Critical Manufacturing MES for Medical Devices

Expect more from your MES

Highly regulated industries need extreme command & control

Working in a highly regulated industry like medical devices requires visibility, command, and control over factory floor operations not seen in other industries because the cost of poor quality could be life-threatening. A total understanding of the supply chain, equipment maintenance, and document control is simply the minimum, but the minimum doesn't increase competitiveness. A paradigm shift in your factory will. A commitment to digital transformation and Industry 4.0 brings together IoT and quality management.

Expect more from your MES

Critical Manufacturing MES is the best-in-class, most comprehensive top-tier Manufacturing Execution System (MES) solution for medical device manufacturing and is easier to use than ever before. It will advance your digital transformation to the next level with advanced capabilities to drive compliance and end-to-end traceability and promote digital transformation with Industry 4.0-ready out-of-the-box modules. It offers real-time visibility across manufacturing operations with an advanced IoT data platform and next-level paperless document control, so validation and audits can be executed easily and efficiently. Critical Manufacturing MES is the market-leading solution with a selection of pre-integrated modules and a secure, container-based process for deployment on cloud, on-prem, or hybrid architectures.

Meeting your needs at every phase

Medical device manufacturing is a complex and highly regulated operation utilizing people, machines, and enterprise-level infrastructure. Critical Manufacturing MES integrates shop floor information and functionalities into a single source of truth for contextualized data to make informed strategic business decisions. When you expect the best from your system, Critical Manufacturing MES delivers. Our MES will support your entire operation with total compliance and real-time performance data. It will help you to identify issues and solve problems even before they impact your production.

Why Critical Manufacturing MES

Critical Manufacturing MES is recognized as a top-tier manufacturing solution in the Gartner Magic Quadrant and the Critical Capabilities report.

Complete end-to-end traceability

As products become more complex with multiple assemblies and sub-assemblies, so does supply chain management and the ability to track all the components that go into end products. Traceability becomes essential for compliance on IoT-enabled products to support maintenance, warranty claims recalls, and regulatory audits. Critical Manufacturing MES offers complete end-to-end traceability and genealogy by the batch, lot, or serialized unit. The “Line Flow” feature allows operations guidance and traceability from the line/cell level to the individual workstation, along with Time Monitoring and Tracking for each operation.

Manage multiple product variations with ease

Manufacturing products that have multiple configurations, managing quality and production is complex. It starts with easing management of variations in the bill-of-materials (BOM) with all the components and sub-assemblies for a single product so the operator can identify differences for error-proof production. Critical Manufacturing MES manages BOM variations to enhance execution, traceability, and quality, now including the new exportable Full Flow Configuration Report, covering any MBR/DMR regulation requirements.

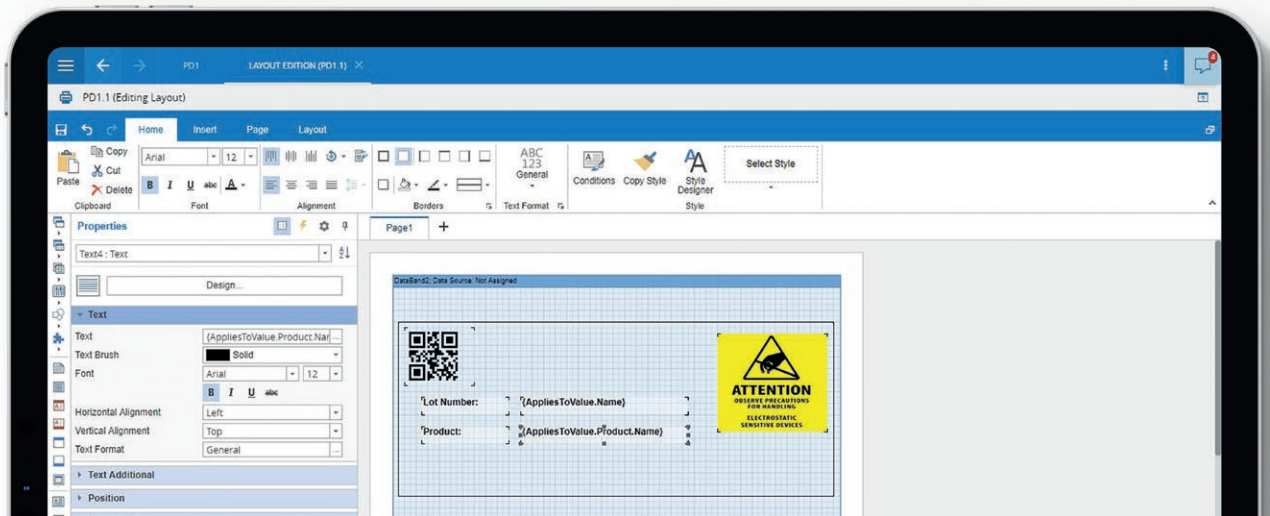
Data analytics platform

A modern manufacturing facility generates large volumes of data through multiple disparate systems and IoT sensors. However, little value is realized without a strong data platform to organize and contextualize the data for making proper decisions to improve performance in every facility. Critical Manufacturing MES generates valuable insights using machine learning and other advanced analytics tools to deliver better business outcomes.

Next generation validation

Critical Manufacturing next-generation validation approach goes beyond the FDA’s guidance for Computer Software Assurance (CSA). You should expect a smooth validation process that maintains end-to-end traceability, executed automatically at any time, in parallel to implementation. This new approach substantially reduces the cost and burden of traditional approaches and speeds up the implementation by reducing the timeline of the validation phase from months to days.

- Enforce regulatory compliance
- Complete end-to-end traceability
- Reduce product variability
- Improve product quality
- Reduce scrap and waste
- Reduce time-to-market
- Reduce machine downtime
- Data-driven production management



Advanced Medical Device use cases

Manufacturers of highly regulated products face significant challenges in optimizing and managing high-mix production with end-to-end traceability and compliance documentation. However, they cannot lose focus on quality and on-time delivery, which is unachievable without an integrated MES.

1.

Ensure the maintenance of high-quality standards throughout all business processes

Ensure the smooth running of all processes and production steps by utilizing a fully integrated quality management suite within your MES that facilitates a closed-loop system with manufacturing, preventing errors from occurring. This suite includes processes such as Non-Conformance Report (NCR) and Corrective and Preventive Actions (CAPA), which enable root cause investigations to identify and prevent the recurrence of issues.

Document management is an integrated feature, ensuring that only the most up-to-date documents are shown to the right people at the right time. Statistical Process Control (SPC) is incorporated too allowing automatic reactions to errors and driving decisive action. Control limits can be composed either manually or automatically based on historical data.

2.

Facilitate traceability and streamline regulatory reporting processes

Critical Manufacturing MES automatically generates fully Electronic Device History Records (eDHR) and batch records (eBR), which are easily searchable and self-auditing. This eliminates the need for manual quality reviews and reduces the risk of documentation errors. The MES ensures compliance with regulatory requirements such as the FDA 21 CFR Parts 11 and 820 and EU Directive 93/42/ EEC on medical devices. It also ensures that all operators have the necessary certification requirements to carry out a process.

3.

Advanced support for AQL and inspection plans Critical Manufacturing MES offers

Advanced support for AQL and inspection plans Critical Manufacturing MES offers enhanced support for Acceptable Quality Level (AQL) and inspection plans. It enables the execution of advanced inspection plans as part of the manufacturing process, including special inspection steps, with full support for using the AQL as a standard inspection method. Sampling involves removing a certain quantity of manufactured products from a batch for random testing in accordance with ISO 2859-1.

The Critical Manufacturing MES also allows for the creation of complex inspection plans based on user-defined parameters, providing greater flexibility in the sampling process.

4.

Fully integrated data platform combined with MES

IoT data platform combined with MES Critical Manufacturing's data platform for medical devices unlocks the potential for multiple use cases:

- Capture data from various equipment interfaces in real-time, allowing immediate action in response to trends or limits. This data can also be stored for future analysis to improve efficiency.
- Collect and store all product and process parameters, going beyond the regulatory requirements for eDHRs. This information can be used for future analysis and increased traceability.
- Collect structured and non-structured equipment data, including images, and store them alongside contextual information from MES for later analysis.

Critical Manufacturing MES V11

The core of your Industry 4.0 digital transformation journey: connect, execute and analyze

Critical Manufacturing MES is essential as your Manufacturing Operation Management (MOM) System for highly regulated industries. The advanced capabilities enable complete shop floor connectivity and data integration to make proper decisions that improve compliance and profitability in every facility while significantly reducing the reliance on paper documentation. These advanced capabilities accelerate validation, increase connectivity, and promote digital transformation.

Manufacturing enterprises need a holistic view of their operations. Critical Manufacturing MES provides a data analytics platform to optimize and automate validation and improve the supply chain, quality, OEE, delivery, and your customers' satisfaction, ultimately increasing revenue while reducing risk.

Expect more from your MES and empower your enterprise using data from your factory to make digital transformation and Industry 4.0 a reality with advanced capabilities from Critical Manufacturing.

Solution map

Critical Manufacturing MES V11 for Medical Devices

Next Generation Validation

Advanced Planning and Scheduling						
Manufacturing Operations	Materials & Containers	Resource Tracking	Routing & Dispatching	Data Collection	Master Data Management and Change Control	Tasks, Checklists & e-signs
Visibility & Intelligence	Dashboards	BI Cards	eDHR/ Genealogy/ Reporting	fabLIVE: Factory Digital Twin	Alarm Management	Augmented Reality
Quality Management	Sampling Based Inspection/AQL	Statistical Process Control (SPC)	CAPA/NCR	Document Management	Experiment Management	
Operational Efficiency	Maintenance Management	Order Management	Labor Management	Costing	Advanced Layout & Printing	Material Logistics
Integration & Automation	Enterprise Integration	Equipment Integration: Connect IoT	Recipe Management	Weigh & Dispense	Factory Automation	

IoT Data Platform

Low Code Platform

Critical
manufacturing
an ASMPT company

Critical Manufacturing provides the most odern, flexible and configurable Manufacturing Execution System (MES) available. Critical Manufacturing MES helps manufacturers stay ahead of stringent product traceability and compliance requirements; reduce risk with inherent closed-loop quality; integrate seamlessly with enterprise systems and factory automation and provide the right insights based on visibility and fast analysis of global production operations.

Be Industry 4.0-ready. Compete effectively and profitably by easily adapting operations to handle any changes in demand, opportunity or requirements, anywhere, at any time.

To learn more about the Company, review our products, or see industry analysts' evaluations, visit:
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