

Moving from Paper-Based Systems to Electronic Batch Records

Technology is constantly evolving around us, and yet many manufacturers continue using paper-based systems to manage and record their activities while manufacturing. In recent times, many of these manufacturers, especially in pharmaceuticals and biotech, are making the move to a Manufacturing Execution System (MES).

Limitations and Costs of Paper-Based Systems

Adhering to regulation and high quality standards can be difficult and costly due to documentation errors. These errors can result in delays and compliance issues, and they are resource intensive because operators and quality managers must spend a lot of time manually recording information and verifying that it was done in accordance to Good Manufacturing Practices (GMPs). Potential problems are not picked up right away since there is a time lag when production is not monitored in real-time. These issues can lead to higher rejection rates for batches and an increased amount of time investigating deviations.

Paper-based systems also present issues with information visibility and cross-communication between departments. Since information has to be entered manually, there is a delay for the data to be analyzed. It can be much harder for operators to plan production, thus decreasing output volume and elongating the production process. Recording data onto paper-based systems can be disruptive for operators during production itself as they must frequently stop. For example, operators can be left waiting when quality managers are not available to make their approvals.

Furthermore, since inventory is not up to date, material usage is delayed and can lead to complications. Since receipts are reported late in the inventory management system, it can lead to irregular counts and other issues that take a lot of time to resolve.

Contrasting Paper-Based Systems with MES

Since MES is a digital solution, it captures data electronically and in real-time. All of the manufacturing data is available for everyone to see at all time; this eliminates the visibility issue. While many companies invest heavily into implementing an automated Enterprise Resource Planning (ERP) system, these systems often lack a sophisticated manufacturing module. Some companies with ERP systems, still record data on spreadsheets and in Word documents. An MES system focuses on the manufacturing operations side of production and promotes the smoother flow of information throughout, creating quality products and ensuring “right the first time” batch production.

Making the Move

Some of the most intimidating aspects of moving to Electronic Batch Records has to do with the perception that it is daunting and time consuming. Often times, manufacturers do not see gaps in their process that can be eliminated via an MES system. It can also be incredibly difficult to justify the cost and having to adopt a new system. Understanding the issues can be the first step in overcoming the intimidation and resistance to change.

It is possible to breakdown the trepidations of the move to MES into four categories:

- Process Disruption

Aside from the drawbacks and limitations of paper-based systems, a number of steps must be taken to trigger the move to Electronic Batch Records and MES systems. In a nutshell, the digital solution affects more than just manufacturing itself. Companies must take a step back and look at the entire production process in terms of planning, execution, control, monitoring, and documentation. Companies might need to reevaluate organizational roles, staffing, and training procedures.

To overcome this, there must be a champion to drive the move. Business cases need to be examined and companies must determine what their overarching goal should be. For example, a company might wish to make the jump to MES in order to improve their compliance documentation and to reduce operational costs, or maybe they want real-time visibility to track production, or even to more quickly resolve non-compliance issues.

MES has many benefits, but one of the most common is that it provides clear instructions to operators to improve compliance and track the manufacturing process on a step-by-step basis.

Like anything, return on investment (ROI) is key. Through eliminating errors and simplifying the production process, companies that use an MES system might see an increase in productivity of about 25%. Since most MES systems are cloud-based and operate on a per user licensing structure, costs can be scaled up or down to meet the needs of companies at a lower price. Using an MES system generates ROI within 12 to 18 months due to the low cost of implementation.

- Internal Organizational Issues

After making the move to an MES system, companies must plan how they will execute the implementation. It is integral to the shifting process for companies to evaluate what is necessary and do their homework. Companies need to identify the Key Performance Indicator (KPI) ahead of time. This can be something as simple as increasing “right the first time” production from 75% to 85%.

Companies must also establish accountability and clear goals need to be put in place in order to find their specific ROI. The company should make an effective plan for uniting the whole organization under a unified goal and following through. One mantra that a company might follow is the Concept of Operations (COO) method. It outlines how operations will be affected and can help further identify benefits that are expected to be gained from deploying an MES system.

The key aspect of COO is to clearly define roles within each department and align them with business policies that must be followed. This can mean working through each [aspect of production](#) (staff scheduling, inventory management, material consumption, tracking, quality approval, and release). Using COO requires all stakeholders and departments to come together in the planning stage with emphasis on management, production managers, quality managers, and even IT.

For example, quality managers must adapt their typical process to accommodate real-time deviations and streamline testing or release. They might plan to shift from trouble-shooting to focusing on “right the first time” compliance enforcement. Again, each department must look within itself and decide how it can adapt to the new process.

- Cost

It is also important to consider how making the shift from paper-based systems to Electronic Batch Records and MES might require a change in IT strategy. Are the current technologies being used able to

integrate with a new system? Does IT need to set up additional architecture or set workers up with tablets or other devices? If the company grows, can their infrastructure sustain itself? Are they able to support increased resource consumption?

Companies may see that they may have to upgrade current devices or add additional ones, or deploy additional resources to cope with consumption. Perhaps a company wishes to move away from regular signatures and starts using barcoded badges. A company may even seek to streamline its inventory system with barcoded labels. These are things that need require planning ahead.

There is also the cost of migrating paper-based records to their digital counterparts. A company must look at its process from a holistic perspective, and understand how different aspects of production interact with each other (how is purchasing handled, how are materials added to inventory, etc...). The advantage with Electronic Batch Records is the amount of reusability. While companies must enter in their data initially, thereafter it becomes automated.

Once the new production system goes live, it's normal to see decreased production output while manufacturing works through issues from the changeover.

- Quality System Change

Once a company moves from its planning stage, it moves to the configuration process. Companies will find themselves needing to thorough vet their software through their own standards and then validating it when implemented. The software is qualified with established standards, including the [Good Automated Manufacturing Practice \(GAMP-5\)](#) validation model. This requires acceptance testing, installation qualification, and site acceptance testing.

Quality may find itself needing to update its [Standard Operating Procedures \(SOPS\)](#) to reflect a new process and that the old process is no longer valid. They also might find that they need more SOPs in the event of reevaluating what is needed for batch records or SOPs for training staff on the process.

Conclusion and Summary

Following a new system implementation, a company will need to monitor its performance against its KPIs and determined ROI. A plan should be made for the criteria and process for changing them, as well. Companies might see immediate results, but should have their longer term goals and expectations laid out. Most importantly, companies should plan to continue streamlining their own processes in order to put themselves into better positions for the future. Their needs will likely change, and so they must pay attention to which features and modules they get the most benefit with.

To summarize, technology has brought about many great new things. In manufacturing, companies can now utilize Electronic Batch Records and Manufacturing Execution Systems (MES) in order to address their production pains. It's hard for the sellers of these systems to explain its benefits, because those are specific to each company. Companies may not readily see how their process can be streamlined or that there are gaps in production or quality. The onus is for companies to set up individual goals and use KPIs

to determine their ROI. However, companies can expect a 25% increase in production output and improved compliance.

Moving to an MES system from a paper-based system is intimidating and does require a company to do its homework, plan ahead, and unify all departments around business goals. Aside from that, there are concerns about production disruption, organizational problems, costs, and changes in quality. For the project to be successful, a company must take a holistic approach. It is hard to identify all potential issues, so companies must be ready to make additional changes.

In the current market landscape, manufacturers are under increased scrutiny to produce “right the first time” products in order to inspire consumer trust and comply with various regulations. Paper-based systems make this difficult and can slow things down. Utilizing an MES system, on the other hand, intrinsically promotes “right the first time” while following GMPs. Additionally, with an MES system, companies can see their process, usage, and inventory in real-time, cutting down on cross-departmental miscommunications and decreasing lulls in production since the production process is now streamlined.

Confucius says it best, *“A green reed which bends in the wind is stronger than the mighty oak which breaks in a storm.”*

Companies that are open to embracing new technologies and constantly improving themselves are the ones that see longevity. Electronic Batch Record Software from InstantGMPTM is one way a company can make the transition from paper-based systems and achieve its goal.

How Can InstantGMPTM Benefit My Company?

[InstantGMPTM PRO](#) provides transition tools for pharmaceutical and biotechnology companies looking to move from paper-based systems. There are no additional IT requirements other than having access to an internet connection and a computer.

Transitioning to Electronic Batch Records and a Manufacturing Execution System can be done in stages and phases if that is what the company wishes. This can help mitigate the learning curve of adopting a new system and initial decrease of output.

As previously mentioned, goals must be outlined by a company and must use KPIs to determine where the benefits are and how the system will produce an ROI. There are specific data points that have been collected as part of market research efforts to illustrate how using InstantGMPTM can help a company reach its goals by satisfying requirements across departments and management:

- **Organization** – Manufacturing information is organized into a cloud-based, centralized database designed for companies that want an entire view of their production process. The information is logically segmented into various modules that capture information from inputting qualified vendors, materials, Master Production Records, and more. The system works in real-time, and is ideal for [inventory management](#) during batch production.
- **Quality and Compliance** – The software is fully validated to FDA standards for software validation and meets the requirements for GAMP-5, as well as [21 CFR Part 11](#) for electronic documentation. Quality signatures are needed at several steps of the production process before a batch can leave the facility (Examples include establishing Specifications or receiving materials

into inventory. Signatures can be expedited by utilizing [barcoded personnel badges](#) that are unique to each user.

- **Traceability** – System generated numbers track the life of a [material](#), [purchased materials](#), [specifications](#), [master production records](#), and [batch production records](#). Vendor lot numbers are recorded upon receiving materials into inventory, and each batch is assigned its own batch production number. [System reports](#) are available to identify specific dates, in what environment, materials, equipment, what personnel and approvers a batch was created with.
- **Automation** – Once the information is inputted, fulfilling the requirements of batch documentation becomes significantly more efficient. Master Records are generated by selecting information from a [planning tool](#) and the rest of the data populates. After initially creating a Master Record, they can be [scaled up or down](#); copied; or versioned up with a couple mouse clicks. Likewise, for batches, at the end of production, the finished product can be added to inventory with only a few additional steps.
- **Security** - InstantGMP™ is 128bit encrypted and two-step authentication is necessary to access the database by an administrator. Personnel badges that are generated by the system can only be used by the person logged in and in the appropriate places. Depending on the role of the person using the system, certain information may be available or hidden to ensure that personnel can only access the information required and further protects sensitive production data. The [audit trail](#) records each and every interaction with the software.
- **Customization and Integration** - [InstantGMP™ PRO](#) can be customized to fit the needs of individual companies and can be integrated with most other systems. It can work alongside ERPs or work as a hybrid system for those not yet ready to make the complete move from a paper-based system. Be sure to watch the [online demo](#) and register for a personalized demonstration. There, we can show how InstantGMP™ PRO can benefit your organization and how it can transform your manufacturing process.