**Drive Quality and Productivity Improvements: Selecting and Utilizing a Manufacturing Execution System**

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Though they make a variety of very different products, all medical device manufacturers share a common goal: quality. By relentlessly pursuing this goal, device manufacturers seek to satisfy existing customers and win new ones, while avoiding the costly and reputation-sullying consequences of repeated field failures and product recalls.

Many times, though, the pursuit of quality is hindered by cumbersome paper-based recordkeeping systems used to track production activity. These paper systems are plagued by human errors that can result in the production and shipment of faulty products. They also make it difficult for manufacturing personnel to trace components and extract critical data needed to improve the process, reducing the efficiency of production and hampering efforts to improve product quality. As companies grow, paper-based systems become ever more unwieldy and problematic, eventually spurring many manufacturers to look for an alternative.

Seeking improved compliance, quality, and efficiency, growing medical device manufacturers are replacing their paper records with automated systems featuring Manufacturing Execution System (MES) software. These software-based systems enforce adherence to correct manufacturing procedures and eliminate both recordkeeping errors and the time-consuming reviews meant to catch them. They also improve component traceability and allow quick and easy access to key product and process data. Other benefits include increased line yield and throughput, as well as significantly reduced cycle time and out-of-box failures.

Before realizing these benefits, a company must travel the road to successful MES operation. Key steps along this road include choosing the right MES product and implementing the system at the company. These steps will have a major impact on the gains that come from computerized recordkeeping.

**Paper-Based Problems**

During production, many medical device firms document compliance by keeping paper device history records (DHRs). Filled out by operators along the production line, DHRs are often marred by omissions, illegible entries, and errors such as values that are outside of specification limits. So firms employ a group of inspectors to check all the DHRs at the end of the process. When these inspectors find omissions or errors in the paperwork, they go back to the operators to try to get the necessary information.

Besides being inefficient, this paper-based recordkeeping system can cause manufacturers many headaches. For example, a process will continue to turn out flawed products until a DHR inspector catches a measurement value that’s “out of spec.” In addition, an omission or illegible DHR entry might require a product to be retested so that the missing value can be obtained. Then there’s always the possibility that DHR mistakes will go undetected, resulting in the shipment of faulty products.

Paper records can impact product quality in other ways as well. With vast quantities of production data stored in numerous file cabinets on the shop floor and elsewhere, it can be difficult or impossible to trace problems back to a particular component or process. And since medical device manufacturers are already struggling with recordkeeping requirements, they’re reluctant or unable to collect and analyze additional data that would help them improve quality. These problems worsen as companies grow and their paperwork systems expand to monstrous proportions.

**A Better Way**

Rather than just tinkering with a badly flawed process, medical device firms can scrap their paper-based recordkeeping systems and replace them with computerized systems run by MES. MES automatically enforces adherence to the manufacturing process, ensuring that all tasks are completed (with an electronic signature, when deemed necessary by the manufacturer), done in the proper sequence, and performed by properly trained operators. In addition, MES ensures that all process data is collected (eliminating paper-related problems such as omissions and illegible entries) and that measurements and test results meet specifications. It also detects non-conformances and makes sure that production problems trigger appropriate corrective actions.

In addition to its key role in the production process, MES replaces scattered file cabinets with a computerized database. This makes it easy for users to trace components and find important product and process information.

MES works in tandem with other software modules supplied by partners of the MES vendor. These include corrective and preventive action modules and software that handles customer complaints.

**Selling the Idea**

Like any other important change at a company, the switch to MES will have to be justified to corporate executives. In addition to a carefully prepared estimate of how much the switch will cost, a pitch to the CEO should include an explanation of how a software-based data-collection system can prevent disasters that can seriously damage the company’s reputation.

For example, MES can prevent repeated field failures by making it easy for engineers to find information that helps them solve a problem caused by a particular component. In addition, the software can help plant personnel trace production problems to a particular machine at a certain time of day. Such information might limit the scope of a recall to a handful of products rather than thousands.

Besides selling the CEO, MES advocates must get the support of the company’s IT steering committee, the group that decides which of the competing IT projects under consideration are most important and schedules them. The pitch to this group should include the benefits and costs of MES, as well as the technology and staff requirements for implementation.

**Choosing a System**

Once corporate management signs off on the switch to MES, the next step is choosing a software package. A good selection process starts with the creation of a cross-functional team tasked with developing business requirements that will be used to evaluate alternatives. These requirements will be matched up with specific features of the products under consideration. Specific requirements are more helpful in the selection process than general ones, which may be met to some degree by all the contenders, making it difficult to choose between them.

Ideally, the team tasked with developing business requirements will be able to focus exclusively on the job for a certain period of time. A team that goes offsite for a week for the sole purpose of producing a list of business requirements will probably do a much better job than a team that must develop requirements during a series of one-hour meetings held over a period of days or weeks.

Once developed, business requirements shouldn’t be carved in stone. The team should be open to adding requirements in response to information acquired during the selection process. While viewing product demonstrations, for example, the team may discover that a couple of the competing software packages meet a corporate need that no one thought could be met by the products under consideration. When the team learns that need can be met, it should be added to the business requirements used to evaluate the products.

Demos of the competing MES products should be viewed by a large group from all areas of the company. Besides providing diverse input that will improve the selection process, the members of this group will pick up information about MES that will be useful when one of the competing systems is installed. For example, personnel unfamiliar with the manufacturing routing concept known as workflow will learn what it is and actually see how workflow can be configured using MES.

When evaluating the products, the group should focus on key attributes such as “out-of-the-box functionality,” which is what the software is designed to offer without custom coding by the user. An example of out-of-the-box functionality is a data field with upper and lower limits. If a program requires users to write custom code to create such a data field, it will probably rank low in out-of-the-box functionality.

If a data field includes upper and lower limits that can be set by users without custom coding, the field is said to be “configurable.” In general, people evaluating MES software should look for a system with many configurable features rather than one that requires coding to customize it for a particular application.

Besides sizing up the different MES products, the selection process should include an assessment of the software vendors. Key questions to answer about the vendors include:

* Are they solid companies with plenty of experience in developing and supporting MES software?
* Will their people be helpful and easy to work with? You may be depending on them for the next 5-10 years.
* How much experience do they have with medical device firms? Software vendors with many medical device customers should be happy to provide that information. Those with little or no medical device experience may be evasive or refuse to answer the question.
* What help can you get from their customers? If the vendor can put you in touch with other customers, they may be able to offer helpful advice on subjects such as how to train people to use MES software, how to phase in implementation, and when and where to use electronic signatures.

Of course, it’s also a good idea to talk to users about each MES alternative and the vendors that sell the products. Feedback from other medical device manufacturers should be especially helpful.

When all the selection information is in, it’s time to make a choice. In all probability, each of the alternatives will have both strong and weak points. So it may be helpful to use a scoring system to rate the options. Scores can be based on how each option measures up to the business requirements, ranked in order of importance.

**Implementing the New System**

With the selection process concluded, the equally important process of MES implementation begins. In most cases, implementation takes place in a number of phases. Many users start by implementing features that will meet the minimum requirements for producing DHRs, and save additional data-collection features for subsequent phases.

Deciding how to phase in MES is one of tasks of the implementation team. Like the team that developed business requirements, the implementation team should be a cross-functional group that includes representatives of all key departments of the company, including IT, manufacturing, and quality. The team should also include a project manager from the software vendor.

One of the most important — and difficult — tasks for the implementation team is educating people about MES. The workings and capabilities of manufacturing software can be hard to grasp for people used to conventional recordkeeping tools. But learning will eventually lead to “buy-in” as people begin to understand what MES can do for them.

The implementation team can also boost buy-in by getting input from people on how the software should be configured. For example, the team can ask operators to test a user interface and suggest ways to improve it. Or the team can ask engineers to critique an MES report format. By soliciting this type of feedback and acting on it, the team gives company personnel an ownership stake in the MES project. Buy-in aside, this feedback is valuable because it will help the team make the system easier to use.

Among companies switching to computerized data-collection systems, a common concern is what happens when the system goes down. Many companies can’t afford manufacturing downtime caused by an MES malfunction. Understandably, however, these companies don’t want to back up their electronic recordkeeping system with an extensive paper-based system like the one they’re replacing.

So the implementation process should include the installation of two electronic systems that will collect and store all of the company’s product and process data. Thus, if one system fails, there can be a seamless switchover to the other without any production downtime.

MES implementation should also include the installation of a plant-wide barcoding system. Barcoding boosts the speed and accuracy of data entry by reducing the amount of production data entered by hand. Ideally, all product components would be barcoded. At a minimum, though, suppliers or plant personnel should barcode expensive components and those that can cause product failure. Barcoding ensures that the serial numbers of these key components will be correctly entered into the system, so they’ll be easy to trace if necessary.

**Impressive Results**

When MES is up and running, medical device manufacturers will notice many welcome changes on the plant floor and beyond. Of course, one of these changes is a dramatic reduction in shop-floor paperwork and file cabinets. Another is the reduction of labor-intensive DHR reviews. With all DHR data entered correctly the first time, some companies have completely done away with end-of-process DHR reviews and inspectors.

One of the most important features of MES is its ability to detect and react to production problems early in the process. If a product or process value is outside of specification limits, for example, MES detects it and automatically takes one or more prescribed actions. These actions could include directing the product to a rework station, sending a message to engineering, and generating a non-conformance report that describes the problem and the specific steps taken to correct it.

MES also provides quick and easy access to product and process data. The system centralizes all data in a searchable form, including both shop-floor data and product performance information from customers and service centers. Thus, MES can provide users with a complete history of a product.

People tapping into the MES database can retrieve valuable process data not normally or easily extracted from paper-based systems. For example, MES can help plant personnel uncover rework loops that reduce manufacturing efficiency and increase the risk of product failure. People tracking rework in paper-based systems must look through paper DHRs to piece together what happened. Some paper recordkeeping systems don’t even require operators to report that rework was done on a product, only that the product was good when it left their station.

The hunt for rework is easier with MES, which can be set up to require the recording of all rework done by an operator. This will help manufacturers zero in on the processes that require the most rework and therefore need improvement.

MES also makes it easy to trace components and assess their condition and performance. This is difficult when data collection is done using a paper-based system. A manufacturer seeking information about a component in a particular type of device would have to retrieve the paper DHRs, as well as any repair data on file at service centers that might be scattered across the country or around the world.

By contrast, a manufacturer can quickly retrieve all the DHR and repair data for a device simply by querying an MES-based data-collection system. This data can be used to quickly trace failures back to components made by particular vendors. For example, a query to the system might show that nine of the last 10 valves that failed in the field were made by Vendor A. This would tell the manufacturer to focus on Vendor A rather than taking the matter up with all its valve suppliers.

The query might also retrieve additional information, such as what went wrong with the valves and whether they were all from the same lot. This information can be supplied to Vendor A to help the supplier solve its quality problem.

With this type of component data, manufacturers can create “scorecards” that help them monitor and compare the performance of different suppliers. These scorecards can provide useful information such as the mean time to failure (MTTF) for each supplier’s products, whether and how much each product’s MTTF is increasing over time, and which supplier’s products have improved the most in a certain time period.

As a key component of the manufacturing process, MES yields many other benefits, including:

* *Less WIP inventory.* Every lot, batch, or unit is tracked through every operation. Improved visibility of work-in-process helps plant personnel identify and eliminate production bottlenecks.
* *Increased line yield.* Early detection of problems, easier access to data leading to their cause, and resulting process and training improvements can increase yield slightly in high-volume processes and boost it more than 10 percent in low-volume operations.
* *Increased throughput and reduced cycle time.* Minimizing wasteful activities such as paperwork, rework, and redundant checks can boost throughput by almost 40 percent and slash cycle time by nearly 25 percent.
* *Fewer non-conformances.* Process improvements made possible by easier and greater access to product and process data can cut non-conformances nearly in half.
* *Fewer out-of-box failures.* MES-related process improvements can also slash field failures by almost 70 percent.

**Conclusion**

Medical device manufacturers can reap many benefits and prevent many headaches by switching from paper recordkeeping systems to automated data-collection systems based on MES software. For those interested in making the switch, the process begins by cataloging the downsides of cumbersome paper-based systems and the potential upsides of a software-based alternative. This information can be used to justify the new system to corporate decision makers.

Once management is sold on the switch, the best course of action is to develop and follow a detailed plan for choosing an MES product and then implementing the chosen system in a way that meets the needs of the company and its personnel. With MES on the job, medical device manufacturers will find that they can effectively manage rapid growth while improving both their production processes and the quality of their products.