Improving Product Quality and Compliance

To be competitive, life sciences companies are striving to attain significant cost savings through operational efficiencies in manufacturing. All this while ensuring compliance to regulatory requirements. Operational excellence is a key goal and is driving manufacturers to implement manufacturing processes that ensure quality, safety, and minimize compliance risk. Oracle offers a comprehensive solution to meet the needs of the life sciences industry.

Life Sciences companies are under constant pressure to reduce costs, improve quality and be compliant. With margins under pressure manufacturers are focused on streamlining and driving efficiencies in all parts of the business. It is a well accepted fact that an increase in manufacturing efficiency and improvements in quality can lend to incremental cost savings. More and more, medical drug manufacturers are opting for comprehensive and preintegrated Supply Chain Management (SCM) applications to integrate and automate all key supply chain activities. This is also helping them embed Lean manufacturing principles across increasingly complex supply chains. Oracle Supply Chain Management solutions provide a robust platform to enable you achieve efficiencies in the supply chain, from realtime demand driven sales and operations planning, and procurement to manufacturing and fulfillment. With Oracle’s solution, organizations are able to substantially enhance their ability to:

- Reduce operational cost and optimize efficiency 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 and optimize efficiency in a regulatory compliant environment

Pharmaceutical manufacturers are implementing lean principles to reduce cycle time and waste in their manufacturing processes. With strict regulatory checks and balances in place and public health at stake, there is the need to ensure consistency of end products. This calls for embedding quality checks right through the manufacturing process. Oracle process manufacturing applications, a part of supply chain management, automates the entire product life cycle for recipe-based manufacturing, from new product development, recipe management, and production to cost, quality, and regulatory management. It allows you to optimize production capacity from raw materials through final product. 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.

The application also provides manufacturing execution system (MES) capabilities through its task-oriented production operator interface, electronic batch record keeping and embedded quality management system functionality. Oracle process manufacturing applications let you formulate products to individual customer specifications, manage stability studies, account for ingredient potency variations, trace batches according to lot number, optimize capacity, and drive continuous process improvement. MES delivers real-time shop floor visibility to multiple layers of management.

With Oracle manufacturing applications you are able to support continuous improvement in manufacturing processes. All this contributing to increased efficiencies, process control and cost reduction.
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 drug development, manufacture, and even distribution. Manufacturers need to have quality-oriented processes for traceability, manage recipe variability, and ensure product consistency.

Oracle’s integrated quality management system lets you collect, distribute, and analyze critical quality data. It helps you seamlessly implement quality improvement programs. It includes integrated support to comply with requirements like 21 CFR Parts 11, 210 and 211. An integrated framework for Electronic Records Electronic Signatures (ERES) supports the implementation of industries best practices around quality data capture points. This helps manufacturers monitor quality levels at different inspection points throughout the supply chain and provides pre-built quality workflows to enforce quality notifications and approvals.

Further, the applications facilitate embedding compliance into core processes with specific capabilities for manufacturing, quality, product safety, and lot/serial number tracking.

Workflow driven processes help you enforce Good Manufacturing Practices (GMP) and the capture of electronic records. Oracle MES adds significant capabilities, not commonly found in other enterprise systems, such as dispensing management, electronic batch records, nonconformance management, integrated operator processing instructions, and standard operating procedures, among others.

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 applications enable 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. Further, the applications empower you to implement rule based recipe management to specify recipe conditions for seasonality and alter recipe for each production run. 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.

By deploying Oracle applications, you can achieve the lowest inventory and the best possible delivery performance. These enable you to become demand driven, forecast accurately and predict demand. 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 life sciences industry. Oracle’s flexible and agile manufacturing applications enable companies to implement lean manufacturing initiatives, which reduce waste and increase efficiencies. 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

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