Product Lifecycle Management in the Medical Device Industry

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PLM technology ensures FDA compliance for medical device companies by providing comprehensive content to support management decisions.

EXECUTIVE OVERVIEW

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) technology ensures FDA compliance integrity by providing comprehensive content to support management decisions across the organization 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 systems:

- Corrective and preventive action (CAPA)
- Design controls
- Records, documents, and change controls
- Material controls
- Equipment and facility controls
- Production and process controls

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The FDA determines compliance by applying QSIT to audit these systems and related records. The FDA has become regimented in looking at the processes and making sure that companies have proper procedures to support all the systems. The agency also wants to ensure that companies have clear management visibility of any discrete event that happens in the systems and an understanding of exactly how discrete events impact the entire organization from a risk management perspective.

The number of observations from FDA audits continues to increase every year with a significant impact on company performance, so meeting the expectations of the FDA should be of primary concern to any medical device company. Many of the world's top medical device companies have deployed PLM as an indispensable enterprise solution for building an automated compliance process to meet all of the FDA's stringent requirements.

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PLM provides a single repository for each of the subsystems audited by the FDA. With data aggregated across all groups, product lines, and manufacturing sites, PLM enables standardization and accountability of critical processes across the organization. In addition, PLM provides the necessary management visibility across all systems to support better risk assessment and decision-making.

The following outlines each of the six target subsystems, explaining how PLM addresses FDA expectations and delivers associated business benefits.

The FDA requires that medical device companies have the following six major quality systems in place:

1. **Corrective and preventative action**
2. **Design controls**
3. **Records, documents and change controls**
4. **Material controls**
5. **Equipment and facility controls**
6. **Production and process controls**

Corrective and Preventive Action

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 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 are mandated to schedule periodic management reviews to verify the project status and confirm that requirements have been achieved with documented evidence. They must be able to track the origin and verification or validation of design inputs, as well as ensure that original design inputs were manifested in the actual product released to market. Additionally, the FDA risk management stipulation requires that processes be in place to determine how postrelease changes or corrective actions impact original design specifications and controls.

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. Companies must demonstrate that they have approved the material suppliers and qualified critical materials as part of the development process.

Analyzing material cost early in the development process is also critical in achieving price targets for new products. For released products, companies must be able to determine if any quality events are related to material or supplier performance.

Equipment and Facility Controls

The FDA requires that all 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. They are also expected to make all equipment changes necessary to address a quality event.

Production and Process Controls

Similar to the equipment and facility 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 process changes to justify requalification decisions.

AUTOMATING BUSINESS PROCESSES WITH PRODUCT LIFECYCLE MANAGEMENT

By implementing PLM, companies can automate document authoring and change management, quality event management, program management, and management reviews. This delivers dramatic improvements in business performance and compliance with QSIT requirements.

Most life sciences 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, quality event management, program 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

Managing documents across the enterprise is a significant challenge, especially for medical device companies that depend on such a wide variety of documents to support compliance. The existing document management and change process in the life sciences industry, although well-defined, is often a fragmented, manual process with no integration with enterprise resource planning or other enterprise solutions. Consisting of a sequence of events, the process causes lengthy delays and requires nonvalue-added activity associated with creating, submitting, cross-checking, reviewing, approving, filing, organizing, and implementing change orders across the organization.

In the current document management process, companies manually handle data via lab notes, reporting templates, design history files located in filing cabinets, hard copy signatures, portable document format documents, and standalone nonintegrated solutions. Re-entry of information into other systems further increases change order cycle time and opens the potential for errors that can escape the manual validation process.

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
- Tracking and management of all revisions
- Standardized format defined for each functional group
- Secure document access and management with user roles and privileges, in compliance with Title 21 of the FDA Code of Federal Regulations Part 11
- Standardized workflows for authoring or revising documents by type
- Automated document review and approval process for internal and external collaboration
- Enterprise resource planning integration for bill of materials transfer and engineering change order cut-ins

Maintaining a central PLM system for document management and change tracking can significantly cut document search time, eliminate errors related to use of incorrect documents, improve record reuse, boost productivity, and reduce operational costs.

By maintaining a central PLM system for document management and change tracking, a company can significantly cut time wasted on searching for documents, eliminate errors related to use of incorrect or outdated documents, improve record reuse, boost productivity, and reduce operational costs.

Quality Event Management

The quality assurance (QA) group manages quality events such as CAPA, nonconforming material reports, complaints, audits, and minimum design requirements. But the quality information might not be effectively aggregated or shared across the enterprise. 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 the events, monitor the status of event, and implement quality improvement. This fosters a reactive, rather than proactive, corporate culture, compromising business performance and regulatory integrity.

The ultimate PLM solution for a medical device company integrates the company's quality management system with the QSIT-compliant data set to share quality data across the enterprise and automate challenging compliance tasks. Two important capabilities needed for compliance are (1) identifying the source of a quality problem and (2) tracking how quality events impact the organization. PLM provides the vital connection between the quality event and the document trail, demonstrating the 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
- Management of quality investigations in real time through closure
- Quality archives to support audit management

By supporting quality event management in synchronized systems, PLM systems result in increased customer satisfaction, improved product quality, and enhanced audit integrity.

By supporting quality event management in synchronized systems, PLM allows companies to expedite notification of regulatory reportable events and more effectively respond to quality events, thereby increasing customer satisfaction, improving product quality, and enhancing audit integrity.

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.

Managing programs across the QSIT subsystems is even more difficult because it is not standardized, creating redundant information, inefficiencies, and errors in the transfer. These errors impact the resolution of quality events and product development cycle time, resulting in clinical and production stoppage, increased unit cost, extended manufacturing transfer times, and significant increases in project cost and compliance risk.

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
- Tracking and enforcement of project milestones
- Direct access to historical design history files content for change impact analysis and reuse

Program management via PLM supports improved decision-making that focuses resources on projects with the most potential, resulting in faster research and development ROI.

Program management via PLM supports improved decision-making to focus resources on projects with the most potential, resulting in faster research and development return on investment. Standardization of the design history file process across the organization ensures compliance and streamlines the design processes to accelerate cycle times for product development and time to market. All the historical design content provides executive management with an easy reference for risk management and reuse of valuable design intellectual property.

Management Reviews

Most medical device companies face the challenges of a communication disconnect between the QA and business organizations within the company. The first obstacle is a "language barrier" between QA and operations. Reports created by QA are often not in a format or wording that is easily understood by management, nor are they presented in a compelling way that will call management to action. Consequently, management has difficulty interpreting the business impact of quality on the company and prioritizing appropriate resources to resolve quality issues.

The second challenge is getting the right information to management. Due to difficulty in synchronizing with other functional groups and aggregating data from multiple unconnected systems, QA cannot get the data it needs in a timely fashion. By the time quality information is presented to senior management, the content is already outdated. Additionally, the messaging aimed at management is incomplete because a disproportionate amount of time is spent gathering the information, leaving no time to analyze the data and make it actionable. As a result, management is reactive instead of proactive on quality, spending time mitigating risk instead of strategically leveraging the knowledge to improve the bottom line.

The third challenge is the lack of cross-functional communication flow. When QA and receive/acknowledge processes require cross-functional input with multiple QSIT systems, it often goes into a black hole—with no visibility into status. The disconnect between groups impacts process performance and compliance integrity during audits. While manual processes make the problem worse, independent automated quality solutions that are not synchronized with enterprise systems used by other functional groups are not the solution either.

The combination of 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. Having an automated system with a common database for all quality information, QA will be able to gather, share, and analyze quality data.

PLM technology 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. Once QA is empowered to get the message out in management's own language, PLM analytics can help clarify the

issues and provide graphic representations that speak to businesspeople in a language they understand. With PLM, companies will be able to present the information in real time through clear communication channels and visibly tie quality to the bottom line, thus keeping management incited to take action.

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 of 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

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CONCLUSION

Life sciences companies need to automate compliance and quality processes to address the FDA's QSIT requirements while improving business process performance and compliance integrity. This requires a tool that can automate and synchronize business processes and content management across all functions and locations of the enterprise.

PLM is the ideal solution for medical device companies seeking to address all FDA expectations with regard to QSIT. By streamlining quality and compliance processes, PLM enables medical device enterprises to reduce time to market, strengthen product quality, reduce cost, and improve response to customer needs.

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