Drive operational certainty in the life sciences industry

Syncade Manufacturing Execution System

Digitize your plant floor operations to make every operator your best operator.

EMERSON

Execute Manufacturing Effectively to Meet Production Goals

The pressure to meet production goals while ensuring product quality can put stress on your operations. Lack of visibility to these goals can lead to asset inefficiencies, increased costs, and potential delays in delivering your product to market. To remain competitive and responsive to market requirements, don't compromise your goals; plan to meet them reliably by digitizing your operations to ensure effective use of resources and time.

To meet production goals, you need to ensure that products are delivered to specification and that all documentation and compliance requirements are met. Reducing excessive work in process inventory, eliminating the inefficient use of resources, and better management of your operations will lead to increased profitability for your organization. Emerson's Syncade manufacturing execution system (MES) will help you gain visibility and improve your manufacturing processes to meet your production goals.

The Syncade MES increases visibility of your operations to accelerate batch release times while ensuring reliable and repeatable production processes in a highly regulated environment. Using innovative technologies, the Syncade MES combines document, equipment, and materials management with electronic workflow to deliver a manufacturing system optimized for operational certainty.

As manufacturers look to emerging market trends such as the Industrial Internet of Things (IIoT) and Pharma 4.0 to create smarter operations, technology that enables digitization becomes even more critical to success. Smarter system integration facilitates the connectivity of data across the enterprise to improve and streamline communication and collaboration. The automation of manual processes and digitization of data delivers real-time production information, while helping to ensure quality and compliance. The Syncade MES helps you build a solid foundation for executing your manufacturing processes – with innovative technology to ensure you are prepared for the future.

Total cost of compliance for a pharmaceutical manufacturing facility can be as high as 25% of the total site operating budget.

–Dean & Bruttin. Pharma Sector Study and Report

Integrate plant-floor data with procedures to make every operator your best operator.

Accelerate time to market

Get product to market faster with integrated workflows and better exception management. Alert the right people at the right time to streamline product approval and release – eliminating inventory on hold while still ensuring product quality.

Improve data integrity through paperless production

Eliminate the effort associated with managing paper records by digitalizing your operations. Shift your focus to managing production goals by streamlining your processes and improving data integrity with electronic records.

Establish repeatable and reliable operations

Manual activities can create inconsistencies in your process, resulting in variability that may lead to rework. Reduce variability by defining your processes electronically to ensure work is done consistently and accurately. Provide operators with a step-by-step workflow, providing the information needed to do the job quickly and efficiently.

Build agility in recipe design and production execution

Build agility into your production processes with an MES that provides the flexibility to respond to varying batch requirements. Use dynamic workflows to drive consistency while maintaining a repeatable approach to recipes. Gain valuable time and improve product quality by ensuring agility is managed in a controlled and documented environment.

Reduce complexity through system integration

Eliminate the need for customized integration between your DCS and MES. Custom integration of systems is difficult to implement and maintain. Managing change in this environment requires systems to be modified and re-validated, creating challenges with data integrity and system performance. With systems that are integrated by design, configuration and implementation are easier, delivering a faster return on investment and confidence in system performance.

Move product to market faster through better exception management.

Accelerate time to market

Production costs rise and inventory sits in storage when an organization uses manual processes to ensure quality and compliance. Working against short product cycles, life sciences organizations must avoid errors in manufacturing and documentation to avoid increases in unreleased inventory and delayed profits.

Today's life sciences organizations continue to look for ways to reduce inventory and accelerate time to market. Emerson's Syncade MES helps create an environment for control, including better management of procedures, equipment, materials, and quality.

Resources managed using integrated workflows improve production visibility and drive toward an overall reduction in exceptions. With an effective MES solution, organizations can improve batch execution times, getting product to market faster while continuing to support quality.

On average, pharmaceutical manufacturers hold 180 days worth of finished goods inventory. Reducing inventories to 80-100 days could free $25 billion of capital.

–McKinsey & Company, Outpacing Change in Pharma Operations.

Standardized batch records. An electronic batch record solution helps keep product moving to market by reducing errors, tracking actions, and addressing deviations simultaneously with batch execution. Standardizing steps in the production process helps drive consistency in your manufacturing operations. To further reduce time to compliance, automatically generated records help to address regulatory requirements.

Efficient exception management. Reduce the time required to identify, review, and resolve process exceptions by investigating exceptions as the batch continues to execute, rather than weeks after completion. Intuitive dashboards summarize exception information without interrupting the production process. Once all exceptions are closed, the associated orders can be auto-released, allowing inventory to be removed from hold.

Improved process consistency. Using step-by-step guidance through electronic workflows, recipes can execute with fewer errors. With an integrated DCS and MES, operators have access to all the process information they need to make timely decisions.

Facility-wide equipment management. With the Syncade MES, operators can manage equipment sets more efficiently. With full visibility to equipment states across the facility, operators know which equipment is available for production and which equipment needs additional attention.

Improve data integrity through paperless production

Many facilities still rely on paper records to document production steps, exceptions, as-executed process data, and batch-release approval signatures. This traditional method, however, often leads to inefficiencies and errors. Time is lost when manually searching through binders or files for compliance information, and errors such as incorrectly transcribed batch data are common.

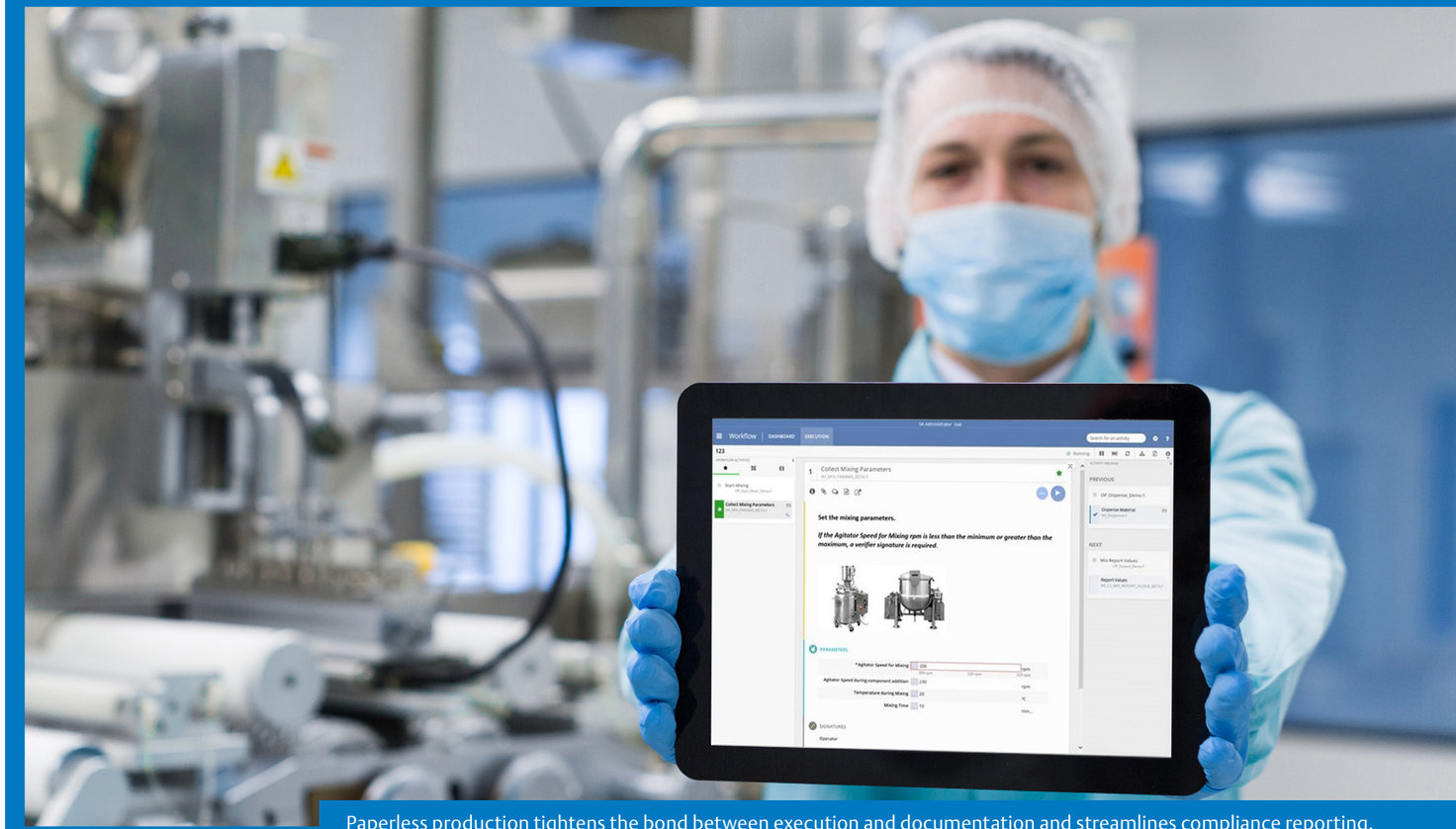
When this information resides in electronic format, a facility can easily track the data and build a robust data integrity strategy. Paperless production tightens the bond between production execution and documentation and streamlines compliance reporting.

By moving from paper to electronic production records, manufacturers can focus on production effectiveness and achieving business goals. Implementing electronic batch records automates documentation to ensure data integrity, helping manufacturers ensure the safety, efficacy, and quality of their products.

Data integrity is achieved when data in all forms is Attributable, Legible, Contemporaneously recorded, an Original or true copy, and Accurate (ALCOA). With paperless manufacturing driven by the Syncade MES, your documentation will support the ALCOA elements for quality and data integrity.

An average of 4 weeks is lost each year waiting on misfiled, mislabeled, untracked, or lost documents.

–Gartner Inc.



Paperless production tightens the bond between execution and documentation and streamlines compliance reporting.

Attributable actions in Legible form. When data is created automatically at the time of execution and stored electronically, the audit trail and batch records provide reliable records of events, which can be attributed to the personnel involved. Easily search for the information you need – recorded by activity, time, and date.

Contemporaneously recorded data. Document events automatically as they occur to ensure the accuracy of the account. Then easily access your data to streamline approvals or support, while reducing your paper footprint. Required approvals and change requests can be electronically directed to the right people, while referencing the original data stored in its original format.

Original or true copies of well-managed data. The thousands of pages of paper documentation required to track original copies of data requires coordination by teams of people. But with effective online data management and the implementation of an electronic batch record, you can eliminate manual record-keeping and easily access the data required to prove compliance and ensure product safety.

Accurate batch records. Improve batch record accuracy and reduce rework by moving to electronic batch records. Combining manual and electronic data from multiple systems spanning the entire facility, batch records include data associated with operators, the manufacturing process, equipment, materials, and supplies. It can also include data from LIMS, ERP, PCS, and more. A paperless process leads to improved resource management, improved inventory management, and reduced material losses.

For improved product release and regulatory review, automate manual activities and strengthen repeatability with workflows.

Establish repeatable and reliable operations

Standard operating procedures support repeatable and reliable operations, but unless you can ensure that personnel are following them, you risk errors that may lead to rework or waste. Without a way to automate manual activities or provide step-by-step guidance and verification, personnel can provide varied inputs to your process.

The Syncade MES helps engineers design recipes that can be executed consistently across the facility. Improved efficiency comes in two ways: from common elements, or building blocks, that can include default values and be reused in other recipes; and from workflows that ensure consistency in execution.

Strengthening your ability to deliver repeatable manufacturing, the Syncade MES brings flexibility to the process and helps manufacturers employ Quality by Design considerations to realize robust, yet flexible, manufacturing.

“The big advantage of Syncade is standardization. SOP and batch records are now created and signed electronically. Data and record alignment have reduced manual errors.”

–Ey Seo, Manufacturing Planning Team Leader, Handok Inc.

Consistent recipe design. Variability occurs for many reasons, such as a lack of standardized recipes, multiple methodologies for recipe creation, and use of workarounds to address a lack of flexibility. The Syncade MES provides recipe standardization where designers can create generic work instructions with common core attributes. Use of these standard objects allows designers to reduce time spent creating recipes and improve consistency in recipe execution.

Clear, enforceable SOPs. To improve consistency between shifts, master recipes include electronic workflows to enforce and document procedures. Workflow instructions and embedded links to SOPs clearly define steps for operators to perform and drive consistency across shifts. In addition, visibility to operator actions enables managers to identify areas where personnel would benefit from training.

Accurate, repeatable material dispensing. Guiding dispensing operators through repeatable workflows, the Syncade MES reduces variability and eliminates errors while driving higher quality through automatic calculation of material potencies. For improved product release and regulatory review, Syncade maintains a complete record of operations, including point-of-use verification of material information such as quality status and expiration dates.

Build agility in recipe design and production execution

Safe, high-quality, and innovative products are hallmarks of the life sciences industry. Delivering to these hallmarks requires complex recipes or varying batch requirements, making flexibility important in production recipes. Without flexibility, manufacturers waste valuable time reconfiguring master recipes to meet their needs.

Master recipes — core to manufacturing operations — ideally contain critical production-relevant data such as bill of material, sampling plans, and critical quality attributes (CQAs). Therefore, manufacturers need a way to easily modify the master recipe without disrupting operations or compromising recipe quality.

The Syncade MES strikes the delicate balance between delivering flexibility and consistency by giving manufacturers the tools to modify master recipes in a consistent way to ensure quality.

Drive manufacturing agility by modifying master recipes while still delivering repeatability.

Choices in execution. During batch execution, operators must make decisions based on current processing conditions. Creating recipes that allow flexibility in execution can be difficult. With the Syncade MES, engineers can author recipes that enable forced sequencing, mandatory field completion, and electronic signatures, while providing the required deviation/exception handling and reporting.

Flexible recipe design. The Syncade MES guides operators through the process step by step using dynamic workflows. When decisions must be made, operators are provided with alternative options to address common manufacturing situations, ensuring the continued quality of the batch.

Master recipe modification. Manual activities and diverse operations can lead to inconsistent work processes that introduce variability, deviations, and rework. A library of common actions allows recipes to be designed with consistent processes, crafting repeatability from the start. Using common building blocks in the Syncade MES, the master recipe can be quickly modified to address unique recipe needs to maintain consistency in the way you operate.

Enable more efficient operations, flexible recipe design, and smoother regulatory compliance.

Reduce complexity through system integration

Although manufacturing operations management (Level 3 of the ISA95 model) is often the level most dependent on manual activities, it must work in tandem with highly automated distributed control systems (Level 2). With a comprehensive integration strategy, both systems can be optimized to reduce the need to wait for manual intervention in the process.

Designed to work together, the DeltaV™ DCS and the Syncade MES provide native integration to eliminate the need for the customized interfaces that may be required by other systems. As software updates occur, the lifecycle of both systems remains linked, giving you confidence that new functionality will not affect your integration.

Together, the systems enable more efficient operations, flexible recipe design, and smoother regulatory compliance. The native integration of the systems also supports data integrity initiatives. Designed for integration, the Emerson systems reduce the complexity of integration and provide confidence in system performance.

Easier roll out and smoother day-to-day operation. Instead of spending time customizing a solution to integrate your MES and DCS, the DeltaV DCS and Syncade MES have been designed to work together. Expedite your system roll out and operate with the confidence that upgrades to the system have been tested by the manufacturer to ensure little to no impact on production.

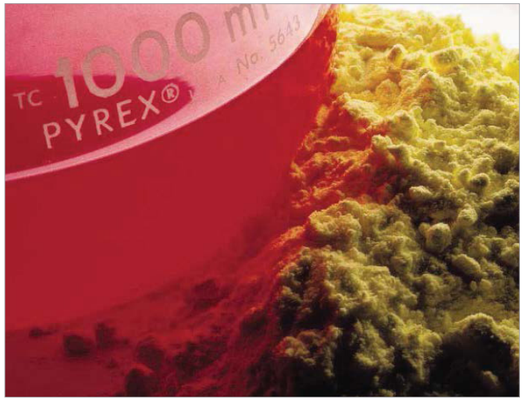
Smooth recipe management. Execution transfers seamlessly between the DeltaV and Syncade systems to reduce complexity of recipe management. When batch execution requires operator intervention, the MES guides the operator step by step, verifies the steps are accomplished correctly, documents the actions, and passes control back to the DCS.

Effective collaboration. Because the DeltaV and Syncade systems can be tightly integrated, team members with proper permissions can view and use information no matter which system they are using. Together they can build better solutions and have the knowledge to make more-informed decisions.

Streamlined document management. When standard operating procedures (SOPs) are printed or stored in separate systems, errors occur and productivity may be lost. Integrating systems or storing the SOPs natively in Syncade allows them to be easily maintained in a single system and accessible to personnel across the enterprise.

MES In Action

Life Sciences companies around the world have found that the Syncade MES supports the design of repeatable and reliable operations that improve data integrity and accelerate time to market while reducing complexity and improving operational agility.



Repligen Automates Document Management and Improves Compliance

Repligen's manufacturing operation includes a three-stage batch process to make proteins. Production requires a very complex manual process and product quality is critical. With a batch processing time of two weeks, reducing process errors is essential.

Using the Syncade MES for document management, Repligen was able to automate their documentation and reduce weekly production issuance time by 63%. Their annual internal review process of controlled documents was also automated, ensuring on-schedule review by all stakeholders. Repligen found that their procedures compliance increased because of better visibility to procedures and improved documentation.

Handok Reduces Paper by 90% while Ensuring Compliance

Handok Inc, a pharmaceutical innovator, was expanding into the global market and needed to ensure it was meeting an increasing number of compliance requirements – especially for global trials run by their multinational partners.

Using the Syncade MES for documentation and weigh and dispense management, Handok was able to convert most of its manual records to electronic, achieving 90% paperless operation company-wide. They also saw a 50% increase in dispensary efficiency and a 46% reduction in batch release time. With less time spent on manual tasks, Handok can now spend more time focusing on innovation.

UCB Uses Integrated MES-DCS Solution to Solve Production Challenges

When designing and building a new biotech facility, one of UCB's main challenges was to implement a seamlessly integrated solution to control their highly complex process. They specified that an integrated MES and DCS require minimum development effort while being flexible enough to allow changes and improvement to recipes.

UCB implemented the DeltaV DCS and Syncade MES to facilitate operational activities and information flow from the plant floor to the ERP system. The integrated solution sped up the design and implementation phases, delivering lifecycle benefits in terms of system maintenance, and enabling tighter process control for increased productivity.

Life science manufacturers strive to create innovative products that help people lead healthier lives. Emerson has the automation expertise, industry experience and technology to solve your greatest cGMP manufacturing challenges and create effective solutions for improving data management, real-time product quality, reliability, and operating costs. From design to implementation and startup to ongoing Operational Certainty, rely on Emerson to stay competitive in a global economy.

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