Ensure Productivity, Compliance, and Quality with Emerson’s Syncade MES
Biotech Firm Automates Manual Document Management Tasks, Saving Time and Money While Improving Compliance

APPLICATION
The manufacturing operation includes a three-stage batch process of fermentation, extraction, and purification to make a family of proteins. The proteins are sold to pharmaceutical manufacturers for use in the production of various drug compounds.

CUSTOMER
Repligen operates the production facility in Waltham, Massachusetts. The facility is staffed by about 80 employees, 30 of whom work in bioprocessing manufacturing.

THE CHALLENGE
Production of Repligen’s products requires very complex manual processes. The finished products are extremely high in value, so close control over the manufacturing processes is critical to ensure that quality product is produced. Total batch processing time is about two weeks, so it’s critical that each manufacturing process not be interrupted due to errors, especially near the end of a batch.

As with many high-value products, annual production quantities are relatively low. Because volumes are low, the most cost-effective production method utilizes manual rather than automated procedures. When executed correctly, manual production is a highly efficient and very precise method for producing low quantities of products that have complex processing requirements.

When a product is produced, manually controlled documents such as Standard Operating Procedures (SOPs) and Work Instructions are critical. These documents must be clear, concise, and complete—and they must be continually updated to reflect changes and improvements to the manufacturing process. Batch records are generated and issued to production in order for the operators to document each step of the process during manufacture of a batch of material.

Numerous procedural and process documents are required with highly detailed information. For example, the facility has about 200 documents, with 15 related to the pure water systems alone. Company quality procedures require review of each controlled document annually.

The manufacturing documents combine the work instructions and the documentation of each step into one production record document referred to as a batch record. Plant personnel execute the work instructions and write the results directly into the production record. Each production record document is 100-200 pages in length. This level of detail is required to ensure consistent completion of validated processes in order to produce quality product. Documentation of each manual step provides a record of all variables that could impact the final product, such as raw materials and solutions that were used during the process.

The protein manufacturing facility was manually issuing and maintaining the controlled documents using a combination of Microsoft Word, Microsoft Excel, and FileMaker Pro. Manual document management was time consuming and expensive—making compliance with internal procedures very difficult.

The facility needed a document management system that would allow the staff to automate manual issuance and maintenance of all documents. The desire was to implement an electronic document management system incrementally to optimize expenditures, reduce technical complexity, and allow for a high degree of in-house project execution.
By using Syncade Suite, Repligen has improved productivity and helped ensure compliance to quality procedures.

— Dan Witt, VP of Operations, Repligen
Improve manufacturing execution to drive your production goals with Emerson’s Syncade manufacturing execution system.

Smart Data. Smart Decisions. Emerson’s Syncade MES allows you to easily manage an integrated electronic solution for all your manual process activities.

Document Management
Organize and manage your electronic documents
• Streamline review and approval
• Manage complete document lifecycle
• Reduce your paper footprint

Electronic Batch Records Management
Drive right first time production with paperless manufacturing
• Deliver right first time
• Review by exception
• Reduce cycle times

Electronic Logbooks
Eliminate the need for paper logbooks
• Minimize shift handover risk
• Improve task management and event visibility
• Resolve issues quickly with electronic knowledge base

Equipment Management
Track and manage equipment
• Optimize equipment usage
• Replace paper equipment logs
• Reduce errors with electronic procedures

Materials Management
Reduce variability and deliver full materials traceability
• Eliminate paper
• Reduce errors
• Verification and reconciliation in real-time

Information Integration
Access the information needed to make decisions
• Integrate real-time plant floor data with business systems
• Coordinate critical functions