

Case Profile

Company Type

Large Biopharma, Mid-size Biopharma, Large CDMO | CMO, Medium CDMO | CMO

Related Molecules

Proteins: mAbs, Biosimilars; Vaccines; Cell & Gene Therapy; Viral Vectors for Gene Therapy

Process Steps

From Vial Thaw to Bulk Drug Substance (BDS) Fill

Success Story

How DISCOVER® Surveys Optimize End-to-End Processes to Reduce Costs and Improve Yields

The biopharmaceutical industry faces the challenge of efficiently producing an ever-increasing number of products in existing facilities. Legacy processes present opportunities to save costs and improve throughput through optimized unit operations.

Through the DISCOVER® survey program, Process Experts from Sartorius Value Chain Services conduct an end-to-end process review by carrying out a process walk-through. Our experts then provide non-binding recommendations to reduce processing time and costs, improve step yields, and increase facility throughput.

Due to a close partnership with a large CDMO, we were entrusted to conduct such a process walk-through for a clinical manufacturing facility.

Customer Challenges

- Long dissolution time for media – some components are difficult to dissolve, and the incumbent single-use mixers had RPM limitations
- High cost of protein capture in clinical manufacturing
- Long TFF processing times due to the need for membrane pre-flushing

Provided Solutions

- Evaluation of the Flexsafe® Pro Mixer, which has high RPM mixing capabilities to address long media dissolution timelines
- Testing of Sartobind® Rapid A, with the entire membrane lifetime used in a single batch
- Pre-flushed, gamma irradiated Hydrosart® Cassette loop assembly

Process Step	Before	After
Media Preparation	Several hours to completely dissolve media	Dissolution time reduced by 50% or more
Chromatography	Pre-packed columns used for 1 batch with few cycles	Sartobind® Rapid A cycled 100x or more in 1 batch utilizing its lifetime
Tangential Flow Filtration (TFF)	Up to one shift for TFF process step	Processing time reduced by 40-50% with pre-flushed membranes

Case Description

- Value Chain Services (VCS) helps optimize customer processes and facilities through DISCOVER® Surveys
- Reduce total cost of ownership (TCO) and improve process yields
- Provide innovative solutions to address challenges observed during end-to-end Gemba Walk

Result | Conclusion

- Media preparation time was reduced by 50%, removing process bottleneck for higher run rates in the future
- Up to 10 × time savings and 3 × cost savings with one-batch, one-membrane approach for chromatography capture
- Up to 50%-time savings for TFF, removing a major downstream process limitation

Keywords

End-to-end processing of mAb's, Viral Vectors, Vaccines; Process Optimization, Cost Savings, Yield improvement, Increase Facility throughput