

# QUALITY MANAGEMENT SYSTEMS

MedTech Quality Management Systems vary widely – with organizations using different software systems, spreadsheets, and manual systems to support and drive processes and data. The following is an example of how different types of software systems are used within a typical medtech company.

## ERP

### (Enterprise Resource Planning)

Originally designed to manage manufacturing processes, Enterprise Resource Planning (ERP) systems now handle most core business processes for companies of all industries. Larger ERP solutions are typically modular in design, with users selecting the modules that they need, including manufacturing, finance, HR, purchasing, supply chain, service delivery, and more. ERP systems may provide integrations to applications that are purpose-built for specific purposes, such as engineering, CAD, and regulatory systems.



## RIM

### (Regulatory Information Management)

Regulatory Information Management (RIM) solutions are designed to support and streamline the activities of regulatory affairs (RA) teams. RIM systems designed for medical device organizations, such as Rimsys, manage product registrations and regulatory submissions, track standards and essential principles, and organize and control product and UDI data.



## PLM

### (Product Life-cycle Management)

Product Lifecycle Management (PLM) solutions are used by engineering and design teams to manage a product from design to obsolescence. PLM software will track product configurations, attributes, and bills of material – along with managing product changes and related processes and documentation.



## LMS

### (Learning Management System)

Learning management systems (LMS) provide centralized solutions for creating, delivering and monitoring employee training and on-going education. An LMS may be a separate system or may be part of an eQMS or other solution.



## CAPA & Non-conformance

Corrective and Preventative Action (CAPA) and Non-conformance solutions allow companies to track any quality-related issue and deviation, and to identify recurring issues and trends. Non-conformances are recorded, evaluated, and addressed using workflows and processes built into the software.



## Complaint Handling

Complaint handling is critical for medtech companies and must be built into the overall quality system. Complaint handling software allows companies to record, track, and respond to complaints coming from multiple sources.



## Document Management

Document management is a central requirement of a medtech company's quality system. Document management, or document control, systems manage document access, change control procedures, and review and approval processes for all essential documents as required by the quality system.



## Risk Management

Risk management is a critical function for medical device companies and leverages information from across the organization and throughout the lifecycle of each product. Risk management software allows medtech companies to detect, mitigate, and prevent potential risks as early as possible and provides tools for evaluating residual and acceptable risk levels.



## Supplier Management

Medtech companies must not only track their own quality processes, but must ensure that their suppliers have adequate systems to ensure product quality as well. Supplier management software allows companies to manage supplier relationships, identify and manage quality issues, and perform supplier quality audits. Supplier management is often managed through a company's ERP or eQMS software.



## Calibration & Preventative Maintenance

Scheduling, performing, evaluating, and documenting equipment calibration and preventative maintenance is critical to a medtech company's quality system and their ability to ensure a consistent level of product quality. This is often managed through a medtech organization's eQMS software.

