



**DIGITAL INDUSTRIES SOFTWARE**

# Driving operational excellence in medtech

How to optimize performance, ensure compliance and build resilient operations  
using manufacturing operations management

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# The changing landscape of MDD manufacturing

Medical device and diagnostics (MDD) manufacturers are navigating one of the most complex industrial environments in history. Redefining how companies design, produce and deliver products is led by global competition, regulatory tightening (United States (U.S.) Food and Drug Administration (FDA), Medical Device Regulation (MDR) and International Organization for Standardization (ISO) 13485) and the demand for more personalized and connected healthcare products.

Simultaneously, cost pressures and sustainability expectations are intensifying, especially when it comes to medical technology (medtech). Manufacturers must master production efficiency, manage supply volatility and ensure product quality and compliance – often with limited resources and increased complexity.



To meet these challenges, manufacturers are accelerating Digital Transformation across the value chain. The ability to make data-driven decisions, automate routine tasks and maintain traceability in real time has become a strategic necessity. Achieving this transformation requires a foundation that connects people, processes and technology using a manufacturing operations management (MOM) platform that unites design, planning, execution, quality and logistics into one digital ecosystem.

# The new imperative for operational excellence

Operational excellence in MDD manufacturing is no longer measured only by efficiency or output – it is defined by agility, compliance and data integrity. The ability to adapt production lines, scale capacity or qualify new suppliers quickly while maintaining validation is now a decisive competitive advantage.

The Digital Twin, which mirrors the physical manufacturing environment to simulate, predict and optimize operations before implementation, powers this agility. With a Digital Twin, manufacturers can model production scenarios, evaluate readiness and anticipate disruptions, reducing risk while improving time-to-market.

At the core of this transformation is MOM. Using Siemens Digital Industries Software's Opcenter™ software orchestrates and executes digital plans in real-world production. It connects product lifecycle management (PLM), enterprise resource planning (ERP) and shop floor automation in a closed loop. This ensures companies can execute every process consistently, trace every record and visualize every deviation in real time. Opcenter is part of the Siemens Xcelerator business platform of software, hardware and services.

This seamless flow of data enables MDD manufacturers to integrate design intent with operational performance, bridging engineering, manufacturing, quality and supply chain disciplines for full visibility and compliance.



# Key drivers and emerging trends of MOM in life sciences

The evolution of MOM reflects the digital journey of life sciences manufacturing. From isolated systems to fully connected operations, today's MOM platforms combine industrial internet of things (IIoT), cloud computing and artificial intelligence (AI) to deliver predictive, compliant and sustainable production.

For MDD companies, several key trends are accelerating adoption:

- Digital compliance and validation: Automated data capture, electronic device history record (eDHR) and audit-ready reporting support consistent regulatory compliance
- Adaptive capacity and cost control: Simulation and planning tools enable agile responses to fluctuating demand, optimizing equipment use and resource allocation



- Integrated quality management: Embedding quality into production processes ensures right first time manufacturing and faster issue resolution
- Sustainability and resilience: MOM systems enable energy monitoring, waste reduction and better resource use, supporting cost efficiency and environmental goals
- Supply chain visibility: Integration between MOM and logistics systems enhances transparency, ensuring continuous product availability and faster response to disruptions

As MOM technology continues to evolve, modular, low-code solutions like Opcenter make Digital Transformation accessible to organizations of all sizes, helping MDD manufacturers achieve operational excellence one step at a time.

# Core components of a modern MDD MOM solution

The value of MOM for medical device and diagnostics companies lies in its ability to provide out-of-the-box (OOTB), validated functionality that aligns with industry-specific requirements for compliance, traceability and efficiency. Opcenter encompasses a full suite of applications designed to deliver these outcomes.

## **Digitalizing shop floor operations using an MES**

A manufacturing execution system (MES) like Opcenter Execution Medical Device and Diagnostics (EX MD&D) provides a unified platform for managing production operations – from work order execution and material tracking to device serialization and batch record management. For MDD manufacturers, it ensures they validated every process step, logged every operator's action and every product record is complete and compliant.

Key benefits include:

- Full traceability and automated eDHR generation
- Integration with equipment and automation systems for data integrity
- Real-time visibility into yield, deviations and throughput
- Rapid new product introduction (NPI) with validated workflows
- Paperless manufacturing that supports regulatory compliance

By digitalizing execution processes, manufacturers can reduce documentation errors, accelerate release cycles and maintain consistent product quality across global sites.

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The transition to eDHRs has been of the utmost importance. Before, we had to review a stack of papers five inches thick for the release of every material batch, which took a full day or more. With Opcenter, we are able to release batches in under 30 minutes."

Rick Larrieu  
Vice President of Global IT Applications and Infrastructure  
Terumo Americas



### **Ensuring compliance and continuous improvement via quality management**

Leveraging a Siemens quality management system (QMS) provides comprehensive support for end-to-end quality and compliance management from design to manufacturing. Opcenter X Quality is a cloud-based QMS that covers all quality-relevant processes at the shop floor level, from product and process controls to handling nonconformances and defining specific actions.

Key capabilities include:

- Quality inspection management with configurable inspection types, structured data capture and complete results documentation
- Advanced statistical process control (SPC) tools, including AI-driven analytics for optimizing product quality across the lifecycle
- Real-time process monitoring for early deviation detection and proactive quality issue prevention
- Nonconformance management that records and tracks issues end-to-end, supporting efficient triage for corrective and preventive actions (CAPA) processes

By embedding quality directly into manufacturing processes, MDD manufacturers can support compliance and meet customer expectations every step of the way.



### **Advanced planning and scheduling from complexity to control**

Fluctuating demand, constrained resources and regulatory-driven production windows make planning and scheduling especially challenging in the MDD sector. Opcenter Advanced Planning and Scheduling (APS) uses real-world constraints to automatically generate optimal production plans – aligning capacity, materials and deadlines.



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Production scheduling with Opcenter is resilient to market changes, unexpected events in production and production planner absence.”

Tanja Jereb  
Chief Procurement Officer  
Novak M

#### Capabilities include:

- Dynamic scenario simulation to evaluate operational readiness
- Integration of a Digital Twin for predictive capacity and maintenance planning
- Real-time synchronization between planning and shop floor execution
- Reduced lead times and improved on-time delivery performance

With Opcenter APS, manufacturers can confidently adapt to change, balance workloads and maintain high service levels while controlling production costs.



**Accelerating innovation via research, development and laboratory**

Innovation in medical devices depends on rigorous research and development (R&D) and validation processes. Using Opcenter Research, Development and Laboratory (RD&L) enables integrated management of formulations, specifications and test results in a single digital environment.

It supports:

- Design control and traceability from concept through validation
- Laboratory information management system (LIMS) for test scheduling and reporting
- Digital Twin simulations to optimize formulations and reduce rework
- Seamless handover from R&D to manufacturing, ensuring product consistency and compliance

By connecting R&D and manufacturing, using Opcenter RD&L shortens development cycles and ensures design intent is preserved throughout production.



### **Turning data into action with manufacturing intelligence**

With complex, highly regulated processes, MDD manufacturers generate vast amounts of data. Using Opcenter Intelligence software consolidates this information, turning data into actionable insights. It aggregates data from multiple systems, creating dashboards that monitor key performance indicators (KPIs), such as yield, cycle time and compliance status.

Key advantages include:

- Real-time visibility of production and quality metrics
- Predictive analytics for proactive decision making
- Cloud-enabled dashboards for global accessibility
- Data-driven insights that drive continuous improvement

This intelligence layer supports a culture of excellence, enabling manufacturers to move from reactive problem solving to predictive performance management.

### **Logistics and supply chain resilience**

Global supply challenges and increasing regulatory oversight make resilient logistics vital for MDD manufacturers. Leveraging Siemens' digital logistics solutions, integrated with Opcenter, provides transparency and control across the supply chain, from component sourcing to product delivery.

Benefits include:

- End-to-end visibility of materials, inventory and shipments
- Scenario modeling to anticipate disruptions and optimize transport networks
- Real-time event monitoring for proactive responses
- Sustainability tracking for packaging, energy use and emissions

By connecting digital logistics with manufacturing operations, MDD companies can ensure they maintain production continuity while optimizing cost and sustainability performance.



# Implementing MOM for sustainable operational excellence

Achieving operational excellence in medical device and diagnostics manufacturing requires a clear strategy and a flexible, scalable digital foundation. Using Opcenter provides the modular platform companies need to translate strategic goals into measurable results, linking design, production, quality and logistics into one connected ecosystem.

1. Assess and prioritize: Identify critical bottlenecks in production, quality or logistics.
2. Start small, scale fast: Pilot Opcenter modules in one facility to validate benefits.
3. Leverage expertise: Use Siemens' training and consulting resources for faster adoption.
4. Engage all stakeholders: Ensure alignment between information technology (IT), engineering and quality teams.
5. Continuously improve: Use analytics to monitor KPIs and identify optimization opportunities.

## **A future-ready manufacturing vision**

Operational excellence in the MDD sector is defined by agility, compliance and resilience. By implementing MOM via Opcenter, manufacturers can:

- Adapt rapidly to market and technology shifts
- Ensure compliance with full traceability and validated processes
- Optimize efficiency via automation and connected planning
- Increase resilience with integrated logistics and data-driven decisions

Leveraging Opcenter enables MDD companies to master complexity and cost while accelerating innovation and safeguarding quality. Digitalization is not just an upgrade – it is the path to sustainable, future-ready manufacturing success.



**Siemens Digital Industries Software** helps organizations of all sizes digitally transform using software, hardware and services from the Siemens Xcelerator business platform. Siemens' software and the comprehensive Digital Twin enable companies to optimize their design, engineering and manufacturing processes to turn today's ideas into the sustainable products of the future. From chips to entire systems, from product to process, across all industries, [Siemens Digital Industries Software](#) – Accelerating transformation.

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