GxP Process Management Software

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White Paper:

Software Automation Trends in the Medical Device Industry

Introduction

The development and manufacturing of a medical device is an increasingly difficult endeavor as competition grows stronger and regulatory constraints broaden. Device companies must look for ways to increase efficiency in their processes so as to remain competitive and in compliance with the various regulatory bodies governing the world's markets.

One potential method for increased efficiency is the use of software solutions to automate the various processes contributing to the development, manufacturing, and marketing of a medical device. Delay to market and non-compliance are just two of the possible negative outcomes with the slow, burdensome paper-based processes that tend to prevail in this industry. Software that ties together the information sharing requirements of the various departments within a device company have been shown to reduce development costs by as much as 25 percent and reduce time to market by a staggering 40 percent.

However, with the growing number of solution types commercially available to the industry and significant functional overlap, the selection process has grown somewhat confusing, especially when trying to maximize the cost-benefit ratio. The aim of this paper is to summarize the different categories of solutions available so as to make the selection process easier and maximize the benefit of software automation in the medical device industry. Furthermore, a new type of software solution is proposed that reaches across departmental barriers and allows information sharing and process automation across the enterprise.

Software Categories

There are several different categories of software solutions available to medical device manufacturers for automating processes. Generally they can be separated into two groups: those that manage business content and processes and those that manage product content and processes. Those that will be examined in this paper are listed below:

Business Content and Process Applications

- Electronic Document Management Systems (EDMS)
- Enterprise Resource Planning (ERP)

Product Content and Process Applications

- Manufacturing Execution System (MES)
- Product Lifecycle Management (PLM)
- Quality Management System (QMS)

ECMS/EDMS

Electronic document management systems are often seen as a component of electronic content management systems (ECMS), but specifically relate to the tracking and storage of electronic documents or images of paper documents. While EDMS may only be a subset of the broader ECMS, it is the most commonly implemented and used set of functionalities within the medical device space. This is most likely due to the large amount of documentation generated in complying with regulations specific to the life sciences industries.

Several researchers have proposed that an EDMS presents significant gains in the dissemination of information and greatly improves communication in a corporate environment. They attribute these gains to availability of information and the ability to query the information based on individual needs and interests.

Areas commonly addressed by the EDMS include the following:

- Retrieval – Users can commonly search on metadata such as document number, title, status, etc.
- Filing – This includes organization and storage of the documents
- Capture – This is the process of converting paper documents into electronic documents via the process of scanning and extracting the "retrieval-based metadata" through automated tools like Optical Character Recognition (OCR)
- Security – The EDMS will often manage the access control level (ACL) to documents and protect sensitive information
- Archival – This protects the documents from damage and natural disasters
- Retention – The system allows the user to configure what gets retained and for how long
- Distribution – Important for issuing and tracking controlled copies that will be distributed outside the system
- Workflow – This allows a workflow to be applied to the documents for purposes such as review and approval. Some systems allow for electronic signatures as part of the workflow
- Collaboration – Important for document creation and review, collaboration allows users to actively work on and edit the document as individuals or as a team
- Versioning – The process by which documents are checked in to or out of the system, resulting in various versions of the document

All of these areas are particularly important to medical device manufacturers. Regulations such as 21 CFR Part 820.40 specifically cite document and record control. Furthermore, good document control practices can save the company time and money.

ERP

Enterprise resource planning systems attempt to integrate all data and processes of the company into a single unified system. They have their origins in manufacturing where they evolved from Manufacturing Resource Planning (MRP). Technically, an ERP system is one that integrates at least two formerly disparate systems. However, today's ERP solutions are much more complex, and generally include the following modules or capabilities:

- Manufacturing – This involves the management of Bills of Materials (BOMs); plant capacity, scheduling, and workflow; cost of goods; and other processes related to manufacturing
- Supply Chain Management – Items managed here include inventory, order entry, purchasing, and other activities related to procurement and supply
- Financials – Accounting items that can be managed here include the general ledger, accounts payable and receivable, fixed assets, and cash
- Projects – Generally related more to capturing the costs of a project, such as time, expense, costing, an billing
- Human Resources – Activities surrounding human resources such as payroll, time, attendance, and benefits may be managed

- Customer Relationship Management (CRM) – Generally refers to the activities surrounding sales, marketing, and customer service

- Data Warehouse – This is often manifested via various interfaces that allow employees, customers, and suppliers to extract data from the system

Due to the expansive nature of the ERP system, implementation is typically lengthy and causes significant interruption and change in the way that employees perform their work. The scope of an ERP system also represents a significant investment and therefore it is not uncommon to implement the system in phases. The accounting and manufacturing pieces are most commonly used in the medical device industry, with larger companies typically choosing to implement more components of the software.

MES

A manufacturing execution system (MES) allows a company to monitor, track, and record critical production activities. They range in complexity from simple systems for tracking Work in Process (WIP) to systems that are fully integrated into every resource utilized in the manufacturing of a device. Perhaps the most important function that an MES system can provide to a device manufacturer is the capability to generate, store, and report on device history records (DHRs).

The concept of an electronic device history record (eDHR) provides many benefits that are not achievable with tracking these records on paper. Because the DHR information is stored electronically in a database, it is easy to extract the data for analysis and reporting purposes. This can be particularly advantageous in the unfortunate case of a recall.

Because the complexity of the MES can approach that of an ERP system, cost and resources may again be stretched during the implementation phase. This may be a factor in slow adoption rate of this type of software solution in the medical device industry.

PLM

Product lifecycle management (PLM) commonly refers to a set of software tools that enables the new product development (NPD) process in a company. PLM focuses on maintaining the data and information around a company's products from an engineering perspective. Researchers have shown benefits with the implementation of PLM that include: reduced time to market, reduced prototyping costs, and savings through data re-use and integration of engineering work flows.
PLM is compromised of four major areas:

- Product and Portfolio Management (PPM) – These tools are aimed at providing management a view of the current projects in development. This can assist with resource planning and comparing project progress versus plan

- Product Design (CAx) – There are a number of tools that aid greatly in the actual design of a new product. The most prominent of these tools are computer aided design (CAD) and computer aided manufacturing (CAM). These tools can greatly reduce the cost prototypes

- Manufacturing Planning Management (MPM) – These tools revolve around building the bill of materials (BOM) for a product and managing the various iterations created during a product's lifecycle. The BOM is often the central view for products in a PLM system

- Product Data Management – These tools are focused on capturing and maintaining the various pieces of product data and information that are created during its development and useful life. Historically, PDM referred specifically to managing the complex 3D CAD files generated by product design tools. PDM has expanded to include other pieces of information associated with the product

Recently, PLM tools have placed a great emphasis on collaboration with vendors in an effort to reduce lead times and manufacturing costs. Incorporating the principles of design for manufacturing (DFM) and concurrent engineering, PLM tools can greatly assist in the interaction device manufacturers have with their suppliers.

PLM solutions are commonly offered by the CAD vendors that developed PLM as an extension of their product design tools. This being the case, they are often well suited for use by engineering and design professionals.

QMS

The quality management system (QMS) can be defined as the set of policies, processes, and procedures intended to ensure quality in the company's business processes. The QMS provides a means to identify, track, and rectify quality issues that arise during the execution of the company's core business processes. Furthermore, the QMS includes processes to put preventative measures in place so as to prevent the recurrence of quality issues.

Software solutions have been developed to automate nearly all aspects of the QMS. Areas commonly addressed by an electronic QMS include the following:

- Process Automation – This involves the data input, storage, and tracking of the various quality events and processes encompassed by the QMS. Additionally, these tools commonly automate the workflow associated with these processes. Common quality events and processes that are automated include customer complaints, non-conformances, and CAPA

- SOP Management – The QMS will typically include some aspect of EDMS to manage the policies and procedures that govern the quality management system. Management of SOPs and policies requires version control, storage and organization, document lifecycle management, and review capabilities

- Reporting – One of the biggest advantages with an electronic QMS is the ability to report on the data captured by way of quality events and processes. Trending and other statistical analyses may be applied to the data to identify root cause and propose corrective and preventative action. These activities are much more difficult if the data exists only on paper

In addition to these core areas, QMS software solutions tailored for medical device manufacturers may also include tools to manage employee training. Regulations require that employees be properly trained and that objective evidence of that training be maintained.

Because compliance with regulations such as the FDA's Quality System Regulation (QSR) and ISO 13485 is essential to the continued prosperity of a medical device manufacturer, a robust and efficient QMS can be very important.

Application Overlap

Because each of the aforementioned technologies manage information, there can be considerable overlap in the functionality that they offer. Choosing from which application to leverage the benefits they bring depends upon the overall IT strategy. Some of the overlapping scenarios include:

- EDMS vs. Quality Document Control: Both manage documents. Both provide for search and retrieval, archive and retention. Whereas EDMS focuses on centralizing documents for the purpose of collaboration and information repurposing across disparate departments, document control emphasizes access security and change control. Whereas EDMS is applicable to general purpose documents, Document Control is required for GxP specific documents.

- ERP vs. PLM: Both touch the bill of materials required to create a product. Product designers using CAD tools generate the BOM, while Purchasing agents drive inventory management using the BOM. Companies must decide which solution is responsible for the BOM, and how the information is transferred between them.

- ERP vs. Quality: Human Resources may use ERP to track employee certifications and corporate based training. Similarly Quality may use a QMS to insure that employees are kept current on changes to work instructions, test methods, SOPs, and other design- or production-based documentation.

Selection Considerations

With a clear understanding of the different software solution types, it is easier to match core functionality with the needs of the organization. It is important to understand the strengths of each type of solution and to evaluate what are the most critical user requirements that must be met.

Beyond the type of solution to be selected and the key functionality desired, there are some other considerations that pertain specifically to software automation in the medical device industry. The first of these and perhaps most important is compliance of the software to regulations, specifically the FDA's 21 CFR Part 820 and Part 11.

One of the greatest gains in efficiency that can be had with the types of software solutions previously mentioned is the implementation of electronic signatures. Much time can be wasted in the manual routing and signing of documents. Several days, weeks, and even months can be spent waiting for the approval of important documents generated in the development of a new medical device. In some cases, this time spent waiting for documents to be reviewed and signed can signify the loss of millions of dollars in sales.

With the gains offered by electronic signatures comes a host of requirements to comply with 21 CFR Part 11 and the other global regulations that are applied to medical device manufacturers. Just a few of these are the need for a full audit trail and user password restrictions. Lastly, validation of the software is very important and is something that should be taken very seriously when selecting a software vendor.

It is well known that validation of the software solution can easily equal or exceed the cost of the software itself. It is vital that the software vendor provide support for the validation efforts required to implement their solutions. Furthermore, a vendor with a validation strategy and products to ease the validation burden and speed implementation should be a point of evaluation.

It is also important to consider the domain expertise of the software vendor. How many medical device customers does the vendor have? Are they familiar with the processes common in the medical device industry and do they have experience in automating those processes? Do they have in-house personnel that have worked in the industry and understand the unique needs and requirements of a medical device customer?

Finally, a key point to remember is that many of these software solutions offer a host tools that will likely never be used in the medical device industry. For example, an MES system allows machinery and equipment to feed data directly into a production record. While this is certainly important for extremely automated, large-scale manufacturing lines, it is unlikely that this level of automation would be used in a device manufacturing environment. The cost to implement and validate such a system would be extremely expensive and may not provide a return on investment for several years. Careful consideration should be given to which parts of any software package will be utilized so as to not unnecessarily spend time, money and resources implementing and validating software that will see minimal use and provide marginal benefit.

In summary, it is important to remember that a software solution that appears to have the greatest amount of functionality or costs the least may not be the best selection if the vendor is lacking in domain expertise and implementation experience in a highly regulated environment.

Conclusion: A Proposal

With all of the different types of software available and the hundreds, if not thousands, of vendors vying for the business of medical device manufacturers, selecting the right solution can be daunting.

A proposal is made to simplify the process and give the greatest return on investment for medical device manufacturers seeking to gain efficiencies through software automation. Each of the software categories described earlier offer significant benefits and functionality. However, no one category offers all of the functionality required by a device manufacturer. Each does however offer a plethora of capabilities that are not needed.

It is proposed that a new category of software should be explored that consists of an integrated suite of software solutions that are tailored to specifically meet the needs of medical device manufacturers. Such a suite should include the following:

- A robust EDMS with sophisticated workflow capabilities for meeting the document needs of all departments; from user requirements generated by marketing to 510(k) submissions compiled by regulatory
- PDM and BOM management capabilities for engineering and design transfer to manufacturing
- A project management solution for the NPD process and other projects
- A robust and highly flexible process automation tool is vital for automating quality processes such as CAPA and customer complaints and manufacturing processes such as DHRs
- A capability to integrate with the company's ERP solution is also essential for manufacturing and design transfer
- A capability to track and manage employee training would be an excellent addition to an integrated medical device software suite
- The suite would have to include the necessary safeguards and traceability to meet 21 CFR Part 11

Combine this integrated software suite with a comprehensive set of validation tools and a vendor with deep domain expertise in the medical device industry and the result is an expansive software solution for the medical device manufacturer.

About MasterControl Solutions

MasterControl Inc. has been at the forefront of providing document control and GxP process management software solutions since 1993. Hundreds of companies worldwide use MasterControl's integrated solutions suite to ensure compliance with FDA regulations such as 21 CFR Parts 11, 210-211, 820, 606; ISO quality standards such as ISO 9000, ISO 13485, ISO 14000; and Sarbanes-Oxley Act requirements. The MasterControl™ GxP process management suite allows companies doing business in regulatory environments to effectively manage document and change control, audits, corrective/preventive actions (CAPA), regulatory training, nonconformance disposition, customer complaints, and other GxP processes. MasterControl incorporates industry best practices for automating and linking every phase of a product's development cycle while also facilitating compliance with regulatory requirements. The combination of MasterControl's integrated platform and a continuum of risk-based software validation products drives down the total cost of ownership and enables customers to extend their investment enterprise-wide. In addition to providing off-the-shelf products, MasterControl also offers comprehensive technical and customer support, including product training, implementation, and validation services.

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