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WHITE PAPER

Fundamental Areas Where Medical Device Manufacturers Can Leverage ERP/CRM Software to Facilitate FDA Compliance

Examining areas of key functionality for consideration in choosing a long term software solution.

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“Medical Device Manufacturers, similar to other manufacturers, have long embraced ERP (Enterprise Resource Planning) and CRM (Customer Relationship Management) software systems. “

Introduction

While every manufacturer in the United States is subject to a multitude of governmental rules and regulations, probably no industries are as fully regulated as those dealing with food, pharmaceuticals and medical devices. The U.S. FDA (Food and Drug Administration) requires companies in these segments to comply with standards for quality, safety, effectiveness, identity and strength. Because the burden is on the manufacturers to prove conformity, they are forced to employ costly, stringent procedures, maintain in-depth documentation and generate a myriad of substantiating reports.

Medical Device Manufacturers are similar to other manufacturers that have long embraced ERP (Enterprise Resource Planning) and CRM (Customer Relationship Management) software systems. However, they have primarily employed them to achieve operational efficiencies as well as further sales and marketing objectives. Indeed, today's sophisticated ERP and CRM systems support a broad set of activities that help manage and coordinate business functions, including production planning, purchasing, inventory control, supplier interaction, order tracking and customer service. However, many Medical Device Manufacturers have also discovered that their choice of ERP and CRM software can play a significant role in their abilities to comply with strict FDA regulations.

Basically, the FDA requires that each manufacturer shall establish and maintain a quality system that is appropriate for the specific medical devices designed or manufactured. The quality system has to be an integrated effort, i.e., a total systems approach to satisfy the particular safety and performance needs of a specific manufacturer, product and user-market. The Quality Assurance activities have to extend beyond inspection and testing spot solutions and must cover all areas that have an effect on the quality, safety and effectiveness of the device. These areas include product development, design verification and validation, component and/or supplier selection, documentation, development of labeling, design transfer, process development and validation, pilot product, routine manufacturing, test/inspection, device history record evaluation, distribution, service or repair and complaints.

“In addition to enhanced operational efficiencies, a well thought-out software choice can facilitate adherence to required procedures and generate the necessary backup reports.”

Not too surprisingly, most of the aforementioned requirements can be satisfied through the judicious selection and utilization of good ERP and CRM software. However, there’s a cautionary note. While most ERP solutions facilitate controls through the real-time integration of accounting, manufacturing and distribution functionalities, the challenge is to find a software solution that also integrates CRM in real-time. The integration of ERP and CRM enables Medical Device Manufacturers to have single-point of contact for visibility into the most current customer-related data, providing quick and easy access to the information needed to make decisions that impact quality and security.

In addition to enhanced operational efficiencies and insight, a well thought-out software choice can facilitate adherence to required procedures and the necessary backup reports.

Let’s take a look at selected ERP and CRM functionalities and how they can serve to satisfy FDA requirements.

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“The Engineering Change Control process is a user-definable workflow type ERP sub-system.”

Engineering Change Control

The Engineering Change Control process is a user-definable workflow type enterprise sub-system. It can augment or even replace the paper trail that usually accompanies any changes to product design data. By providing mechanisms, audit trails and archives, Engineering Change Control functionality gives Medical Device Manufacturers ready access to documentation on prior product versions. In this manner, the manufacturer has the ability to address questions relating to product defects in older product versions. Comprehensive ECC documentation also enables manufacturers to easily revert to the production of prior product versions, if necessary, to suit the requirements of a particular customer or conform to FDA requirements.

According to FDA’s publication in 21 CFR 820.40, Medical Device Manufacturers are required to

- Employ written procedures for the approval and distribution of documents. The approval procedures must ensure that the documents meet the requirements of the QS/GMP as well as adequacy for their intended use. Obsolete documents must be removed from circulation, and document approvals must include a signature and date. Removal (or prevention of use) of obsolete documents must also be verified. Written procedures (manufacturing, design, quality control, laboratory, etc.) need to be signed and dated as approved.
- Sign and date as approved all reviewed Device Master Record (DMR) and Device History Record (DHR) documents. All documents prepared to comply with the QS/GMP must be available at the point at which they are to be used or otherwise needed.
- Review and approve all changes to documents with changes communicated to appropriate personnel in a timely manner and maintained. Document change records must include a description of the change, identification of the affected documents, an appropriate approval signature, approval date and effective date of the change. No changes are to be implemented prior to approval. The approving official should be the same person or from the same department as the original approver. If not, there must be documentation that specifically designates who is responsible for approving the change.

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“This routing of ECOs through user-defined statuses is achieved by means of a status routing file in which all possible from/to statuses are held.”

Engineering Change Orders, typically the hub of an Engineering Change Control system, can satisfy most of these stringent documentation requirements. The Engineering Change Order (ECO) cycle is typically governed by user-defined status codes. Each user-defined status is associated with a system status that enables the system to “relate” to the user-defined statuses. Typically, the link between the user-defined status and the system status is not a one-to-one relationship, i.e., any number of user-defined statuses can be associated with a single system status. For example, while the system may only recognize the fact that an ECO is “in progress,” users of the ECC system can define a string of statuses through which an ECO must pass during its “in progress” phases. This routing of ECOs through user-defined statuses is achieved by means of a status routing file in which all possible from/to statuses are held.

Also, typically associated with user-defined statuses are events. When an ECO is moved into a status, any associated events are raised. Once an ECO has been raised, the ECC user must identify all products affected by the change, which is an FDA requirement. At least one product must be specified before an ECO can be moved from the system status of “new” to “in progress.” A “where-used” query, which includes all routes identified as being under ECC, is provided to aid the user in identifying possible candidates. Also available on the “where-used” query are lists of existing jobs, purchase orders and sales orders relating to the products. These can be placed on hold manually, if necessary.

When the ECO is moved from “new” to “in progress,” the current revisions/releases of the Bills of Material (BOMs) and routings for all products listed on the ECO and for all routes flagged as being subject to ECC are copied to separate tables. All maintenance of BOMs and routings for ECC controlled products are performed against these tables.

Advanced Planning & Scheduling

“Selected AP&S solutions also enable manufacturers to define quality items relating to a machine, product and customer.”

Advanced Planning and Scheduling

Advanced Planning and Scheduling (APS), often an integral part of an ERP software solution, enables manufacturing management to gain a real-time picture of current shop floor activities. This capability allows the manager to invoke last minute production adjustments to make allowances for absentee workers, machine down times and bottlenecks as well as to accommodate rush orders. Typically, APS software provides the ability to run a variety of reports that give managers better insight into factory operations and further compliance with FDA quality controls. These include manufacturing route details, bills of material details, resource usage, cell and work center details as well as specifics for each machine on the factory floor.

Selected APS solutions also enable manufacturers to define quality items relating to a machine, product and customer. The data can be manually and/or automatically collected and stored in a database, which can then be queried directly or brought into an analysis tool – an essential for FDA compliance.

The Quality monitoring capability enables instant checks for trends and “blips” in the collected data and can be configured to send warnings to other users when processes are going out of tolerance.

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“A Lot and Serial Tracking module forms a ‘secure file’ of information gained from the entire manufacturing process – from the testing of raw materials through to the completion of finished goods.”

Inventory Tracking

According to FDA’s publication 21 CFR 820.60, manufacturers are required to have written procedures for identifying products during all stages of receipt, production, distribution and installation to prevent mix-ups. However, not all ERP systems are equal when it comes to the breadth and depth of inventory tracking. Therefore, it is critical for Medical Device Manufacturers to ascertain whether the inventory tracking module of the chosen ERP solution provides the “bells and whistles” necessary to facilitate FDA compliance. The ability of the system to perform both Lot and Serial Tracking is of vital importance.

A Lot and Serial Tracking module forms a ‘secure file’ of information gained from the entire manufacturing process – from the testing of raw materials through to the completion of finished goods. It is done by recording material movement through receiving, manufacturing, assembly, inspection, stocking and final dispatch. It provides the ability to trace where a product originated through to where it went with full upward and downward traceability of all inventory transactions. Some of the key features to look for are two-stage receiving, shelf life control of stock, archives of history, bin/lot and serial number cross-referencing and reject control/return documentation. A practical feature is the ability to assign lot numbers manually or automatically and that can be either numeric or alphanumeric. The database of information helps to ascertain compliance with FDA quality regulations. The secure file must be fully accessible and non-alterable.

The traceability requirement should not be confused with the tracking regulation under FDA’s 21 CFR 821. The tracking regulation requires certain devices to be tracked to the end user or patient through the entire distribution process.

Components of a device subject to traceability requirements must be identified with a control number where appropriate. Therefore, in selecting an ERP system, it is vital that any solution selected accommodate large field lengths. Manufacturers must define which components are to be identified with control numbers and provide justification for those that are not identified with control numbers.



“RMA (Return Materials Authorization) and RTV (Return to Vendor) ERP software system applications can play a vital role in tracking returned or exchanged items sold to customers or bought from suppliers.”

Handling of Returns

The QS/GMP requires manufacturers to evaluate their suppliers and to evaluate their quality data for problems. One method of doing this is to record the percentage of “essential” component rejects per lot, as well as the percentage of lots rejected. If the manufacturer has the raw accept/reject data in a form that can be evaluated to determine supplier performance and is periodically doing this evaluation, this would be acceptable in lieu of recorded percentages.

Both RMA (Return Materials Authorization) and RTV (Return to Vendor) ERP software system applications can play a vital role in tracking returned or exchanged items sold to customers or bought from suppliers. Typically, the software automatically generates RMA/RTV tracking documents noting the reasons for the return and/ or exchange. The documents are linked with cross-shipments, inventory and credit control as well as invoices and credit notes, providing many investigative pathways. By defining and applying customized RMA codes, trends can be ascertained and analyzed for quality control purposes and FDA compliance. With a click, manufacturers should have the ability to see all customer purchases for any specific model by purchase date.

According to FDA’s publication 21 CFR 820.75, manufacturers must make the determination as to whether the firm’s processes are or may be contributing to defective devices. There are several ways of making this assessment, for example;

Process validation information should be reviewed to identify defect characteristics and the rate of expected defects of each characteristic for the finished product. If the rate of defects is found to be exceeded during in-process or finished device acceptance, the processes may be out-of-control or were not properly validated.

Also, the first and last product test results should be reviewed for continuous processes such as extrusion or injection molding, automated soldering, automated filling lines, automated testing, etc., which may show test failures of the last test product.

Business Analytics & Report Writer

“Business Analytics (a.k.a., Business Intelligence) software enables users to create multi-dimensional views of their financial and operational data to determine patterns and underlying trends, gauge performance and reveal new pathways.”

Business Analytics

Medical Device Manufacturers must be able to quickly and easily access the information they need to make decisions that impact quality and security. While many organizations have deployed enterprise applications to improve operational processes, these same organizations fail to provide employees with the insight needed to make quality related business decisions. However, a business can use the data from existing systems to create rich business performance information that serves as a knowledge base for decisions that impact FDA compliance. Business Analytics (a.k.a., Business Intelligence) software enables users to create multi-dimensional views of their financial and operational data to determine patterns and underlying trends, gauge performance and reveal new pathways. Business Analytics often includes a series of data mining cubes to produce dynamic, general and enterprise specific metrics, ratios and analyses. An administrator toolset will typically allow for the manipulation of the cubes to accommodate requirements, usually without any special On-line Analytical Processing (OLAP) knowledge.

Report Writer

While the FDA requires the regular submission of compliance reports, the organization can request special reports. Therefore, it is essential that manufacturers of medical devices have the ability to create these reports with minimal effort. While all ERP systems offer report generation, not all enable the easy generation of customized reports. For the ready generation of these reports, it is advisable that the ERP Report Writer module have access to all files and fields within the database, that reports are completely user-definable enabling the retrieval of desired data in a preferred format and that the reports can interface with an Office Automation module for easy email disbursement.

Electronic Signatures & FDA Requirements

“Medical Device Manufacturers choosing ERP and CRM software solutions must make sure they are totally integrated and draw from a single database that is updated in real time.”

Electronic Signatures

A fairly new requirement of FDA-regulated medical device manufacturing companies concerns Section 21 Part 11 of the Code of Federal Regulations. The code establishes the standards by which the Food and Drug Administration will accept electronic records and electronic signatures as equivalent to paper records and handwritten signatures. The rule governs electronic records throughout their life cycle from creation through modification, storage, and final transmission to the FDA.

The creation of this regulation and the FDA's encouragement of the use of electronic records and signatures have placed a significant burden on the developers and users of data collection, management, reporting, and analysis software in regulated industries.

Two important components of compliance are the positive identification of the person creating or modifying data records, and the use of audit trails for the data and system parameters affecting its collection and management.

FDA Requirements – Single Point of Contact

The FDA requires that the customers of Medical Device Manufacturers have a single point of contact for any service or product recall related questions. A knowledge base that includes technical documentation is required to be easily accessed and up to date according to standards set forth in the FDA's publication in 21 CFR 820.40. Here again, Medical Device Manufacturers choosing ERP and CRM software solutions must make sure they are totally integrated and draw from a single database that is updated in real time.

Unfortunately, most CRM products offer only batch integration in which data entered into the CRM system must be copied after-the-fact or offline into the ERP system. This is a weakness of these systems and precludes the assurance that users are always working with the most current data. For FDA compliance, a CRM system must offer real-time synchronization of its database with the customer, vendor, inventory, order entry, accounts receivable and accounts payable files of integrated ERP systems.

“Not all ERP and CRM solutions offer the functionality to offer compliance with the above requirements. But there are integrated ERP/CRM packages that do, such as SYSPRO.”

Summary - The Correct Prescription

Not all ERP and CRM solutions offer all the functionality for compliance with the above requirements. But there are integrated ERP/CRM solutions that do, such as SYSPRO. However, Medical Device Manufacturers must look beyond usual ERP/CRM fundamentals to more unique functionality, such as: FDA regulated security; shared document library with audit trail for service and quality assurance; change control with audit trail traceability; ability to view data as graphs, with drill down analysis; custom calculations to facilitate complex analysis; ability to export data to spreadsheets or text documents; e-signature capabilities through MS Office; and a Product Configuration module to ensure that all parts of a device are compatible.

Equally as important, the software should offer product tracking by both serial and lot numbers and perform service trends analysis to support regulatory compliance reporting. Moreover, the software should also maintain a knowledge base of technical and clinical support issues and manage maintenance contracts and product warranties.

Today, there are many choices in CRM technologies. Most offer strengths in traditional areas such as sales and service, while others go beyond the norm to offer a suitable prescription to remedy the noted stringent requirements placed on the medical device manufacturing industry by the FDA and other regulatory bodies. In most cases, CRM software is designed to do much more than help pass the “FDA test.” Aside from the software’s ability to reduce the painstaking process of generating complex reports, it can help improve market penetration, promote clear communication with customers and vendors, assist in maintaining quality control and, of course, help retain customers by improving service, responsiveness and company-wide knowledge and reliability. Those contemplating CRM systems would be wise to look for packages that aid in regulatory compliance and enhance all aspects of customer relations.

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“While there’s no one piece of software that monitors full FDA compliance, SYSPRO, by offering all the above mentioned functionalities, makes giant strides in this effort.”

One of the significant advances that enterprise software systems, such as SYSPRO, have brought to the Medical Equipment Manufacturing sector is the ability to keep costs down while staying FDA and ISO compliant. While there’s no one piece of software that monitors full FDA compliance, SYSPRO, by offering all the above mentioned functionalities, makes giant strides in this effort. In addition to making FDA compliance easier to achieve, SYSPRO also offers the tools that enable Medical Device Manufacturers to remain competitive.

SYSPRO consistently performs “gap analysis” to determine the software needs of various market segments, such as medical device manufacturing. Moreover, SYSPRO continually adds functionality, such as bar coding, Internet Web applications and Microsoft .NET capabilities that greatly facilitate all aspects of doing business.

For example, SYSPRO e.net solutions easily enables medical device manufacturers to develop around the core SYSPRO ERP application to meet specific business requirements without affecting the security or integrity of the core system.

SYSPRO also offers an “out-of-the-box” Web application, called “Executive Dashboard.” It gives senior managers the ability to look at the company from the “30,000-foot” level and then drill down into specific areas. It enables visibility across the entire supply chain. This is important from both the management standpoint and also from the compliance point of view.

SYSPRO software manages four key components: design, manufacturing, distribution and maintenance/service. The FDA requires medical device manufacturers to manage these components with equal acuity. Because SYSPRO facilitates this quadruple focus, it is an excellent fit for medical device manufacturers. SYSPRO provides the 360° solution that they require.

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Glossary of Terms

Advanced Planning & Scheduling

The ability to obtain a “live” picture of the shop floor in order to plan workloads against available capacity to accommodate rush shipments, broken equipment and absentee workers.

CRM

CRM (**C**ustomer **R**elationship **M**anagement) is a combination of customer-focused methodologies that coordinate and optimize Marketing, Sales and Service with the goal of compounding sales and stimulating growth through superior customer satisfaction.

DHR

Device History Record – a record that includes dates of manufacture, component specifications and software specifications for each device, batch, lot or unit, including the dates of manufacture, the quantity manufactured, the quantity released for distribution and the acceptance records which demonstrate that the device is manufactured in accordance with the DMR.

DMR

Device Master Record – a record that includes device specifications, production process specifications, quality assurance procedures, packaging and labeling specifications and installation, maintenance and servicing procedures.

ERP

ERP (**E**nterprise **R**esource **P**lanning) is a business management system that integrates all aspects of the business, including accounting, manufacturing and distribution.

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Glossary of Terms

Executive Dashboard

A means by which authorized individuals can obtain meaningful business metrics to obtain an overall “picture” of the company’s current health with the ability to “drill-down” for visibility into specific areas.

Food & Drug Administration

The Food and Drug Administration – a U.S. government regulatory body responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, the nation’s food supply, cosmetics, and products that emit radiation.

Product Configurator

Software that enables non-technical personnel to configure products based upon compatibility rules of parts and sub-systems.

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