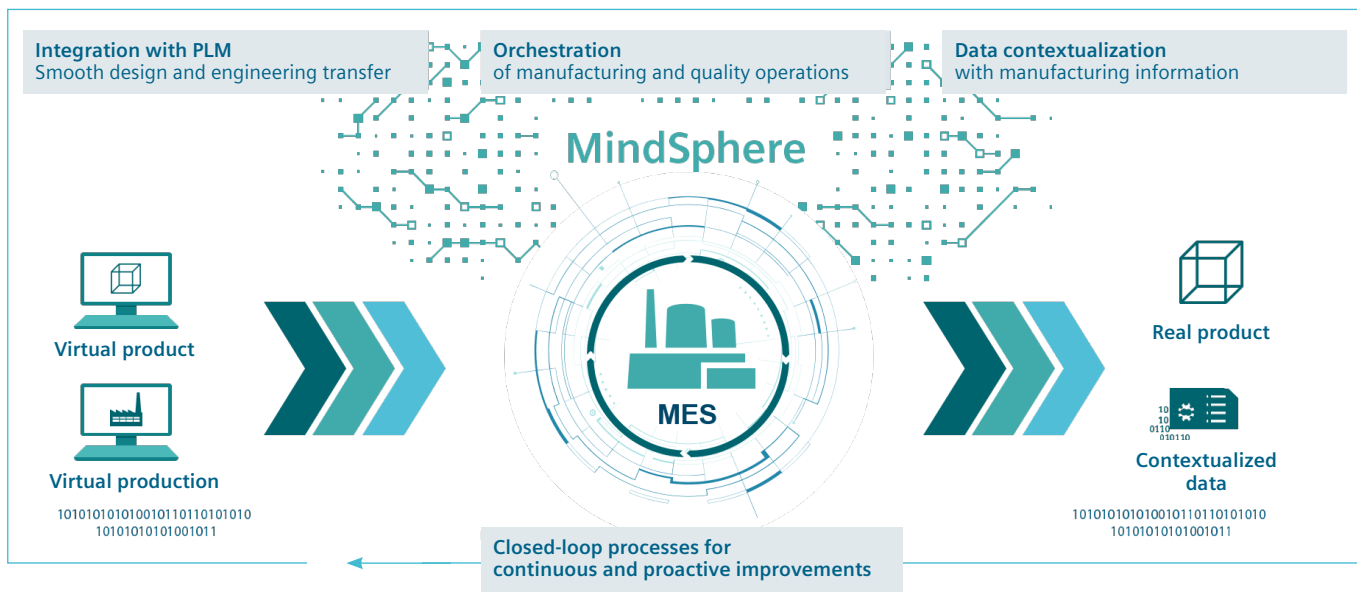
Manufacturing execution system

Smart manufacturing

systems, such as the bill-of-materials (BOM) and bill-of-process (BOP). The MES is used to orchestrate all manufacturing activities according to those instructions and shop floor availability.

Using MES enables you to control and enforce the manufacturing process, providing real-time visibility,

track-and-trace and full genealogy for production operations. MES can also be used to dispatch materials and jobs, allocate resources, collect and contextualize data, enforce process steps and operator certification, deliver work instructions and enable paperless plant floors.



Challenge 1: accelerated product innovation



New technologies are reshaping the medical device industry and R&D investments are growing: connected devices, wearable technologies, IoMT and device-as-a-service are just examples of innovation trends.

Key insights:

- A clear majority (79.2 percent) of medtech executives perceive connected health as a key growth opportunity theme in the medical device and healthcare industry²
- Medtech R&D spend forecast to grow by 4.3 percent compound annual growth rate (CAGR) to \$34B in 2022³
- Compared to other global manufacturers, medical device companies are far more likely to strategically prioritize R&D and product development than any other manufacturing industry
- KPMG reported 33 percent of medical devices manufacturers perceive the “efficiency in research and product development processes” as the second biggest challenge over the next one to two years⁴

Complexity of new product introductions

Medtech manufacturers should expect an increase in complexity and the number of new product development and introduction (NPDI) processes. New technologies and products will drive competition in the upcoming years. Medtech manufacturers should be exploring ways to accelerate their time-to-market.

Accelerating speed-to-market while increasing efficiency

Medtech manufacturers will be facing new competitors, many from the small and medium business (SMB) and startup market segments. Incumbent

manufacturers will need to respond with increased speed-to-market, quickly addressing demand while managing the lengthy process of regulatory approvals. With agile companies across the globe that have a lower cost of production, medtech manufacturers will have to justify a price premium with consistently superb product performance.

At the same time, medtech companies must be continuously increasing their efficiency – both in operations and capital. To improve project efficiency and execution, manufacturers will need to reduce their cost of delivering projects. They will have to increase employee productivity and collaboration by simplifying and standardizing work processes, enabling improvement of project cycle time performance and on-time deliveries.

To improve capital efficiency, manufacturers will have to be selective to implement cost-effective improvements. They will not only need to execute projects on time, on budget and on specification, but they will have to expedite time-to-production and plan for long-term operability, maintainability and reliability.

Increasing potential for errors in accelerated change environment

Innovation will require increased flexibility and integration between product design, engineering and manufacturing. A disconnected system for design, process engineering and manufacturing engineering results in error-prone processes that increase the probability of product delays, unforeseen errors and field failures – especially for NPI.



Speeding up NPI while delivering high-quality change management

Integrated MES can create a closed-loop manufacturing process to produce a collaborative environment, keep up with competition and efficiently manage change. Closed-loop processes enable fast learning about new product issues, complexities and possible solutions, providing actionable information to design and engineering departments to implement change.

- Using MES provides real manufacturing data to feed simulation and modeling of products and processes to support design for manufacturability and quality by design. It enables you to leverage simulation to shorten commissioning and validation times while increasing process reliability and product quality
- Using MES ensures process robustness and consistency to minimize unexpected downtime and delays/shortages to meet demand
- Using MES enables you to detect, fix and prevent errors more easily and quickly, providing end-to-end traceability from supplier to finished goods
- Using MES ensures quality execution and compliance with nonconformance reporting and corrective and preventive action (CAPA) enforcement connected to quality processes from design to production

*Using MES:
Speeds up NPI
Ensures enforcement of quality
Feeds simulation
Prevents errors*



Challenge 2: intelligent data analytics



Increased complexity in products, global supply chains, regulatory landscapes and the rise of the Internet of Medical Things are generating big data, including exponential growth in digital sources of various types, input rates, communication channels and accuracy. Most medical device manufacturers are currently unable to analyze the data they already have so they can understand its impact on quality and cost. Leveraging real-time and big-data analysis will only get more difficult, yet it will be a critical competitive differentiator. The manufacturers that do it well will improve their decision-making processes and their position in the market.

Key Insights:

- According to Axendia, 66 percent of all medical device companies still use paper documents during production¹
- A large majority (66.7 percent) of medical device executives perceive intelligent data analytics as one of the major themes for growth opportunities²
- Sixty-four percent of medical device providers perceive the consumer experience is greatly improved due to operations in IoMT programs
- Those with an integrated and digital approach to design, engineering and production execution are four times more likely to monitor analytics and use intelligent data¹

Shift from managing documents to using metrics

With big data, the manufacturing mindset needs to shift from managing documents – still on paper or digitized documents in siloed systems – to using

metrics that are derived from across the value chain. Providing visibility and access to business metrics across manufacturing operations requires an integrated platform that can contextualize data from various functions and synthesize it into global performance views.

Standardizing data for analysis

Data across the enterprise must be standardized to create overall performance visibility and continuous quality improvement. With data in various systems and formats today, manufacturers will need to create data models and master data formats to maintain consistency in the analysis of product performance, using functional and physical attributes along with connected requirements, design and operational information.

Sustainable, transferable enterprise intelligence

Without a supporting digital infrastructure, medical device manufacturers have relied on the tribal knowledge of their operators and engineers for improving designs and processes. Although there is a risk those individuals will leave or retire, taking that know-how with them, the reality is the complexity and volume of data is simply too great for humans to comprehend, or interpolate from system-to-system.

Medical device manufacturers must harness their data into enterprise intelligence and retain that intelligence over time. This is critical for maintaining competitiveness and achieving long-term market leadership.



Creating digital models that leverage real-world performance

Regulatory agencies are increasingly looking at real-world data (RWD) as input sources for monitoring safety and adverse events of medical devices as they are used by clinicians and patients. They are using the information to make regulatory decisions. The models are also being used by: payors to support coverage decisions, providers to develop guidelines for clinical practice and generally across the healthcare community for decision support.

To benefit from these large volumes of RWD, medical device manufacturers must adopt digital solutions that capture learning from the real world, integrate it with data coming from other relevant sources (supply chain, design, engineering, manufacturing, etc.) and enhance it to create predictive insights for decision-making.

MES is central to creating intelligent data analytics

Using MES is key to creating a seamless business intelligence infrastructure for medical device manufacturers. As the orchestration layer between engineering and manufacturing execution, MES is used to control all aspects of real-world production and interfaces with the operators, machines, automation, materials and facilities. MES enables the user to collect raw data from all these inputs and contextualizes that data with meaningful manufacturing information. In this process, data is standardized so that it may be useful to systems across the enterprise.

Using MES is central to capturing manufacturing know-how and integrating it into an enterprise-wide platform so this contextually relevant information can be transferred to design and process engineering, continuously improving quality and costs. For short-term, real-time performance indicators, MES is equipped to feed enterprise manufacturing intelligence (EMI) so users can understand key performance indicators (KPIs) such as overall equipment efficiency (OEE), production efficiency, utilization, throughput, waste, etc.

In a longer term, more strategic view, MES facilitates the use of lifecycle analytics applications for end-to-end big data intelligence across the entire product lifecycle (from design to utilization) and the supply chain (from supplier to manufacturer to consumer). Employing MES provides these applications with meaningful and relevant manufacturing data for analysis. When product-quality issues arise, it is the manufacturing data that must be analyzed to understand if the issue is a matter of design or manufacturing process. If it is a design issue, manufacturing data must be analyzed to determine the impact of a potential design change on manufacturing performance. You can do this kind of predictive analysis only if you have lifecycle analytics enriched with manufacturing data from the MES.

These connected, lifecycle-wide intelligence functions support the shift from managing documents to managing operations using meaningful metrics that can advance product quality and operational efficiency.

Using MES:

Standardizes manufacturing operations data from the shop floor and automation – making it useful for enterprise analytics

Facilitates capturing manufacturing know-how digitally

Enables the shift to enterprise-wide metrics management

Provides the intelligence for creating digital models of production performance



Challenge 3: mass customization and 3D printing



Patients are bringing a consumer mindset to healthcare interactions and companies are creating consumer-oriented technologies to improve the experience. Innovation is allowing the personalization of devices at scale. Healthcare reimbursement models are becoming more closely tied to patient satisfaction, elevating the urgency for an improved experience.

Key insights:

- Currently, 20 percent of knee implant recipients report not being satisfied with the results of their surgery, with pain and limited mobility leading the list of complaints. By using a custom-designed knee implant that considers the unique structure of the existing bone in the joint, it's possible to improve outcomes across the board³
- In 2011, the FDA approved the first 3D-printed knee. In December 2014, the *Washington Post* highlighted the first physician to use the fully customized implant⁶
- Fifty percent of medical device chief executive officers (CEOs) perceive personalization and customization as the most disruptive business model
- Shrinking lot size to meet the needs of personalized medicine

As we move to personalized medicine, manufacturing complexity will increase while lot sizes will shrink to one. Manufacturers will need to more closely integrate engineering, modeling and simulation with manufacturing

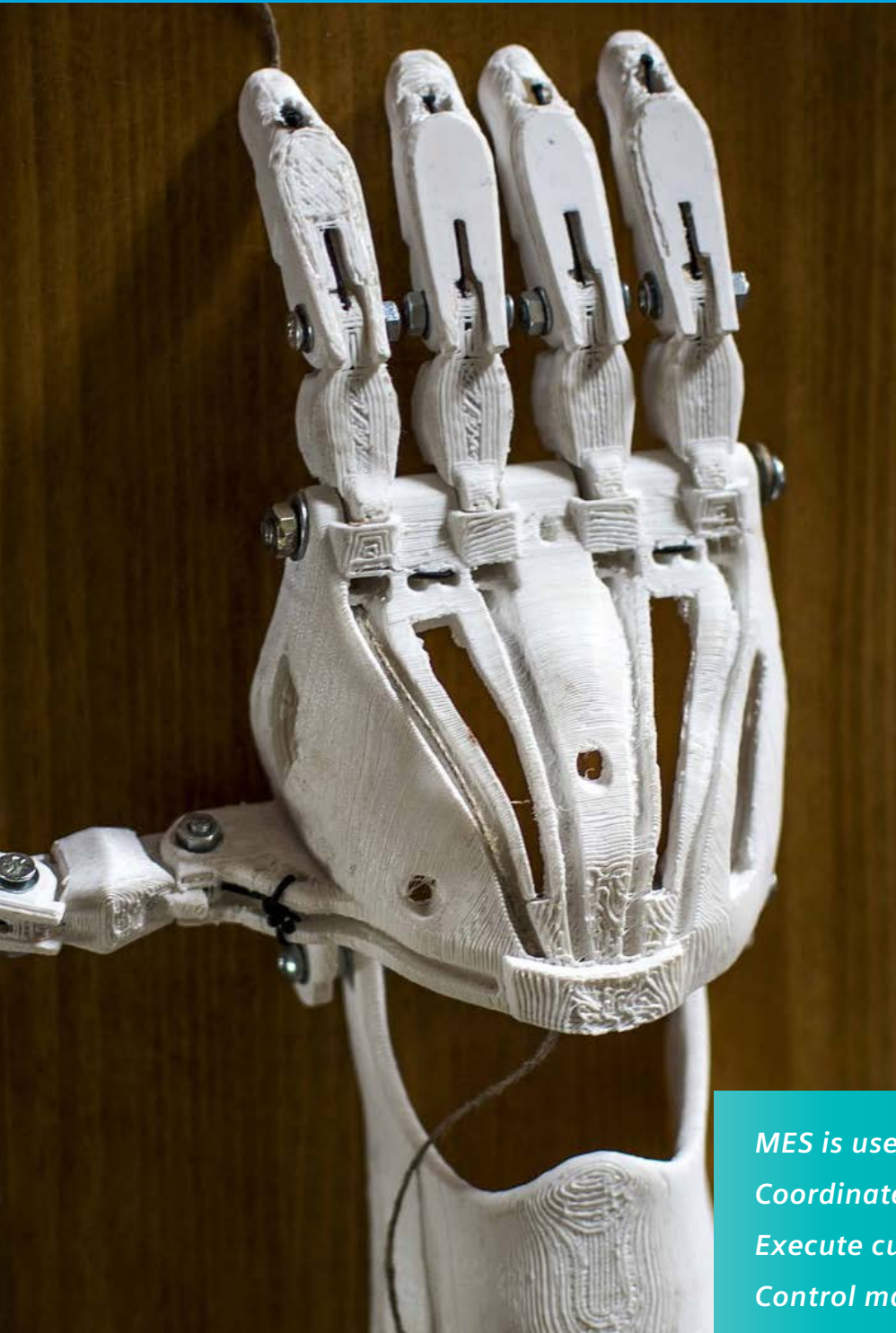
production. Additive manufacturing (AM) and 3D printing will be required to support mass customization and reduce variable manufacturing costs. That will require increased visibility into direct materials, direct labor and variable manufacturing overhead to control costs.

Focus on the outcome for each patient

Outcomes for patients will more strongly influence patient satisfaction as consumers become more educated and expectations rise. Manufacturers will need to use simulation and modeling to identify the best product for each patient, improving the characterization and understanding of each customized product. Patient-specific jigs and tooling will be required to improve outcomes using off-the-shelf (OTS) implantable devices. Tighter cost controls over product manufacturing will be required as a shift occurs from selling products to selling outcomes.

Handling the increased complexity of mass customization and 3D printing

The mass-customization trend today will increasingly require the adoption of 3D printing and AM in serial production environments. The coordination of multiple 3D printers or 3D printing systems, the provision of the right print job file (PJF) to the right printer, and the orchestration of materials/machines/orders all will require MES.



Let us look at some of the details of the role of MES in AM and 3D printing environments.

- Production is planned and executed according to customized patient orders: a typical scenario involves connecting to ERP and integrating with production scheduling software
- Production is executed according to a predefined and approved process: A typical scenario involves multiple production steps, including 3D printing, machining, painting, assembly, recycling and mixing of powders, managing substrate thickness and treatment thresholds, etc.
- 3D printing must be maximized for cost and time efficiency: The MES must support maximizing 3D printer usage, such as printing products from different work orders at the same time
- The MES must be used to create the full product genealogy tracking and pedigree, including raw material and tools used

In addition, data from the shop floor will be required to enhance cost center visibility to ensure cost efficiency is maintained

MES is used to:

Coordinate 3D printing systems

Execute custom orders

Control machines and materials

Produce genealogy and pedigree

Provide cost visibility

Challenge 4: market consolidation and technology partnerships



Large medical device companies' drive for scale and strength in their chosen core business areas compels them to pursue M&A strategies as well as technology partnerships to achieve dominance.

Key insights:

- The industry has evolved over the last several decades from a fast-growing market to a maturing one, driven by a slowdown in production volume. As a result, the industry is experiencing accelerating consolidation
- Abbott Laboratories acquired St. Jude Medical for \$25B. The acquisition is an important part of the company's ongoing effort to develop a strong, diverse portfolio of devices, diagnostics and pharmaceuticals for cardiovascular diseases²
- Johnson & Johnson (J&J) acquired Abbott's eye surgery business for \$4.33B. The deal allows Abbott to focus on its core business and divest from noncore business. It also allows J&J to expand its portfolio and become a larger presence in vision care
- Almost half of CEOs (45.8 percent) believe they will rely on partnerships to drive their organization's growth over the next three years²

M&A leads to a multitude of disparate systems

As M&A activity brings together manufacturing environments from previously separate companies, disparate systems and point solutions will need to be consolidated to achieve visibility and control quality and cost.

M&A may lead to culture clashes and miscommunication

Bringing together organizations will require extensive communications not only to coordinate innovation, compliance and quality, but also to overcome cultural differences. Manufacturers will not only need to manage organizations, but also leverage technology to support a common digital footprint and foster communication and cooperation.

Driving an increase in technology partnerships

The rise of high tech in MD&D is driving manufacturers to new competitive areas where they may not have all the capabilities and knowledge in house. Manufacturers will need to establish strategic partnerships with high tech manufacturers to augment their skills and enable them to deliver new devices to market.



MES is used to:

Coordinate 3D printing systems

Execute custom orders

Control machines and materials

Produce genealogy and pedigree

Provide cost visibility

Accelerating M&A and partnership synergies

Manufacturers will rely heavily on MES to unify disparate manufacturing operations for both newly acquired companies as well as technology partners. MES must be built for global manufacturing operations, collaboration, visibility, control and analytics across the global operations, partner ecosystem and supply network.

- MES systems must be enterprise-ready, enabled to exercise control across global manufacturing footprints, with complete end-to-end traceability and 5M enforcement (manpower, machine, materials, methods and measures)
- MES systems must support data aggregation across cloud-based IoT applications for big data analytics – facilitating understanding of performance across dispersed operations
- MES systems must support multi-plant collaboration for efficient and scalable change management

To ensure their MES supports this type of global manufacturing environment, manufacturers must meet several platform requirements:

- Multi-site capabilities that are easy to use out-of-the-box (OOTB)
- Ability to customize the manufacturing process using OOTB data modeling capabilities
- Definition of standard operations, which will accelerate the ability to define a newly acquired company's operations
- Ability to define centrally and customize locally – the MES should allow for local requirements and preferences
- Integration with scheduling solutions to identify plants with available capacity or equipment to create efficiencies

A global MES connects the enterprise, gets information flowing across multiple sites and partners in a rapid, consistent fashion to increase speed, agility and efficiency. The ability to lift-and-shift – allowing the propagation of manufacturing processes and instructions from one facility to another – creates rapid implementation at lower cost. Control over all global operations is imperative to produce consistent quality, ensure reliability and lower prices for end products, including complex devices.

As consolidation continues, MES is critical to increase innovation velocity and scale operations across disparate manufacturing operations.

Using MES:

Unifies systems across acquired companies

Orchestrates global production while allowing local customization

Supports multilingual and multi-cultural enterprises

Connects production across partner operations



Challenge 5: restrictive regulatory environments with global differences



The regulatory environment for the medical device industry still constrains innovation and speed-to-market. “Our primary research shows that medical device companies list regulators/government agencies as the top business disruptor,” says Sandra Rodriguez, Market Analyst at Axendia. In the United States, the FDA initiatives are shifting focus to product quality versus traditional compliance. The EU Commission’s proposal for the regulations on medical devices establish a modernized and more robust legislative framework to ensure better production of public health and patient safety – presenting new challenges for operations in that geography.

Regulatory inspections are disruptive, and companies are finding it difficult to manage and respond to inquiries, and product recalls are still rising. With social media and consumer engagement, the repercussions of recalls will be more damaging to medical device company brands.

Key insights:

- A restrictive regulatory environment is the biggest growth challenge perceived by medical device manufacturers (58.3 percent)²
- According to Axendia, 85 percent of medical device manufacturers define the role of quality as compliance with regulations or internal policies or procedures. Only 10 percent define the role of quality as driving product/process improvements⁷

Quality inspections will become more difficult to manage

When product traceability is hidden in paper records and downstream data is not integrated into the product master record, it is impossible to properly conduct root-cause analysis and define preventive actions, resulting in regulatory agency actions or recalls.

Manufacturers must collect data throughout the product lifecycle

Manufacturers in the US will be required to expand the data collected across the product lifecycle and respond to the FDA Regulatory Framework for the Total Product Lifecycle (TPLC). Medical device companies will collect data, including concept, prototype, feasibility, stability, clinical, design transfer, manufacturing, in-process testing, product release, quality inspections, nonconformance reports (NCRs), CAPA, field actions, adverse events, post-market surveillance, complaints and obsolescence.

Quality and compliance are often confused

Medical device companies focus on compliance activities because the FDA guidance demands it. Compliance does not equal quality and having great compliance does not ensure high-quality products. Quality and compliance are often confused.

Manufacturers need to understand the FDA’s quality metrics guidance

“Our primary research on the medtech industry’s ability to build a culture of quality and innovation shows only 62 percent of manufacturers are familiar with FDA’s Medical Device Industry Consortium (MDIC) Case for Quality,” says Rodriguez. The agency recognizes manufacturers who are high performers and will shift their resources to products/areas that need more attention. Manufacturers should learn about and become active in the FDA’s Case for Quality.



Audit

Using MES:

Allows regulatory inspections to be easily managed

Enables manufacturers to focus on quality and delivering compliance as a by-product

Supports FDA requirements and enables manufactures to perform well in the FDA's Case for Quality initiative

Supports EU MDR requirements

MES is the source of data from the shop floor – enriching TPLC intelligence

EU regulations bring important improvements

The EU MDR contains a series of important improvements to modernize the current system. They include:

- Stricter ex-ante control for high-risk devices via a new pre-market scrutiny mechanism with the involvement of a pool of experts at the EU level
- The reinforcement of criteria for designation and processes for oversight of notified bodies
- The inclusion of certain aesthetic devices that present the same characteristics and risk profile as analogous medical devices within the scope of these regulations
- The introduction of a new risk classification system for in-vitro diagnostic medical devices in line with international guidance
- Improved transparency by establishing a comprehensive EU database of medical devices and a traceability system based on unique device identification (UDI)
- The introduction of an implant card containing information about implanted medical devices for a patient
- The reinforcement of the rules on clinical evidence, including an EU-wide coordinated procedure for authorizing multicenter clinical investigations
- The strengthening of post-market surveillance requirements for manufacturers
- Improved coordination mechanisms between EU countries in the fields of vigilance and market surveillance

Focusing on product quality and compliance

The MES automatically controls the manufacturing environment according to product and process definitions, while simultaneously collecting as-built data. Although the opportunities for errors, NCRs and field failures are dramatically reduced, compliance becomes a by-product of a digitally controlled process. Managing inspections is greatly simplified, reducing the time and overhead of producing documented evidence with technology solutions that provide rich, timely and accurate data.

Manufacturers must leverage MES to automatically create device history records, accelerating their ability to respond to inspections and more intelligently prevent quality issues.

Access to real-time data and full traceability allow better decision-making and predictive analytics across the product lifecycle. MES provides this source of data for TPLC.

Ultimately, using MES supports the FDA's case for quality. The FDA is looking for manufacturers to adopt technologies like MES to allow them to focus on efforts that improve product quality, rather than focusing on documenting compliance. Medical device manufacturers that adopt MES will be in a much stronger position to reduce the amount of regulatory scrutiny relative to manufacturers that don't.

As with FDA regulations, using MES is critical for supporting EU regulatory requirements. Using MES enables you to automatically record as-built data, providing visibility into useful manufacturing data that can add to the entire product lifecycle from R&D to manufacturing to patient (post market) and back using closed-loop feedback.



Challenge 6: value-based care and healthcare cost pressure



The movement toward value-based care will have far-reaching implications. Value-based care is a payment model for providers (health systems and physicians) that is based on patient outcomes rather than the amount of services provided. In a fee-based approach, a physician gets paid regardless of whether the patient's health improved because of those services. In a value-based model, payment is reduced for poor-patient outcomes or complications resulting from service.

Value-based care along with regulatory and other governmental financial pressure are intensifying the need for cost efficiency in medical devices. Examples include the government excise tax on medical devices, the FDA UDI initiative and hospitals reducing spending on equipment due to perceived reduction in reimbursement under a value-based care model.

To support outcome-based models, manufacturers of imaging and diagnostic equipment, such as X-ray, computed tomography (CT), magnetic resonance imaging (MRI), molecular imaging and ultrasound, are beginning to shift from selling capital equipment like diagnostic and imaging machines to selling images, studies and tests to improve outcomes.

Key insights:

- Nearly two-thirds of healthcare payments are now based on value⁸
- Value-based care strategies are having a great impact in terms of care quality (77 percent), patient engagement (73 percent) and provider relationships improvement (64 percent)⁹

Medical device companies will shift from right-first-time to best-first-time

Value-based care and government regulations are increasing the strain on capital investment and operating budgets for healthcare providers and caregivers. As a result, both providers and medical device manufacturers are implementing outcome-based models, shifting from asset acquisition to fee-for-outcome. Quality requirements will have a stricter standard – not simply must the device perform as intended, but it must improve the patient's health.

Remaining flexible to meet diverse price/margin sensitivities

There is an increasing recognition of the need for off-grid devices for developing countries. With the challenge of managing chronic disease globally, the medical device industry must find the right balance between addressing global opportunities and removing the health differences between mature and emerging economies.

Using a platform approach like the automotive industry, medical device manufacturers will look to make simple product configurations to serve these regions.

Pricing pressure will drive differentiation and efficiency

Given intense pricing pressure, manufacturers will look to achieve price premium via consistent product performance. They will need to develop new, differentiated product and service offerings faster. Their products will need to generate more value and higher outcome per care than the competition. Manufacturers will look for new opportunities to drive cost efficiency in production.



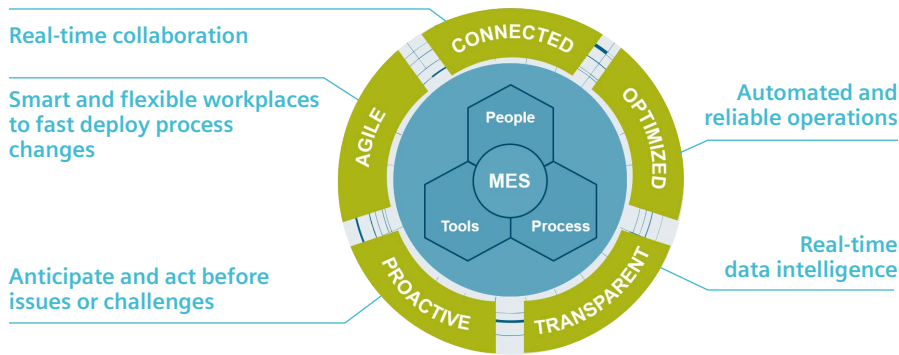
*Using MES:
Controls costs
Ensures quality with 5M control
Supports flexibility across
production environments*

MES helps control cost and quality in various production environments

Although MES will continue to underpin cost efficiency and product quality, it will also supply the data from the as-built production environment as a source of information to understand the next level of quality; that the product not only operated as intended in the field, but also led to a positive patient outcome.

Using MES will also enable the flexibility that manufacturers will need to orchestrate a global manufacturing enterprise while supporting local needs, price points and preferences. That's the beauty of the MES system – it knows what resources are on local production lines and can optimize production based on manufacturing orders.

Meeting the requirements for your digital transformation journey



The MES platform needed by medical device manufacturers to meet the challenges trending in the industry has rigorous requirements. It must be built to enable smart manufacturing and provide a set of capabilities that transform current operations.

MES built for smart manufacturing must support the following capabilities:

Optimized – automated and reliable operations

The core of MES is to enable operational excellence, which translates into high margin, high quality and accelerated time-to-market. MES delivers:

- Reliable, predictable production capacity
- Increased asset uptime and production efficiency
- Highly automated production and material handling with minimal human interaction
- Minimized cost of quality and production

Connected – real-time collaboration

Your MES platform must connect a global operational footprint and retain institutional knowledge for ongoing improvement:

- Continuously pull traditional datasets along with new sensor and location-based datasets
- Collaboration across departments (for example, feedback from production to product development)
- Real-time, data-enabling collaboration with suppliers and customers

Proactive – anticipate and act before problems arise

MES must enable you to systemize quality into the fabric of production, facilitating predictions and preventing potential issues before they create product defects or other disruptions:

- Predictive anomaly identification and resolution
- Automated restocking and replenishment
- Early identification of supplier quality issues
- Real-time safety monitoring

Agile – smart and flexible workplaces to rapidly deploy process changes

With growing customization, personalization and geographic differences, MES must support an agile manufacturing environment.

- Flexible and adaptable scheduling and changeovers
- Implement product changes to see impact in real time
- Configurable factory layouts and equipment

Transparent – real-time data intelligence

MES will provide critical as-built production intelligence with the appropriate context and translation to be consumed across the product lifecycle in pursuit of innovation, quality and value.

- Live metrics and tools to support quick and consistent decision-making
- Real-time linkages to customer demand forecasts
- Feedback into design to improve product and process quality

These capabilities are uniquely delivered by an integrated MES platform that is designed and built to enable smart manufacturing. As we consider the challenges and trends emerging for medical device manufacturers, it is clear operating without the foundation of MES is not an option.



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Primary research data and analysis conducted by Axendia, Inc., contributed to this white paper.

About Axendia, Inc.

Axendia is a leading analyst and strategic advisory firm focused exclusively on the Life-Sciences markets. Since 2005, Industry stakeholders and regulators have relied on Axendia for trusted advice on Business, Regulatory and Technology issues and trends based on trusted sources. Axendia serves the entire Life-Science ecosystem ranging from start-ups to Fortune 100 companies including: Life-Science Organization, Technology & Service Providers, and Regulatory Agencies.

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