

Process Management Solution

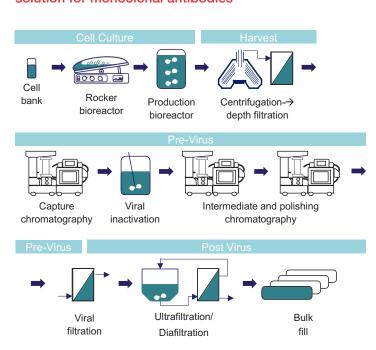
Monoclonal antibody production

Bioprocessing labs and manufacturing researchers in the production of monoclonal antibody substances play a critical role in ensuring the safety, efficiency, and quality of therapeutic products.

The Process Management Solution for Thermo Scientific™ SampleManager™ software is designed to support bioprocessing manufacturing workflows for monoclonal antibodies. The solution manages recipes and guides analysts through the manufacturing process of monoclonal antibodies to increase productivity while meeting the required quality, performance and meta data parameters. In addition, recipes are directly linked to a sample result management system to easily store test records and instantly review the results enhancing the analysts experience.

The Process Management Solution communicates with the labs existing equipment enabling bidirectional instrument communication. This allows analysts to transfer sample identification and sequence data instantly while receiving the results in return. Labs producing a product by a batch process can insert their master recipes, unit operations, procedures and phases into the system and receive the electronic batch record or accumulate the final report data with ease.

End-to-end bioprocessing manufacturing workflow solution for monoclonal antibodies





Productivity

- Increased production run a higher quantity of successful batches in a reduced time with visibility into results
- Centralized data repository centralize all the data generated throughout the production process in a secure and easily accessible platform

Cost efficiency

- Reduction in batch/manual errors reduces batch and manual errors enabling labs to save costs associated with expensive rework and waste
- Optimized resource utilization helps to optimize allocation of resources, thereby reducing processing time and operational costs

Quality control

- Quality assurance ensures consistent quality by automatically validating data entries that are within ranges and without omissions
- Batch management track different production batches effectively, ensuring consistency and quality in production

Adherence and reporting

- Adherence to industry standards supports adherence to industry standards and guidelines such as ISA-88, ensuring processes are aligning with best practices
- Custom reports generate custom reports for internal reviews and regulatory agency reviews

Workflow optimization

- Process standardization standardized work instructions enforce consistency and structure in executing batches
- Sample management streamlines and enhances sample management including labeling, tracking, and inventory management

Integration

- Integration with ERP and MES integrate with Enterprise Resource Planning (ERP) and Manufacturing Execution System (MES) for simplified operations and data flow
- Interoperability communicate with other software systems easily, ensuring seamless data exchange and workflow integration

Solution capabilities

End-to-end process management

Includes:

- Laboratory execution overview
- Electronic batch records
- Recipe management
- Inventory management
- Equipment management
- Instrument integration
- Laboratory process navigation integration

Monoclonal antibody master recipes and unit procedures Includes:

- Bioprocessing SOPs
- Monoclonal antibody bioprocessing master recipes
- Unit procedure flow diagrams
- Unit procedure LES methods
- A full suite of unit operations

Partner with Thermo Fisher Scientific for your process management workflows to increase efficiency, compliance, and quality control, leading to enhanced productivity and product quality.

Ready for a demo of the solution? Scan the QR code





Learn more at thermofisher.com/processmanagementsoftware