SARTORIUS

Customer Case Study

Driving Cost-Efficient mAb Manufacturing Through Scalable, Connected Membrane Chromatography

Customer profile

Company name:
Enzene Biosciences

Company location:
Pune, India

Company type:
CDMO

Industry:
Biologics and biosimilars

Speciality:
Continuous manufacturing

Company profile:
www.enzene.com

Customer Challenge

With global demand for therapeutic monoclonal antibodies (mAbs) continuing to rise, manufacturers are under increasing pressure to reduce cost of goods (COGs), accelerate production timelines, and maintain flexibility across manufacturing scales. However, traditional resin-based downstream processes are often constrained by long cycle times, high buffer consumption, and large, infrastructure-intensive equipment.

Enzene Biosciences, a leading contract development and manufacturing organization (CDMO) in India, partnered with Sartorius to evaluate membrane chromatography as an alternative to resin-based processes. This approach also offered a compelling opportunity for process intensification by reducing equipment footprint, minimizing fixed costs, and improving operational efficiency.

ENZENE

Background Information

Membrane chromatography offers a modern alternative to resin-based purification by relying on convective rather than diffusive mass transfer. This enables higher flow rates, shorter residence times, and reduced process durations, while supporting linear scalability from process development to manufacturing.

Chromatography membranes also provide clear operational advantages. Column handling activities are eliminated, freeing up valuable resources and reducing facility downtime. These technologies also require lower upfront investment with a smaller equipment footprint compared to resins, minimizing facility space requirements.

Together, these process and operational efficiency gains enable flexible manufacturing in multi-product facilities and support process intensification initiatives.

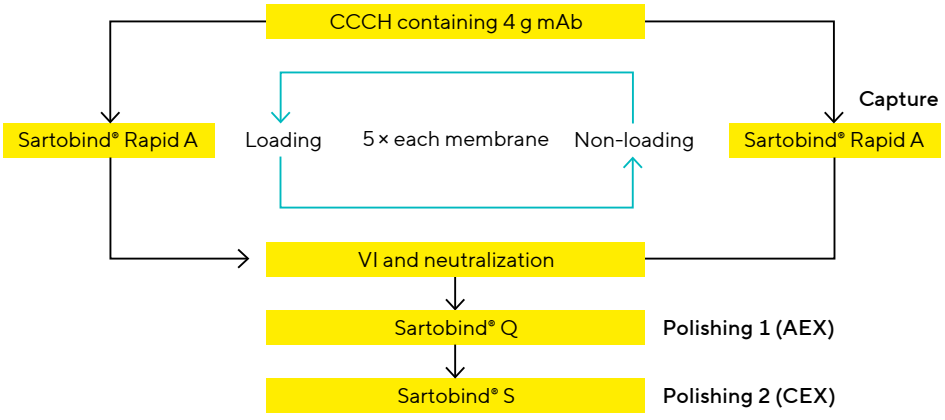
Provided Solution

To design an intensified mAb purification process, we evaluated the performance of a fully connected purification workflow using Sartobind® membranes (Figure 1). The process includes:

- Sartobind® Rapid A for affinity capture
- Sartobind® Q for anion-exchange (AEX) in flow-through mode to remove DNA and host cell protein (HCP)
- Sartobind® S for cation-exchange (CEX) in overload bind-elute mode to remove aggregates

The work was carried out at small scale, serving as a proof of concept. Despite the reduced scale, the findings are transferable to production scale, as membrane chromatography exhibits linear scalability and consistent performance across different device sizes. This ensures that the observed process efficiencies, impurity clearance performance, and cycle time reductions can be reliably implemented in commercial manufacturing environments.

Figure 1: Overview of the small-scale, membrane-based mAb purification process, showing the sequential use of Sartobind® chromatography devices for capture and polishing, with all process steps directly connected in-line.



Note. A total of 4 g mAb were purified from a clarified cell culture harvest (CCCH), with two Sartobind® Rapid A devices operated in batch multi-column chromatography (B-MCC) mode followed by polishing with Sartobind® Q and Sartobind® S. VI = virus inactivation.

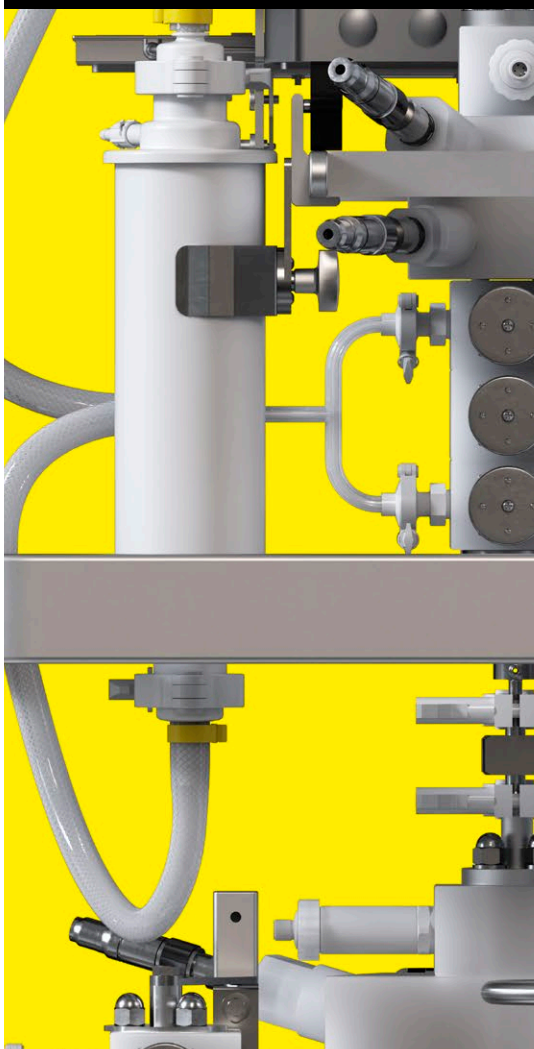
Project key indicators

Keywords:
Process intensification, connected processing, membrane chromatography, Sartobind® Rapid A, Sartobind® Q, Sartobind® S, bind-elute, flow-through, overload bind-elute, monoclonal antibody, downstream processing

Process steps:
Capture, polishing

Provided solutions:
A fully connected membrane chromatography process using:

- Sartobind® Rapid A
- Sartobind® Q
- Sartobind® S



Results

The integrated workflow demonstrated strong and consistent performance across development studies (Table 1):

- High product recovery rates under optimized conditions
- Significant HCP and DNA reduction with Sartobind® Q
- Effective aggregate removal with Sartobind® S
- Reduced equipment footprint and process complexity

Table 1: Summary of analytical results for the fully membrane-based purification process using only Sartobind® chromatography devices.

Analytical results	Sartobind® Rapid A		Sartobind® Q (AEX)		Sartobind® S (CEX)	
	Load	Output	Load	Output	Load	Output
mAb [g]	4.22	4.82	4.32	3.92	3.8	3.9
mAb [mg/mL]	1.9	7.8	5.0	4.2	3.9	3.5
mAb step recovery [%]	114.4		90.8		101.6	
mAb total process recovery [%]			91.4			
HCP LRV	2.60		1.66		N/A	
hcDNA LRV	3.0		1.6		N/A	
Monomer peak [%]	N/A	97.6	97.9	97.8	98.0	97.9
HMWS [%]	N/A	0.9	0.9	0.9	0.7	0.7
LMWS [%]	N/A	1.5	1.2	1.3	1.3	1.4

Note. HCP and hcDNA levels after Sartobind® S were both below the detection limit. LRV = log reduction value

Collectively, these results support meaningful COGs reductions driven by shorter processing times, minimized facility dependency, and simplified workflows.

Conclusion

By working collaboratively, Enzene and Sartorius demonstrated that membrane-based purification can serve as a powerful and flexible alternative to traditional resin workflows. Through the implementation of Sartobind® Rapid A, Q, and S membranes into a connected process, a streamlined purification strategy was developed, reducing operational complexity, facility footprint, and overall process time — ultimately lowering COGs. This partnership illustrates how combining complementary expertise can accelerate innovation and expand market reach, thereby improving patient access to high-quality antibody therapeutics.

At a Glance

Fully membrane-based purification platform

> 90% overall **mAb recovery**

Reduced process time and **minimized buffer consumption**

Up to **3x faster** **capture than traditional** resin processes

> 4 log **HCP reduction,** hcDNA below detection limit

Cost-effective mAb **production**

Before

- Traditional resin-based downstream processes with long cycle times and high buffer consumption
- Large equipment footprint and infrastructure-intensive workflows
- Higher fixed and variable manufacturing costs due to hold tanks and intermediate storage steps

After

- Connected membrane process with reduced or eliminated hold tanks, smaller facility footprint, and lower fixed costs
- Faster, more efficient purification with reduced operational complexity and improved cost-effectiveness

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