Biotech Firm Automates Manual Document Management Tasks, Saving Time and Money While Improving Compliance

RESULTS

- Issuance time per Batch Record reduced from 4 to 2 hours; One week's Production Records issuance time reduced from 16 to 6 hours.
- Automated annual internal review process for controlled documents ensures on-schedule review by all relevant personnel.
- Internal procedures compliance increased by enhanced document update capability.
- System can be maintained by limited in-house staff.

"By using Syncade suite, Repligen has improved productivity and helped ensure compliance to quality procedures."

Dan Witt
VP of Operations

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.

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.

SYNCADE® Smart Operations Management Suite

For more information:
www.EmersonProcess.com/Syncade

EMERSON™ Process Management

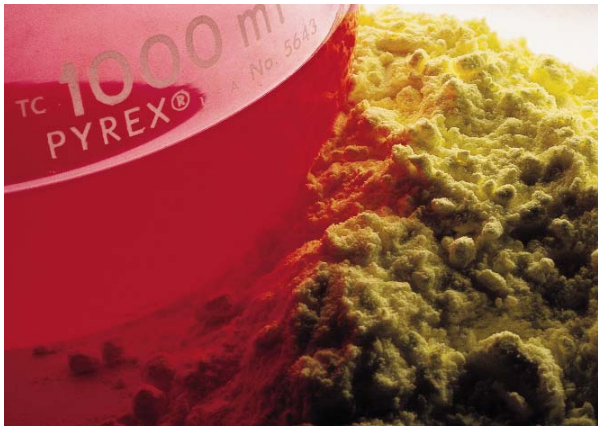
When a product is produced, manually controlled documents such as Standard Operating Procedures (SOPs) and Work Instructions are critical. These documents must be clear, concise and complete—and they must be continually updated to reflect changes and improvements to the manufacturing process. Batch Records 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.



SOLUTION

The facility evaluated five different electronic document management solutions, and decided to purchase Emerson Process Management's Syncade™ Smart Operation Management Suite. Syncade suite is a group of software modules that provide flexible and integrated solutions for the management of integrated manufacturing systems. Each software element is modular and scalable, thus enabling the user to address a specific function and then add capability as needed in the future.

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Key factors in the selection of Syncade suite were that it is built from the ground up for batch, available in modules, and designed for compliance in the life sciences industry. Existing customer references were favorable and spanned the range from industry giants to smaller specialty manufacturers similar to Repligen.

Repligen staff implemented Syncade suite internally with the assistance of Emerson Process Management, to gain in-house expertise for ongoing operation and enhancement of the solution. With only a small staff of production and IT personnel, in-house implementation was done using a first-in-kind approach and rolled out in a step-by-step fashion. Because Syncade suite is modular, the plant could purchase and implement each required module at its own pace, spreading out capital expenditures, saving money on purchase cost and greatly simplifying implementation.

The installed system has provided a number of benefits. With the old manual document management system, it took about 4 hours to issue a Production Record due to time intensive manual procedures, including rubber stamping batch ID numbers. With Syncade suite, a production record can be issued in one to two hours. On average, the issuance of all production documentation using the electronic system has reduced Quality Assurance time from approximately 16 hours to 4-6 hours per week.

Syncade suite also gives Repligen much better control of documents and revisions. Industry practice requires biannual review of controlled documents. The old system did not enforce this practice because the entire remind-and-review process was manual. Syncade suite automatically sends out timely email reminders for review of each document, and it also allows for electronic routing of documents for review and approval. Email reminders become more frequent as a review due date is approached, assuring adherence to the review and approval schedule.

Repligen's customers include FDA-regulated companies, and as such they are responsible for the quality of all of the raw materials that go into their products. These customers perform frequent audits of their raw material suppliers, and they are very pleased with Repligen's implementation of Syncade suite and consequent improved internal compliance.

SYNCADE® Smart Operations Management Suite

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