

Camstar Medical Device Suite for cardiovascular manufacturers

Enabling lean manufacturing and quality that is built into the process

Benefits

- Replace costly paper and manual processes with self-auditing electronic device history records
- Eliminate manufacturing errors and ensure compliance by systematically enforcing processes and materials
- Provide visibility into product issues in real-time, and analyze as manufactured data needed to find root causes
- Use timely production and quality KPIs to make fast, effective decisions

Summary

Camstar™ Medical Device Suite software for cardiovascular manufacturers enables lean manufacturing and the ability to build quality into the process. Camstar Medical Device Suite enables world class cardiovascular manufacturing in discrete, process and box-build environments that produce batches, lots and single units.

Operation benefits include: lean manufacturing and increased efficiency; preventing manufacturing errors; reducing cost of goods and poor product quality, and improved decisions.

Quality benefits include: rapidly resolving issues; minimizing risk; reducing recalls, complaints and incidents; improving decisions and ensuring compliance and effective action.

By using Camstar manufacturing execution system (MES) to systematically improve operations and quality, you can:

Eliminate nonvalue-add activities

- Eliminate paper-based device history record (DHR) documentation, review and report consolidation
- Better utilize resources, including redeploying employees to productive work
- Focus operators on making products rather than paperwork

Systematically standardize and enforce processes across all sites

- Require complete and accurate data collection, and automatically hold material when required
- Use only qualified materials, equipment, operators and procedures
- Prevent use of expired and nonconforming materials
- Eliminate dependency on labor-intensive quality oversight

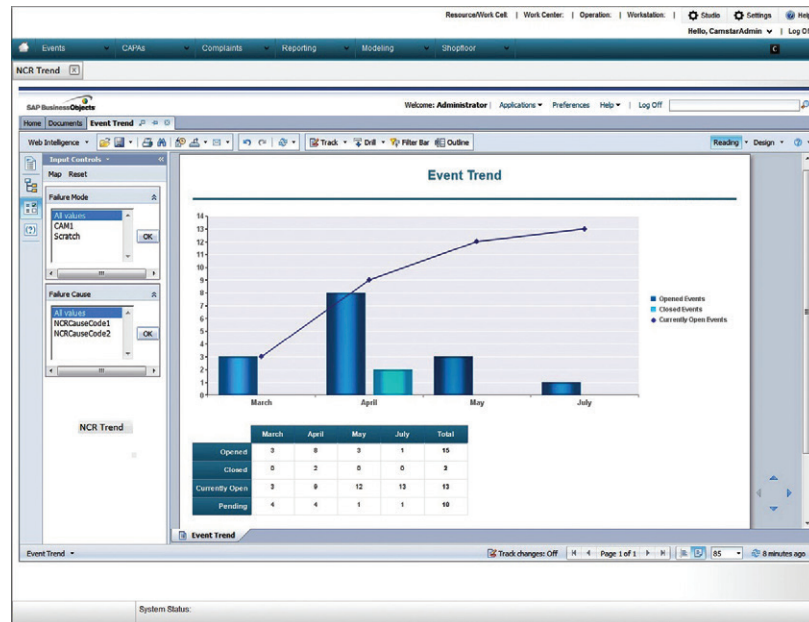
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Gain real-time visibility and control across the manufacturing supply chain

- Provide visibility into complete, accurate and real-time work-in-process (WIP)
- Optimize schedules based on waiting and cycle times
- Report the real-time actual value of material used and scrapped, actual production and quality labor

Accelerate trace analysis, root cause diagnosis and issue resolution

- View all manufacturing and quality data across all sites in seconds
- Search and filter for suspect lots/units by component, subassembly, equipment, specification revision, operator, etc.



Lower cost of good quality and poor quality

- Prevent errors (poka-yoke) with instant enforcement
- Make the product right the first time to reduce scrap and rework
- Gain instant access to complete product and process audit trails
- Systematically enforce compliance with regulations, including Title 21 Code of Federal Regulations (CFR) Parts 11 and 820

Make fact-based operational and strategic decisions

- Provide visibility into real-time metrics and key performance indicators (KPIs) for production and quality
- View quality and operational metrics by factory and across multiple factories
- Receive exception-based alerts to expedite issue detection and resolution

Continuously improve product quality and new designs

- View real-time product and process performance data
- Use actual occurrence rate of failure modes to prioritize risk
- Identify common failures by product/process
- Use a single authoritative source for product, process and quality engineering collaboration



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