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Ingenuity for life

Camstar Medical Device Suite

Ensuring product quality, compliance and increased profitability for discrete, batch and combination-device manufacturers

Benefits

- Proactively build quality into the manufacturing process
- Identify, analyze and prevent errors throughout every production step
- Provide visibility into the performance of all components and tests
- Maintain a single as-built record across discrete and batch processes for combination and hybrid products
- Close the loop on continuous improvement initiatives
- Define, distribute and enforce process and engineering changes to any global factory
- Move to a review by exception product release process

Summary

Camstar™ Medical Device Suite is a leading solution in the medical device and diagnostics industry for error-proofing processes, paperless manufacturing and electronic device history records (eDHR) and electronic batch records (eBR). Emerging, midsize and global companies are faced with the challenge of balancing cost reductions and regulatory compliance while consistently producing high-quality products. Camstar Medical Device Suite has a proven track record of helping medical device and diagnostic companies excel in the face of these challenges. Camstar Medical Device Suite is an industry specific solution, built using best practices in medical device manufacturing for faster implementation out-of-the-box. When coupled with the industry expertise of the Siemens PLM Software global services team, it makes success possible in diverse manufacturing environments. Companies of all sizes can benefit from the same industry-leading solution from Siemens PLM Software.

Providing a powerful and flexible tool

Camstar Medical Device Suite is a unique configuration of Camstar Enterprise platform. By effectively addressing the full range of business challenges that the industry faces, Camstar Medical Device Suite helps you accelerate innovation, reduce cost, and achieve the highest quality products while making compliance a by-product of excellent manufacturing processes.

It does this by enabling you to build quality into the manufacturing process instead of testing quality coming out of the process at every step, from raw materials to finished goods with a complete, self-auditing eDHR/eBR.

Camstar Medical Device Suite 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.

The solution is highly functional and flexible and provides the most advanced and intuitive user experience.

Paperless manufacturing

Replace paper based manufacturing processes with a fully electronic self-auditing manufacturing execution system 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.

Camstar Medical Device Suite

Features

- Enforce the correct operator, machine, materials/recipe, processes and measurements at every step
- Create a centralized view of quality performance
- Use asset utilization monitoring to determine overall equipment effectiveness
- Enforce multi-tiered bills-of-material (BOMs) and configuration options for discrete processes and ingredients/recipes for batch processes.
- Track and trace forward and backward genealogy
- Real-time data collection and enforcement in manufacturing provides automatic generation and notification of nonconformances

Automated enforcement and control

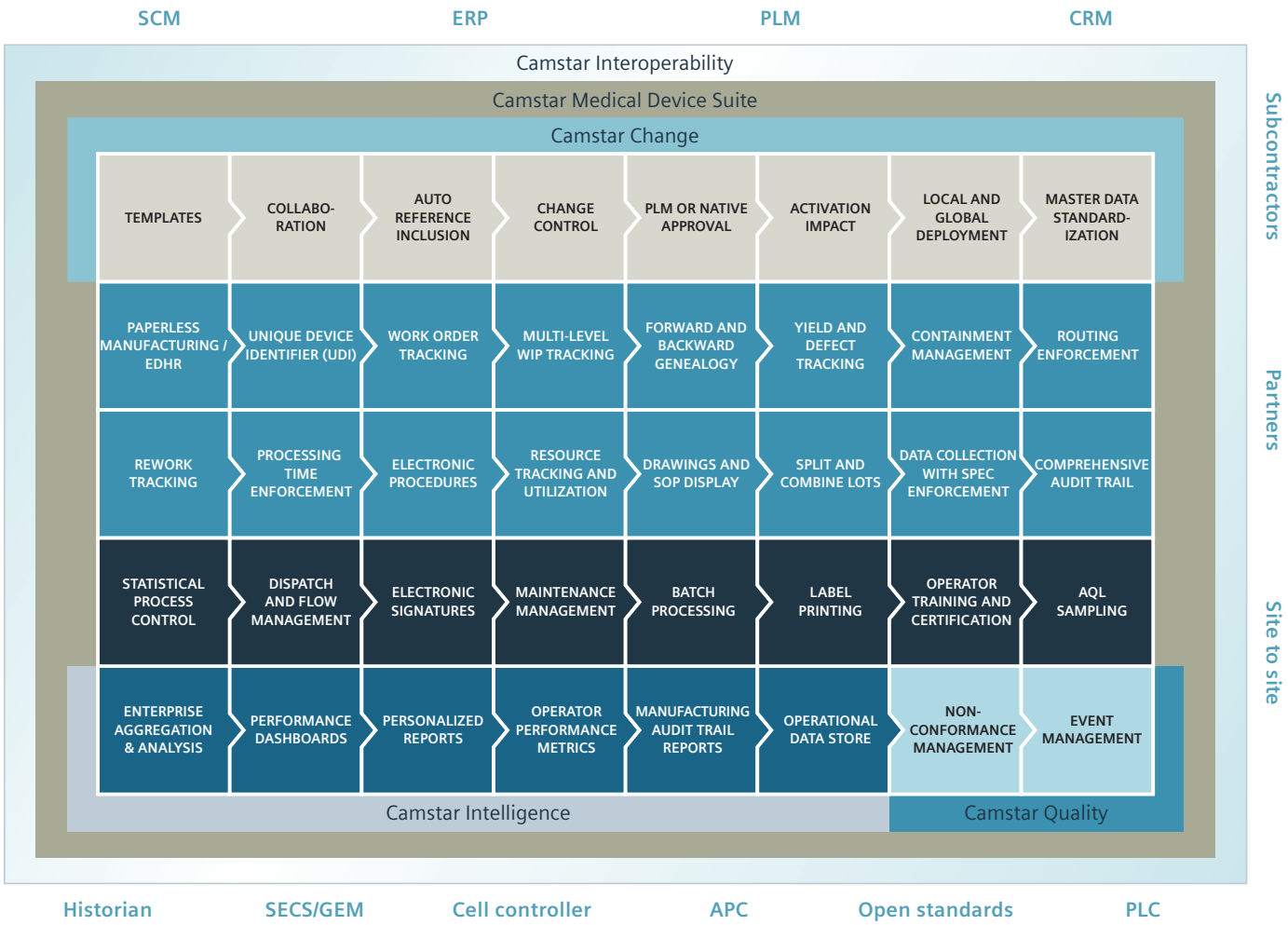
Collect information and enforce business rules to achieve error-proof processes. Ensure the right procedures, operators, equipment and materials are used within specification and in the right sequence. Move to a review by exception product release process as a result of an automated, self-auditing electronic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

Lean and Six Sigma enablement

Lean and Six-Sigma initiatives are driven by data to establish a baseline, identify improvements, analyze results and control processes. Camstar Medical Device Suite provides the foundation by enabling you to collect integrated product, process and quality data in a structured electronic format in a matter of seconds. You can make your processes mistake-proof with systemic enforcement to ensure control, closing the loop on continuous improvement initiatives.

Global process data management

Define, approve, distribute and enforce process and engineering changes to any global factory. Complete audit trails make it possible to understand the impact of engineering change orders (ECOs) and the effectivity of corrective and preventive actions. Intelligent root



cause analysis enables you to discover the true source of the problem by leveraging a growing knowledge base of granular product design, process design, manufacturing (as-built and inspection), field use and quality event data.

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, 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

Camstar Batch Processing provides 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 Camstar Medical Device Suite, Batch Processing enables a complete eBR and eDHR as one fully traceable as-built record.

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