

Driving innovation in bioprocessing

Introduction

When Thermo Fisher Scientific's Bioprocessing Collaboration Center (BCC) underwent their \$50 million expansion, they realized the need for a Laboratory Information Management System (LIMS) to support the team's digitalization efforts to manage and organize data and workflows for their process development activities. The BCC management team investigated laboratory software options on the market and ultimately decided on Thermo Scientific[™] SampleManager[™] Software.

After installing SampleManager software, the BCC and the Thermo Fisher Digital Science Solutions team collaborated to create an end-to-end solution to support bioprocess manufacturing workflows for monoclonal antibodies (mAbs). This Process Management solution addresses the challenges faced by labs who manage their data manually and lack a centralized system to ensure consistency and traceability. Based on the ISA88 batch control standard, the solution enables the management of bioprocessing development activities from creation of master and control recipes to batch execution.

Bioprocessing Collaboration Center

Thermo Fisher's BCC in St. Louis, Missouri, is strategically positioned to leverage the company's expertise in singleuse technologies and biologics product development and manufacturing. By combining the knowledge and resources of Thermo Fisher's bioproduction and pharma services businesses, the BCC will drive innovation and enhance productivity for biopharma customers. The BCC focuses on developing innovative bioprocessing technologies, products, and services to streamline workflows and enable faster and more efficient product launches. This will be achieved by using Thermo Fisher's expertise in GMP biologics manufacturing and bioprocessing technologies such as bioreactors, cell culture media, chromatography, and analytical tools. The BCC will deliver new single-use bioprocessing technologies and drive crucial process improvements, data management, and quality enhancements for biopharma customers. The center aims to provide true value to customers in the biopharma industry.



thermo scientific

Data integrity and repeatability challenges

Prior to implementing SampleManager software, the team faced several challenges. They relied on handwritten records, manual data entry, and USB portable storage to move and share data. This led to inefficiencies and potential errors in managing and organizing their data, which were a significant risk to data integrity. Each team member operated based on their own understanding of standard operating procedures rather than completing work in a standardized, repeatable format, creating uncertainties in bioprocessing workflows; lack of alignment and consistency hindered the overall workflow and data management process.

Moreover, the team encountered issues such as loss of paper records, inconsistent adherence to written procedures, incomplete data, difficulties attributing analysts to specific tasks, and data being trapped on paper and thus inaccessible to learn from or collaborate on. These challenges further complicated data retrieval, analysis, and storage of previous work, impeding the progress of their research and development activities.

Choosing SampleManager software & collaborating

Following a thorough evaluation of various LIMS offerings, the laboratory ultimately selected SampleManager software as their preferred solution, surpassing competing products. The decision was primarily influenced by SampleManager software's reputation as a market leader within the industry, coupled with its association to Thermo Fisher. In addition, the advantage of consolidating all scientific requirements under a single provider greatly streamlined the service and support procedures across the laboratory. The BCC sought a software provider capable of collaborating to develop a solution aligned with their specific requirements including the ISA88 batch control standard. The Digital Science Solutions team successfully facilitated this collaboration, resulting in the creation of the Process Management Solution for SampleManager software. This solution embodies exemplary practices from the industry, incorporating master recipes that have been written, tested, and used by BCC's engineers and scientists every day.

A solution for mAb production

The Process Management Solution for SampleManager software enables customers to manage bioprocessing development activities from creation of master and control recipes to batch execution. Master recipes are defined in the system as ordered collections of Laboratory Execution System (LES) lab methods along with predefined recipe parameters. Master recipes are copied as templates to control recipes where recipe parameters can be updated to reflect the nuances of the product being produced. Control recipes are then used in batch execution where all process data and meta data from the batch are automatically stored and collected in the SampleManager software database. This makes the data easily accessible in a reportable format without omissions, leading to fewer manual errors. Additionally, the unique electronic batch record is easily accessed for real-time decision making, resulting in a higher number of successful batches.



Implementation approach

The implementation process of the software involved comprehensive training for the team. The Digital Science Solutions team worked with the core team to create a training program that would get the lab up and running as quickly as possible while still ensuring everyone was confident with the software. The BCC lab team attended four SampleManager software courses, followed by site leaders providing additional training based on materials generated to support the installation.

"The support received during sales, implementation, and post-implementation from the SampleManager software team was exceptional, leveraging their deep understanding of the software." - Josh Speer, Digitalization Technologist, Bioprocessing Collaboration Center

The value

The lab realized the benefits provided from the Process Management Solution from day one. Notable value documented by the lab included the following:

- Data traceability: SampleManager software ensures data traceability by recording instrument solution serial numbers, tracking maintenance and calibration, scanning/attaching contractor work records, and utilizing personnel ID access restrictions.
- **Time savings:** The introduction of SampleManager software requires the operations team to document their workflows, replacing "subject expertise" with standardized processes, saving time and reducing errors.
- Improved scientific rigor: The SampleManager Process Management Batch process facilitates the creation of a rich data set for routine actions and supported Design of Experiment/Quality by Design approaches. The use of electronic lab notebooks (ELN) centralized secure storage for experimental observations and analysis.
- Enhanced workflow efficiency: Standardized processes and a centralized system eliminates differing understandings among participants, reducing bioprocessing uncertainty and improving overall efficiency.
- Sustainability impact: The transition to SampleManager software resulted in reduced paper usage and potentially fewer experiments abandoned due to process instability, making the BCC a more efficient and sought-after partner.





Implementing SampleManager software as an end-to-end process management solution addressed the challenges faced by the lab, resulting in improved data traceability, time savings, enhanced scientific rigor, increased workflow efficiency, and positive sustainability impacts. By leveraging the expertise and support of Thermo Fisher as a single provider for scientific needs, the lab achieved seamless implementation and ongoing success in their bioprocess manufacturing workflows.

Partnering with Thermo Fisher Scientific

Thermo Fisher offers a comprehensive range of services to help you develop your biologics from the initial research phase to commercialization. Our proven systems and highly experienced technical support are available to assist you at every step of the process. With the help of our dedicated team and extensive **resources**, you can discover flexible approaches that will advance your programs towards IND (investigational new drug) or CTA (clinical trial application).

Ready to discuss digitizing your biologics, large molecule or cell therapy development? **Contact us** to begin the discussions now.

Learn more at thermofisher.com/processmanagementsolution

Not for use in diagnostic procedures. © 2024 Thermo Fisher Scientific Inc. All rights reserved. All trademarks are the property of Thermo Fisher Scientific and its subsidiaries unless otherwise specified.

