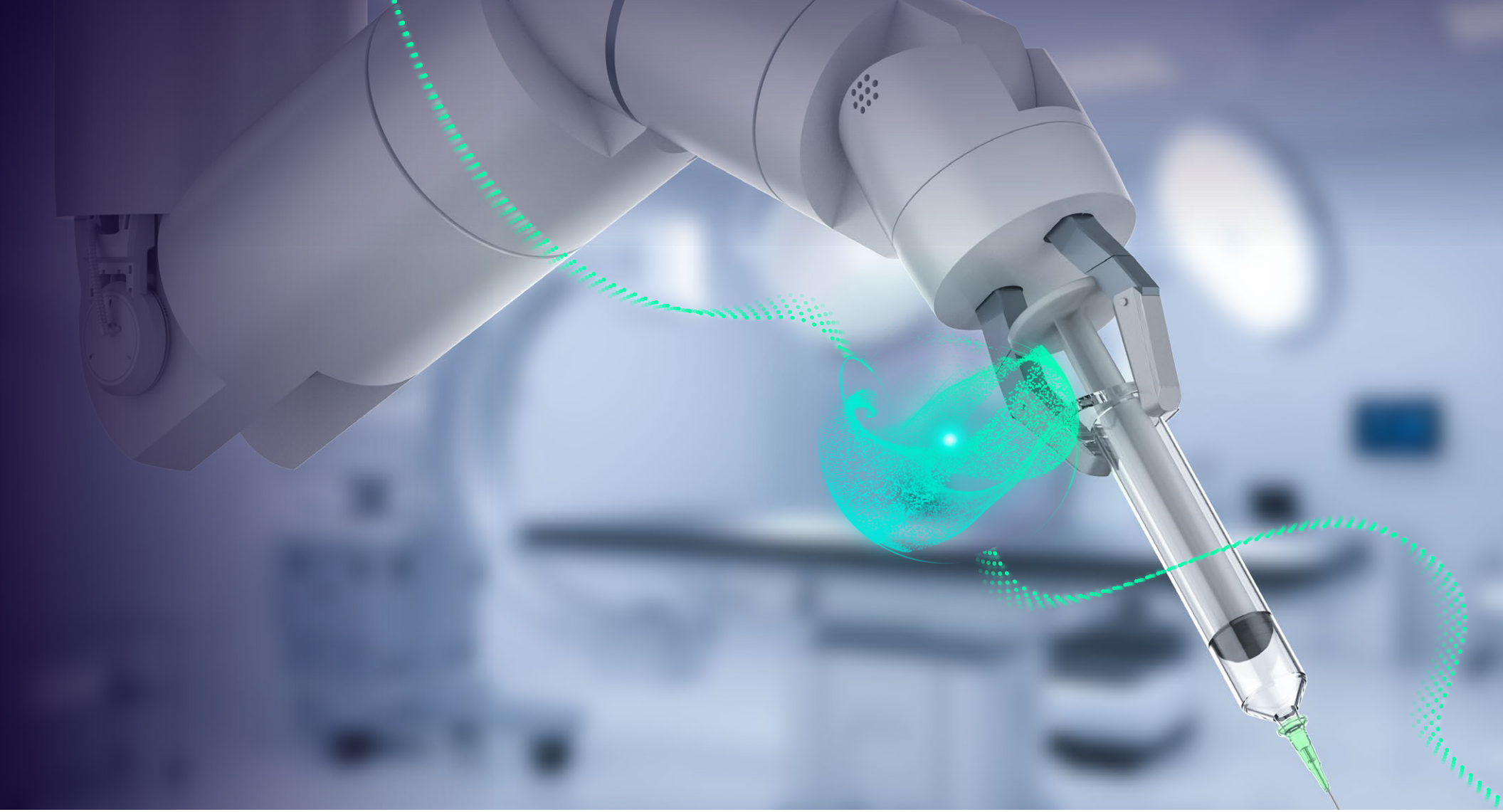

Control Shop Floor Efficiency

Execution & Enforcement improves medical device compliance
with perfect eDHRs and automated practices

siemens.com

Regulatory Trends

Can your manufacturing processes keep up with the changing focus from compliance to product quality, while maintaining the agility to address changing demand surges?

The emergence of digitalization has allowed government regulators to reevaluate and modernize their methods to ensure consumer safety, product efficacy and regulatory compliance in the modern age.

From January 2017 to September 2019, the Food and Drug Administration (FDA) recalled 134 drugs and 34 medical devices in the U.S., primarily due to product quality issues.[1] One of the main goals of the FDA's approach identifies key areas to improve overall performance, including traceability, production control and data visibility.

This new emphasis on manufacturing quality comes as the complexity of medical device products is increasing. Technologies such as customized orthopedics, connected diagnostics, the internet of medical things (IoMT) and wearables greatly impacts production cycles. To keep the connection between product, design and execution strong, design teams need to know the limitations of production and the shop floor must be able to adjust quickly to new requirements.

The challenge is how to simultaneously satisfy compliance regulations, maintain product quality and stay on the cutting edge of innovation and agility. The majority of medical device manufacturers still work from paper Device History Records (DHRs), which makes it impossible to properly conduct root cause analysis investigation and preventive actions.

Siemens Operational Excellence for Medical Devices includes an Execution and Enforcement solution that eliminates dependence on paper. It enables automated production that can be simulated, scheduled and executed using enforced routes, yielding quality-controlled devices with a perfect Electronic Device History Record (eDHR).

[1] Source: Journal of the American Pharmacists Association. August 1, 2020. Learn more

Manufacturers benefit from consistent data that can be analyzed, summarized and reported to provide continuous visibility to production performance.

The Opcenter Manufacturing Execution System (MES) supports:

- Smart collaboration between product design, manufacturing and quality
- Reduced lead times to respond to customer demands and deliver high-quality products
- Flexible workplaces to quickly deploy process and product changes
- Improved supply chain collaboration and coordination
- Proactive compliance and traceability into production processes

Operational Excellence for Medical Devices automates manufacturing workflows across operators and machinery for improved compliance and decision-making

Siemens offers Operational Excellence tools to help with the challenges of today's medical device manufacturing market

Error-proof your manufacturing process

Central to MES is controlling the 5Ms of manufacturing: material, man, machine, measure and method. That means ensuring that resources are available, operators are properly trained, the correct equipment is used, accurate test data is collected, and the right processes are followed. An MES created specifically for the needs of medical device manufacturers can help manage the 5Ms by streamlining floor operations and reducing errors.

Siemens Opcenter Execution for Medical Devices applies strict process and quality-control compliance and provides immediate access to self-auditing, flawless eDHRs. It confirms the correct operator, machine, materials/recipe, processes and measurements at every step, creating a centralized view of quality performance.

The option of implementing as a cloud-based MES system means turning a factory into a digital hub where production is optimized and errors can be prevented before they occur. Detailed production schedules match production line and equipment availability and performance to optimize efficiency. Plus all manufacturing data can be analyzed, summarized and reported to provide continuous visibility into production performance in the cloud for globalized collaboration and control.

Providing manufacturers with:

- Paperless manufacturing
- Identification, analysis and prevention of errors
- Advanced planning and scheduling
- Manufacturing enforcement and quality
- Closed-Loop Manufacturing and change enforcement

Actual customer value gained

65% **Reduction in overall DHR review time**

20% **Less manufacturing lead time**

Improve compliance and quality processes with greater control delivering new visibility, flexibility & efficiency

Digitalizing the medical device manufacturing process not only improves shop-floor production, but can improve time to market, eliminate regulatory headaches and better maintain product quality. Siemens customizable Opcenter Execution solutions connect with other systems — including MOM and ERP — to help you modernize and automate operations.

> "Our team now has excess capacity to do process improvements, to implement cost reductions and improve product quality."
>
> **Edwards Lifesciences**

Reduce costs

Lower overhead with the redeployment of manpower, elimination of paper records and implementation of error-proofing processes.

Improve productivity

Abolish non-value-added DHR activities related to data collection, calculations and documentation review.

Expand capacity

Improve utilization of assets and human capital through real-time visibility.

Increase throughput

Provide better process enforcements and right-the-first-time production with real-time, granular visibility.

Enhance product/process yield

Reduce scrap and rework through accurate data collection, implementation of improved procedures, use of the right equipment and more.

Decrease WIP and FG inventory

Automation drives inventory reduction with improved process and product visibility, multi-level tracking & tracing and faster cycle times.

About Siemens Operational Excellence for Medical Devices

Siemens Operational Excellence for Medical Devices enables operational agility, with real-time visibility, control and speed throughout the manufacturing process. It leads to high-quality, efficient medical device production that is regulatory compliant and provides perfect eDHRs.

Our solutions help companies of all sizes leverage digital systems to produce innovations that meet tomorrow's challenges.

For more information on Siemens Operational Excellence for Medical Devices, visit siemens.com or follow us on LinkedIn and Twitter.

Siemens Operational Excellence
Where today meets tomorrow.

Headquarters:	**+1 972 987 3000**
Americas:	**+1 314 264 8499**
EMEA:	**+44 (0) 1276 413200**
Asia- Pacific:	**+852 2230 3333**