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Ingenuity for life

Opcenter Execution Medical Device and Diagnostics Rapid Implementation Package

Accelerating time-to-market for emerging MDD manufacturers

Benefits

- Accelerate time-to-market
- Support regulatory approval process
- Improve product quality with paperless manufacturing
- Reduce time and cost of implementation
- Scale efficient production
- Expedite the change management process

Summary

Opcenter™ Execution for Medical Device and Diagnostics (Opcenter EX MDD) Rapid Implementation Package gives firms access to a leading manufacturing execution system (MES) to better compete in this complex market. Designed to especially facilitate small and mid-sized business (SMB) and emerging manufacturers, it is a terrific option for companies that require speed to market while operating with constrained resources. As part of that, compliance with regulation must be complete and efficient, and product quality must be ensured.

Opcenter EX MDD, which is part of the Xcelerator™ portfolio, the comprehensive and integrated portfolio of software and services from Siemens Digital Industries Software, is a leading solution for error-proofing processes, paperless manufacturing, electronic device history records

(eDHR) and electronic batch records (eBR). Opcenter EX MDD Rapid Implementation Package is a preconfigured version of the full solution, which comes with out-of-the-box (OOTB) functionality that accelerates the path to digital manufacturing.

Coupled with OOTB configurations, Opcenter EX MDD Rapid Implementation Package uses templates and a predefined validation package to reduce the time and cost of implementing the solution, as well as reducing the resources required on behalf of the customer. Cloud-based infrastructure as a service (IaaS) and managed services further reduce the cost of operations and maintenance. Getting started with the MES solution is rapid and secure, while providing the foundation for growth.

With Opcenter EX MDD Rapid Implementation Package you get access to a best-in-class MES solution for medical devices, reducing costs and implementation time without compromising quality and flexibility.

Main features include

- Best-in-class MES for MDD
- Risk-based approach to validation
- Enterprise resource planning (ERP) integration
- Cloud hosting options
- Self-auditing eDHR/eBR
- Work order dispatch management
- Material management
- Tracking and tracing
- Sample data collection
- Nonconformance management

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- Electronic work instructions (EWI)
- Workflow management
- Bill-of-process (BOP)
- Weigh and dispensing
- eKanban

Best-in-class manufacturing execution

Opcenter EX MDD is built on the Opcenter Execution Core. Configured specifically for the medical device and diagnostics industry, Opcenter EX MDD helps you accelerate innovation, reduce cost and achieve the highest quality products while making compliance a byproduct of excellent manufacturing processes.

The solution builds quality into the manufacturing process at every step avoiding non-conformance rather than fixing them afterwards. From raw materials to finished goods, quality is enforced while producing a complete, self-auditing eDHR/eBR.

Siemens' MDD solution has been deployed with impressive results in a variety of medical device product segments, including diagnostics, orthopedics, cardiovascular, hospital and wound care, diabetes care, renal, blood care, vision and imaging. MDD companies now have access to a best-in-class manufacturing execution system tailored to meet the needs of a resource-constrained environment.

Opcenter EX MDD Rapid Implementation Package

Opcenter EX MDD Rapid Implementation Package leverages out-of-the-box features and preconfigured functionality to accelerate the timeline for go-live. Using a templated approach for MDD, manufacturers quickly implement mature, proven processes that reflect years of expertise in the industry. This model reduces the cost of adoption as well as the requirement for highly experienced internal customer resources.

Validation package

The validation package uses a risk-based approach. It assumes an out-of-the-box implementation where the functionalities have been already pre-tested by Siemens quality department. Validation documentation is comprehensive; its output includes the master validation plan, functional requirement specification (FRS), failure modes and effects analysis (FMEA), IQ testing, operational qualification (OQ) testing, performance qualification (PQ) testing, trace matrix and master validation report.

Cloud support

Siemens offers the option of hosting the solution as an infrastructure as a service. This means that both the application and environment, including upgrades and maintenance, will be completely managed by Siemens. This option lowers the total cost of ownership and is particularly appreciated by customers with limited information technology (IT) resources.

Paperless manufacturing

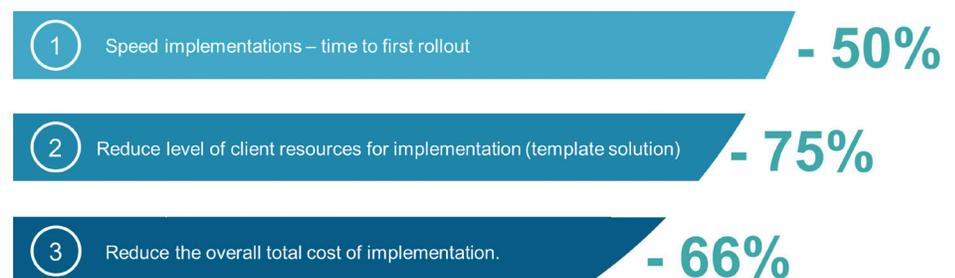
Using the same software employed by leading global MDD manufacturers, our customers can replace paper-based manufacturing processes with a fully electronic self-auditing MES that streamlines the process, reduces cost and enforces product quality and compliance. The result is paperless manufacturing and a complete, searchable electronic device/batch history record. There is no paper, printing, moving or storage.

Automated enforcement and control

Collect information and enforce business rules to achieve error-proof processes. Make sure the right procedures, operators, equipment and materials are used within specification and in the right sequence. Move to a review by exception product release process as a result of an automated, self-auditing electronic device history record.



Measured results



Containment management and forward/backward traceability

Use configurable searches such as where-used analysis to identify suspect at-risk material based on unique criteria, such as a component lot, machine, operator, a specific shift, etc. Configure dynamic actions based on your business rules, then take quick action, such as hold, rework, material review board (MRB), quarantine, etc. All products, components and supplied materials are completely traceable.

Statistical process control

Apply statistical process control to qualify and detect data that is collected during the manufacturing process, allowing manufacturers to identify, analyze, solve and prevent problems while production continues. Reduce material production delays, equipment downtime and scrap.

Event and nonconformance management

Create a centralized view of quality performance to prevent patterns that lead to poor quality. Identify and document all types of events, regardless of source or type that can potentially impact final product quality. When appropriate, escalate to a nonconformance designation and apply standard risk criteria to triage and enforce structured failure analysis, facilitate root cause identification, quarantine and route for final disposition. Real-time collection and enforcement in manufacturing allows automatic generation and notification of nonconformance.

Easy-to-use batch processing

Siemens' batch processing capabilities provide easy-to-use scale and recipe management needed for batch processes in medical device combination product and diagnostics product manufacturing. Batch processing enables specific functionality for simple weighing and dispensing environments where individual batch orders are processed. As an integral part of Opcenter EX MDD, batch processing enables a complete eBR and eDHR as one fully traceable as-built record.

Opcenter EX MDD Rapid Implementation Package versus Opcenter EX MDD

Implementing Opcenter EX Implementation Package means applying the OOTB functionalities of the product while maintaining the flexibility to extend the project afterwards.

	Opcenter EX MDD Rapid Implementation Package	Opcenter EX MDD
DB support		
Microsoft SQL	Yes	Yes
Oracle	Yes	Yes
Infrastructure		
On-premises	Yes	Yes
On-cloud	Yes	Yes
Functionalities		
Full access to product OOTB functionalities	Yes	Yes
Product - modules		
Core functionalities	Yes	Yes
Dispatch management	Yes	Yes
Electronic signature	Yes	Yes
Batch processing	Yes	Yes
Label printing	Yes	Yes
Maintenance management	Yes	Yes
Operator training and certification	Yes	Yes
Acceptable quality level (AQL) sampling	Yes	Yes
Quality nonconformance	Yes	Yes
Quality event	Yes	Yes
Statistical process control	Yes	Yes
ERP integration	Preconfigured	To implement project based
Implementation of custom functionalities	Not allowed during the first implementation	Yes

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