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

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