ORACLE AGILE PLM FOR THE MEDICAL DEVICE INDUSTRY

In the medical device industry, efficiently meeting U.S. Food and Drug Administration (FDA) requirements is a key to business success. Product lifecycle management (PLM) ensures FDA compliance integrity by providing comprehensive content to support management decisions across the organizations and individual functional groups. By uniting product information with processes, people and technology, PLM enables medical device companies to effectively and economically assure compliance.

Leveraging Product Lifecycle Management to Address Quality System Inspection Techniques

The FDA method for evaluating compliance is the Quality System Inspection Technique (QSIT). As part of the QSIT, the FDA targets six major quality systems that medical device companies must have in place. The agency also requires that management demonstrate knowledge of the interrelationships of activities across these six major systems:

- **Corrective and preventative action (CAPA)** — The FDA requires that all medical device companies properly handle quality events to determine criticality and timely resolution. Managing a quality event adequately requires understanding exactly what documents, product lines, and processes are impacted by the event throughout the organization; identifying what needs to be modified to solve the problems; and following through on the corrective action.

- **Design controls** — The FDA requires that all medical device companies’ design control processes provide visibility across all projects and related design activities. Companies must be able to track the origin and verification or validation of design inputs, ensure that original design inputs were manifested in the actual product released to market and they must be able to confirm that requirements have been achieved with documented evidence. Additionally, the FDA risk management stipulation requires that processes be in place to determine how post release changes or corrective actions impact original design specifications and controls.
The number of observations from FDA audits continues to increase every year with a significant impact on company performance. Meeting the expectations of the FDA should be of primary concern to medical device companies.

Records, documents and change controls—The FDA requires that all medical device companies maintain a secure, comprehensive and centralized system to manage all quality procedures, product documents, and manufacturing procedures, as well as track all changes, for easy retrieval to support QSIT audit requirements. The FDA also expects the document management system to enable the company to identify all documents impacted by quality events and product changes.

Material controls—The FDA requires that medical device companies maintain a system to track all materials and associated suppliers used in production to ensure the quality of those materials and the final products satisfy design specifications. Analyzing material cost early in the development process is also critical in achieving price targets for new products.

Equipment and facility controls—The FDA requires that medical device companies establish and enforce one set of global standard operating procedures for all facility operations worldwide. Companies must also be able to determine if any quality events are related to equipment at a particular facility and are expected to make all equipment changes necessary to address a quality event.

Production and process controls—The FDA requires that all medical device companies maintain and enforce one set of production processes across all global manufacturing operations. Companies must be able to identify any quality events related to production processes, manage how quality events and design changes impact manufacturing, and determine all risk associated with production changes.

Automating Business Processes with Product Lifecycle Management

Most life science companies currently manage quality and address the QSIT requirements by using a combination of manual, paper-based processes or discrete point solutions for document authoring and change management, program management, quality event management, and management reviews. Companies can automate each of the four vital business processes by implementing PLM, thereby delivering dramatic improvements in business performance and compliance with QSIT requirements.

Document Authoring and Change Management—Existing document management and change processes in the medical device industry is often fragmented, with no integration to ERP or other enterprise solutions. PLM revolutionizes the document management process by providing an essential foundation for archiving and sharing product data, managing change, automating compliance and providing secure collaboration with external partners. PLM allows companies to create a compliant data set consisting of all documents, decisions and activities to support each of the QSIT systems. Synchronization of this information across each system improves business performance and compliance integrity. PLM supports document authoring and change management with the following capabilities:

- A common database for all enterprise content, including quality management system (QMS)-standard operating procedures (SOPs), design history files, digital medical records and regulatory data and records
- Continuous record of all product data and change history and tracking and management of all revisions
- Standardized format defined for each functional group and standardized workflows for authoring or revising documents by type
- Secure document access and management with user roles and privileges, in compliance with Title 21 of the FDA Code of Federal Regulations Part 11
- Automated document review and approval process for internal and external collaboration
Program Management—Efforts such as design history files, clinical trials, manufacturing transfers and CAPA management require formal program management and must be included in the overall program portfolio analysis for the company. The medical device industry currently faces challenges in assessing program performance and status, forecasting program readiness and completion and prioritizing resource allocation. To support program management, PLM provides:

- Standard support for all enterprise projects such as design history files, manufacturing transfers, clinical trials, regulatory submissions and CAPA management
- Synchronization of project plans with document and quality system in one database
- Resource management and tracking and enforcement of project milestones
- Direct access to design history files content for change impact analysis and reuse

Quality Event Management—The quality assurance (QA) group manages quality events such as CAPA, nonconforming material reports, complaints, audits and minimum design requirements. Without PLM, linking quality and compliance information with the supporting records across disparate document and quality management systems is cumbersome, inefficient and costly. Consequently, cross-functional investigation of quality events is fragmented, making it difficult to achieve timely reporting of events, monitor the status of events and implement quality improvement. PLM enables companies to share data quality across the enterprise and automate challenging compliance tasks. PLM provides the vital connection between the quality event and the document trail, demonstrating cause and impact of the event as well as the required changes across all systems and processes audited by the QSIT. To support quality event management, PLM provides:

- Closed-loop quality event management with root cause analysis and required change(s)
- One database, one system and standard processes to manage all quality events
- Integration of quality events to digital health records, digital medical records, and QMS SOPs to support risk management assessment
- Enterprise visibility of quality event impact and management of quality investigations in real time through closure
- Quality archives to support audit management

Management Reviews—Most medical device companies face the challenges of a communication disconnect between the QA and business organizations within the company. These challenges negatively impacts company performance, market share, customer satisfaction and staff morale. To solve the problems, the QA organization needs to present management with a graphic representation of the financial impact of quality illustrating the cost of recalls, CAPA, inventory, new product introduction, and knowledge lost.

PLM provides a single repository for quality data and the platform to establish a common dialogue and shared priorities with business organizations to foster a compliance culture across the organization. In addition, PLM can provide the added advantage of analytics that process quality data and translate it into actionable information. By providing visibility and insight to people across the enterprise, PLM helps companies use quality data to make timely decisions that matter to the business. To support management reviews, PLM provides:

- Automated real-time reporting for all enterprise activities
- Standard reports for document management, quality events and projects
...• Custom ‘dashboards’ to present critical information faster
• Cross-functional analysis of all data in a graphical format
• Content synchronization with other enterprise tools such as enterprise resource planning and manufacturing execution systems

Oracle Agile PLM Applications
Agile PLM is a modular suite of applications, allowing customers to choose and implement the combination of modules that best suit their business model, existing systems and needs. Agile PLM provides fully integrated modules for the following PLM processes:

Product Collaboration: Helps users share product data and structure and manage change across the global product network

Product Cost Management: Enables companies to manage product costs through early and real-time cost visibility

Product Quality Management: Drives improved product quality and customer satisfaction by integrating customer, product, quality and regulatory information within a closed-loop corrective action system

Product Governance & Compliance: Enables organizations to manage product, substance and material compliance against standards and regulatory requirements

Engineering Data Management: Organizes and manages product design assets to support globally distributed engineering teams

Product Portfolio Management: Provides tightly synchronized program and product information, maximized resource utilization, and cross-program visibility and decision support throughout the product lifecycle

Engineering Collaboration: Ensures engineering processes are fully leveraged throughout the product lifecycle, driving engineering best practices across the enterprise. Integrates PLM with all leading MCAD and ECAD packages

Variant Management: Provides a best-practice approach to managing portfolios of related products and product variants across the lifecycle

Product Lifecycle Analytics: Delivers preconfigured, yet flexible dashboards and reporting facilities for the production of accurate, detailed reports covering every aspect of the product lifecycle

Product Data Quality: Provides organizations with an integrated suite of data quality tools that provide an end-to-end solution to measure, improve, and manage the quality of data from any domain, including customer and product data

Product Data Hub: Oracle Product Information Management Data Hub is an enterprise data management solution that enables customers to centralize all product information from heterogeneous systems, creating a single view of product information that can be leveraged across all functional departments.

AutoVue Enterprise Visualization: Enables companies to drive effective decision-making, optimize the NPI/NPD and change management processes, and enable secure supplier collaboration by delivering best-in-class document and CAD (MCAD and ECAD) visualization and collaboration capabilities directly within Agile PLM.
"Oracle’s Agile platform provides us with a single source of truth and enables us to demonstrate the necessary internal controls over our product records that we need to ensure regulatory compliance.”

David Rudzinsky, Senior Vice President, Information Systems and Chief Information Officer, Hologic

Case Study: Hologic

Hologic is a leading developer, manufacturer, and supplier of premium diagnostics, medical imaging systems and surgical products. Hologic adopted Agile PLM to reduce engineering change order cycle time, automate the ECO system to reduce overhead costs, integrate the ECO system with their existing Oracle’s manufacturing resource planning (MRP) and enterprise resource planning (ERP) systems, and to ensure compliance with FDA regulations.

With Agile PLM, Hologic was able to:

- Accelerate execution of product enhancements and design changes
- Ensured compliance with industry and financial regulations
- Reduce the ECO cycle time from 40 days to 4 days
- Reduce overhead costs by eliminating expensive paper-based processes

Contact Us

For more information about Oracle Agile PLM applications, visit oracle.com or call +1.800.ORACLE1 to speak to an Oracle representative.