EMPOWERING OPERATIONS

CRITICAL MANUFACTURING

Critical Manufacturing MES
FOR MEDICAL DEVICE MANUFACTURING

Improve Compliance, Increase Efficiency, Enhance Process Control

Critical Manufacturing MES makes it easy for Medical Device manufacturers to design, deploy and monitor operations. Preconfigured or customizable toolsets provide a high-level view of operations, or zoom in to potential problem areas and take corrective action quickly, efficiently and consistently. Integrated and automated, Critical Manufacturing MES allows proper support for compliance with FDA's Title 21CFR Parts 11 and 820, without the potential inaccuracies of a paper-based system, or the inefficiencies of redundant manual processes.

Challenge:

Medical Device manufactures are beset with exploding demand for customization and quality. They need to manage thousands of data points efficiently, meet stringent compliance requirements and maintain profitability without sacrificing throughput or quality.

Advantages:

- Capture highly-granular historic and process data
- Enforce training requirements, sign offs, and data validity checks
- Schedule calibrations and other maintenance activities
- Set up advanced reporting, analytics, role-specific workflows and action plans

Results:

Users avoid the haphazard processes the can derail quality and profitability. Critical Manufacturing MES provides improved traceability capabilities, streamlines the cost and process of compliance, and maximizes efficiency to help Medical Device producers get to market quickly.

Learn more: http: / / www.criticalmanufacturing.com / en / medical-device-industry

IMPROVE COMPLIANCE

Advanced Data Collection providing flexible limits, dynamic samples, readings, groupings and calculations in manual, automated or mixed modes. Fully integrated with Statistical Process Control (SPC) and Exception Management.

Out of Control Action Plans (OCAPS) defining role-specific workflows for quality control, analysis, containment, corrective and preventive product or process actions. Protocols are automatically triggered by equipment, SPC rules, EDC limits or any MES action, or by manual operator decision.

Advanced Statistical Process Control integrating automatic data collection, exceptions, resource and materials tracking with trigger quality protocols, notifications and action steps.

Electronic Signatures and Records supporting FDA's Title 21 CFR Part 11 regulations for electronic signatures, equivalent to handwritten signatures executed on paper and trustworthy and reliable electronic records and audit trails equivalent to paper records.

Labeling Requirements dynamically generated interactively design, preview and print labels, with context driven information for text, images or barcodes, attached to the corresponding material units, supporting CFR Title 21 part 820 labeling requirements.

Full Traceability allowing easy-to-establish high-performance tracking in single or clustered equipment, across hierarchical flows, while maintaining all sub-material traceability and high-level material integrity. Data can be collected at any level: batch, lot, sub-lot or even at unit ID or serial number level.

ENHANCE PROCESS CONTROL

Maintenance Management and Calibration allowing Microsoft Outlook™ calendar-friendly equipment management based on ad hoc or usage based schedules including bill-of-parts and checklists, calibration dates and other user defined fields.

Specification Management modeling the factory environment and master data management functions, including version-control and role-specific approvals.

Electronic Failure Catalogue associating failure types with a high-definition image catalog that includes analysis, pass / fail parameters and action protocols with fast, real-time navigation and deep zoom capability.

Automated Platform reducing human error with advanced point & click configuration and service and message mapping over multiple communication protocols. Advanced data collection and recipe management modules eliminate errors in both recipe selection and data collection.

Operator Training and Certification defines necessary training and certifications, including scope and expiration, and is easily configured for a range of operational roles.

Robust Security ensuring highly-compliant control and protection in multi-level security options allow different configurations for visibility or execution permissions at the graphical user interface, API and object level.

INCREASE EFFICIENCY

Material Tracking providing complete WIP transactional information for complex material structures and containers, including manual or automatic assemble / disassemble, grade, replace, transfer, empty, split-by-product with low effort and high performance.

Advanced Reports, Analytics and Business Intelligence available out of the box, including such critical KPIs as OEE, PPH, cycle time, yield and uptime. A preconfigured data warehouse enables interactive data slicing, analysis, advanced data mining, and real time cost monitoring. Existing reports can be modified and new reports can be created and published on-the-fly.

ERP Integration syncs MES with production orders, inventory status, scheduling and other operational data within the ERP system, with synchronous or asynchronous data buffering in the event the ERP is unavailable.

Online Dashboards displaying instant graphical information navigable online for material, resource or any other user defined query, available configured or end-user defined with online information in chart report, table or graphical interactive modes.

"In our industry, there is no 'standard platform'. We needed to find an MES solution that would help us to change with our always-shifting workflow requirements and very quickly get compliant products to market. Critical Manufacturing MES was a clear winner at an early stage."

Critical Manufacturing medical device customer

Critical Manufacturing provides manufacturers in complex industries a manufacturing execution and intelligence system that empowers organizations to achieve their goals. Our state-of-the-art products and services enable users to drive down cost, flexibly meet market demands, and ultimately achieve greater agility, visibility and reliability. To achieve that success, we have gathered an experienced team of internationally renowned industry experts to continue to innovate, lead the industry, and serve our clients. With headquarters and main technical center in Porto (Maia), Portugal, our phenomenal growth has inspired the establishment of additional operations in Europe, China, Taiwan and the US. Contact us to learn how we help our clients use IT to achieve greater success in their enterprise.

Manufacturing & R&D
America, Europe and Asia

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Critical Group

Provides business critical solutions across industries such as aerospace, defense and telecommunications, under stringent quality certifications like NATO and CMMI Level 5.

Experience

Our engineers provide solutions for some of the most challenging MES green-field and migration projects worldwide. Their experience is at your service.

Innovation

Our solutions address the most important industry challenges through cutting-edge innovative products and technologies.

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