

Using Process Modeling to Quantify the Benefits of an Integrated mAb Flow-Through Polishing Solution

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Introduction

The bioprocessing industry currently addresses a dual demand: processes that reduce cost of goods (CoG) while maintaining product quality and integrating existing manufacturing facilities. One potential opportunity for significant process improvement while driving down process expenses is in the final polishing step, which typically consists of a series of downstream unit operations and flow through chromatography operations. A fully connected flow-through polishing process can offer significant advantages over a traditional polishing template.

Before the buffer process modeling tool, a new template was created that incorporated an all-flow-through polishing train. Leveraging experimental data to populate the template models, results comparing the new flow-through polishing process to a traditional process template highlight significant benefits with the integrated flow-through solution - 40% cost of goods reduction, 80% reduction in buffer volume usage, 75% reduction in polishing process time, and a reduction in footprint. A sensitivity analysis highlights that these benefits are essentially independent of process scale, and are achieved as footprint size increases.

Methods

Flow-Through Polishing

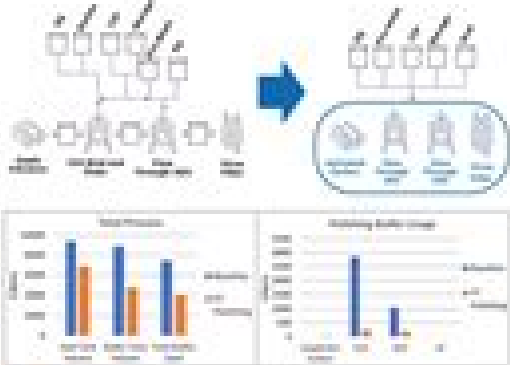
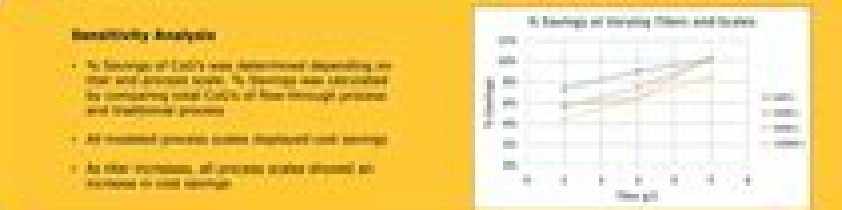
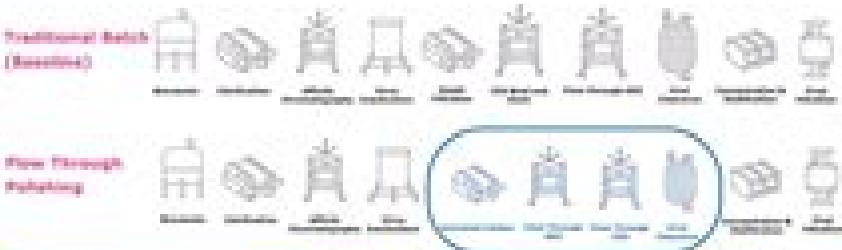
- Polish stream is substituted with activated carbon
- Ion-exchange chromatography (IEX) and cation exchange chromatography (CEX) are modified
- Experimental data suggests 40% capacity can be increased following activated carbon
- CEX is run in a flow-through mode, instead of fixed & elute
- Ion-exchange follows flow-through CEX
- All feed and streams are connected without feed steps

Modeling Assumptions

- All modeling was performed using Bufferline-Process software

Parameter	Traditional Process	CEX 40%	CEX 75%	Model Assumptions
Technology	Activated Carbon Filter	Activated Carbon	Activated Carbon	Activated Carbon
Flow	100%	100%	100%	100%
Capacity	100% (100 gal)	100% (100 gal)	100% (100 gal)	100% (100 gal)
4 to 100	100 gal	100	100	100 gal
4 to 100	100	100	100	100

- Flow through polishing yields matched to baseline process
- Baseline process assumptions per 10000 units & assumptions
- Flow through polishing utilizes one dual as opposed to four for traditional polishing
- 4 connections per facility, 2000+ full batch producing 1 gal units, 143 facilities per year



Buffer Usage

- Less buffer and buffer volume is necessary due to connecting to flow-through CEX as opposed to fixed-mode CEX. Also, less buffer is required for IEX due to less required flow
- Intermediate feed steps are removed for flow-through polishing, as well as one buffer tank, leading to a decrease in footprint
- 40% less buffer for the full process, 80% less buffer for polishing alone

Summary

Process modeling shows that a flow-through polishing process offers many advantages over a traditional process

- Reduction of cost of goods by 40% mainly due to a decrease in required intermediate and end feeding, only one dual as opposed to several
- Process time for polishing can be decreased by 75%, lowering labor requirements and possibly increasing productivity
- Cost of goods savings found at all scales, and increases with higher production rates
- Significantly less buffer required for polishing (80% less), which means material costs but also translates to footprint reduction

Mab Through Time Pamphlet

Madeleine Callaghan



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