EMI Helps Transform Medical Device Manufacturing

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Executive Overview
Today’s manufacturers make increasing use of enterprise manufacturing intelligence (EMI) solutions, which offer the potential to improve processes and reduce costs, to help address their key challenges. The term enterprise manufacturing intelligence, also sometime referred to as “operational intelligence” or “manufacturing intelligence,” applies to the technology and practices available to tap into the vast amount of plant data; contextualizing and exposing it as intelligent information with analytics, dashboards, and other visualization tools.

While EMI is not a new technology, its use is growing. This is partly due to new and improved ancillary technologies and tools, such as mobile devices, collaborative tools, analytics, visualization technologies; and better integration capabilities; and partly because of the enormous benefits that can be realized.

So what value are manufacturers realizing from implementing EMI applications? According to one US medical device manufacturer, the company used EMI technology to collect, integrate, and analyze data; reduce silos to improve collaboration; and increase its manufacturing efficiencies.

This report describes how one medical device manufacturer implemented Oracle Manufacturing Operations Center to provide the company with the ability to collect, integrate, and visualize data. As a result the company was able to develop a more collaborative EMI environment that helped improve efficiencies and reduce costs.
Challenge of Moving to an Automated Paperless System

This particular company manufactures medical devices for minimally invasive surgery for sports medicine professionals. The company, which introduced over 500 new products last year, deployed several Oracle solutions for its production and upstream processes. The goal was to move to a paperless production facility that could comply with FDA’s 21 CFR Part 11 (electronic records and signatures) and other relevant regulatory requirements. To help meet future regulations, the system also provides electronic genealogy and traceability for the products.

Prior to this implementation, the company spent an enormous amount of time validating data and systems using manual, paper-based processes. Due to FDA and other regulatory requirements, its production documentation involved as many as two million sheets of paper each year, straining operations. Obviously, there was a strong need to automate the process and move to a more efficient paperless operation.

Linking EMI and PLM Technologies

The company implemented Oracle Discrete Manufacturing and Oracle Manufacturing Operations Center for process monitoring, data inspection, and lot status. The Quality Collection software module included links to legacy systems that allows the company to track device history and eliminate paper records. It also uses the system for other applications. These include work order status monitoring, progress and conformance, and production scheduling.

Oracle’s Agile product lifecycle management applications provide an engineering content management platform to integrate and consolidate the legacy data, allow collaborative concurrent change control, and provide the electronic device master record. The applications provide integration to the manufacturing process to enable the company to control the bill of material
(BOM) change release, delivery of production methods, manufacturing specifications, and electronic machine program files and content.

**Using EMI to Improve Shop Floor Visibility**

The technology enables a highly configurable and rigorous change control workflow process that helps enforce configuration management methodologies and core engineering best practices. According to the company, the application allows for agile production and enforced workflow, including change control processes.

Oracle Manufacturing Operations Center (MOC) enables real-time visibility and dashboards with drill down capability that provide plant management with needed visibility, while increasing shop-floor agility. Other metrics utilized in the software focus on overall equipment effectiveness (OEE).

**Faster, More Accurate Decisions**

Some of the advanced analytics enable the company to transform its process. Dashboards now indicate machine availability, trends, and downtime. Previously siloed data from CNC machines were integrated using the technology. Different dashboards were employed to view the process, including dashboards for machine availability, machine trends, and production loss and capacity.

The new EMI software also enables the company to adapt the production process on the fly to accommodate process interruptions and special product insertions, which typically occur a couple of times a month.

According to the company, Oracle Manufacturing Operations Center provides visibility and intelligence “out of the box.” This translates into direct cost savings. It also helps improve throughput, reduce waste, and reduce inventory while minimizing human errors to make the company more agile, able to respond quickly to changes and, and able to make decisions faster.
Employee Involvement Develops an EMI Culture

The company’s project team spent a lot of time involving employees in the process to develop a sense of ownership in the system and to help them embrace the new process. The company believes that the system will enable it to expand, transform and keep up with business growth.

The company uses a highly configurable and rigorous change control workflow process that enforces configuration management methodologies and core engineering best practices.

By using the technology, employees developed an EMI culture that allows faster decision making and agility in the production process. Top management’s commitment to the solution and employee training and awareness were key to the organization’s readiness and implementation success.

Scope Creep Can Impact Schedules

When new requirements are added after the initial specification, scope creep can impact project schedules. The project team involved the stakeholders in the process and, as a result, received additional inputs for requirements that it had not anticipated. The company found it difficult to prevent scope creep because once stakeholders anticipated the potential benefits; many want to add new features. Recognizing the positive impact of adding individual employee requests, the company was willing to delay the implementation schedule. While the additional scope impacted the original schedule, it also helped cultivate employee involvement and buy in for the new technology.

It’s also important to recognize that, if not included in original requirements, FDA regulatory requirements can also impact timelines.

Recommendations

EMI helps empower today’s workers with powerful analysis tools and other knowledge-based information to help them make better decisions, faster.
Workers need to be able to make effective decisions quickly using information that makes sense. And companies need to be able to measure and prove the value.

ARC’s recommendations include:

- Companies should implement EMI technologies to integrate data, systems, and information to make knowledge available to employees.
- Companies should use EMI to unlock the value of manufacturing databases and spreadsheets and use the data to help knowledge-workers to make insightful and creative decisions that can improve manufacturing efficiencies.
- Companies should use EMI to move from a manual paper-based facility to an automated paperless facility that meets regulations for compliance.
- Use EMI to help improve production, particularly when custom products interrupt manufacturing.
- Involve employees in the process; get buy in for the new technology and collect requirements as early as possible to prevent scope creep.
- Use EMI to improve manufacturing agility, improve production and quality, meet regulatory requirements, and reduce costs.

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