



Achieving Cost Efficiencies and Compliance in Manufacturing

With competition intense, medical device manufacturers are innovating to be agile and respond faster to market demands. All this while ensuring compliance to regulatory requirements. Operational excellence is a key goal and is driving manufacturers to implement cost effective manufacturing processes that ensure quality, safety, and minimize compliance risk. Oracle offers the industry's most flexible and comprehensive solution to meet the needs of medical device manufacturers.

Medical device manufacturers are an important part of the healthcare value chain. They are under constant pressure to reduce costs, improve quality and be compliant. A lapse in product quality, at any stage of the product lifecycle, manifest's itself in product safety issues and defective products. With margins under pressure manufacturers are focused on streamlining and driving efficiencies in all parts of the business. More and more, medical device manufacturers are opting for comprehensive and preintegrated Supply Chain Management (SCM) applications to integrate and automate all key supply chain activities and implement Lean manufacturing principles across increasingly complex supply chains. Oracle Supply Chain Management solution provides a robust platform to enable you achieve efficiencies in the supply chain, from design, planning, and procurement to manufacturing and fulfillment. With Oracle's solution organizations are able to substantially enhance their ability to:

- Reduce operational cost in a regulatory compliant environment
- Control and improve product quality and, ensure regulatory compliance
- Create a real-time demand driven sales and operations planning process

Reduce operational cost in a regulatory compliant environment

Medical device manufacturers are implementing lean principles to reduce cycle time and waste in their manufacturing processes. Oracle manufacturing applications, a part of supply chain management, lets you optimize production capacity from raw materials through final product—regardless of manufacturing methodology. Oracle applications are built to suit manufacturing requirements through a Lean data model and improve the synchronization of production with customer demand and supplier capacity.

Oracle provides comprehensive and flexible mixed mode manufacturing solution, which allows you to automate and validate every stage of the product lifecycle—from design concept to quality release. The application also provides manufacturing execution system (MES) capabilities through its embedded quality management system functionality. Medical device manufacturers can quickly and cost-effectively meet demand through efficient mass customization, build to order, and project manufacturing methodologies.

With Oracle manufacturing applications you are able to support continuous improvement in manufacturing processes for increased efficiencies and reduce costs.

"Oracle ERP applications are an important part of our Lean manufacturing strategy. Oracle gives us system-generated metrics and continuous inventory analysis – real-time information necessary for inventory reduction and predictable performance."

Mike Parrilla
VP of Manufacturing
Hologic

Control and improve product quality and, ensure regulatory compliance

Federal regulations require companies to maintain a secure audit trail of information about every phase of a medical device's development, manufacture, and even distribution. Manufacturers of medical devices are required to report all adverse reactions in a timely manner. In addition to responding to adverse events as they arise, manufacturers are increasingly focused on proactive identification of safety issues.

Oracle's integrated quality management system lets you collect, distribute, and analyze critical quality data. Its helps you seamlessly implement quality improvement programs. It includes support to comply with 21 CFR Part 11. Creation and maintenance of regulatory compliant device history records (DHRs) and device master records (DMRs) is simplified. Oracle E-Records lowers the cost of compliance by streamlining your ability to comply with regulatory requirements.

Oracle's product complaint management solution addresses important elements of the corrective and preventive action (CAPA) quality measures required by 21 CFR Parts and 820. Comprehensive capabilities for product-safety monitoring and compliance help you manage product complaints and adverse events reporting. In addition, it lets you monitor trends and gain valuable insight into differentiators that can help you plan, manufacture, and sell your next-generation products.

Create a real-time demand driven sales and operations planning process

To be able to respond quickly to market requirements, you need to have the ability to analyze, assess, and forecast demand in real-time. This is required for planners to plan production capacity so manufacturing can meet shifting demands without interruption.

Oracle's SCM application enables real-time demand sensing and collaborative consensus forecasting. It helps you to sense demand in real-time, improve forecasting accuracy, shape your demand for profitability, and provides a path to evolve to a real time sales and operations (S&OP) planning process. Most importantly, the application enables you to focus on what is important to you, and evolves at your own pace.

Oracle solution allows you to model any necessary level of complexity in your supply chain and promote a seamless flow of information and materials across your extended supply chain. This allows you to provide visibility into your requirements to all tiers of your supply chain so that you can get visibility into all of the issues and constraints in your supply chain. It also controls critical purchases by sourcing items/commodities and services only from approved suppliers.

With Oracle you can implement an effective and well-managed S&OP process that lets you balance supply and demand to achieve operational excellence.

Oracle's end-to-end solution

Oracle is committed to the medical devices industry. Only Oracle offers a complete and integrated Supply Chain Management application with industry specific functionality to streamline quality and compliance. With Oracle you can achieve continuous improvement in your processes and implement current Good Manufacturing Practices (GMP) to achieve operational efficiencies and reduce costs to compete better.

Contact Us

To learn more, call +1.800.ORACLE1 to speak to an Oracle representative or visit oracle.com/industries/healthcare

Outside North America, visit oracle.com/corporate/contact to find the phone number for your local Oracle office.

"We have more than 500 suppliers worldwide and a network of 150 distributors in more than 100 countries, and Oracle E-Business Suite integrated them all into a value chain in just a few months. We share our mission with our customers, suppliers, and distributors: better service, higher quality, and faster delivery."

Jose Antonio Bautista
Oracle E-Business Suite Implementation Leader
Sedecal

Did You Know?

- 10 of the top 10 medical device companies run Oracle Applications
- 10 of the top 10 medical device companies run Oracle Technology
- 20 of the top 20 pharmaceutical companies run Oracle Applications
- 20 of the top 20 pharmaceutical companies run Oracle Technology
- 12 of the 12 pharmaceutical companies of Fortune Magazine's 2005 global top 500 run Oracle Applications
- 10 of the top 10 Contract Research Organizations run Oracle Applications

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