

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

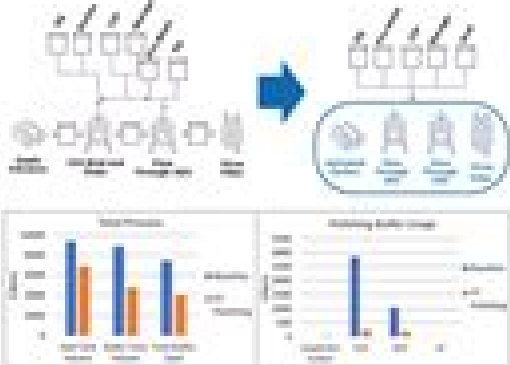
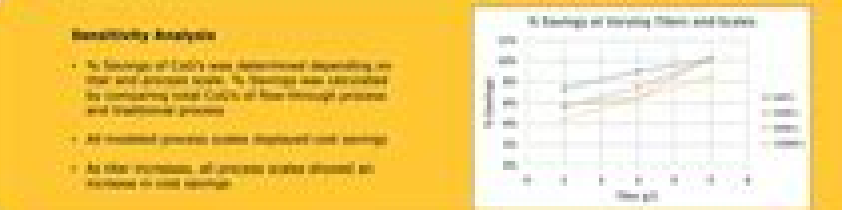
- Polish stream is substituted with activated carbon
- Ion-exchange chromatography (IEX) and cation exchange chromatography (CEX) are modified
- Experimental data suggests 400 capacity can be increased following activated carbon
- CEX is run in a flow-through mode, instead of fixed & elute
- Ion-exchange 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 100	CEX 150	CEX 200
Footprint	1000 sq ft	1000 sq ft	1000 sq ft	1000 sq ft
Time	1000 min	1000 min	1000 min	1000 min
Capacity	1000 gal	1000 gal	1000 gal	1000 gal
4 to 100	1000 gal	1000 gal	1000 gal	1000 gal
1000	1000 gal	1000 gal	1000 gal	1000 gal

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



Buffer Usage

- Less buffer and buffer volume is necessary due to connecting to flow-through CEX as opposed to fixed/variable CEX. Also, less buffer is required for IEX due to less required time
- Intermediate feed tanks 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 one 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 times
- Significantly less buffer required for polishing (80% less), which means material costs but also translates to footprint reduction

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Table of Contents Mab Through Time Pamphlet

1. Understanding the eBook Mab Through Time Pamphlet
 - The Rise of Digital Reading Mab Through Time Pamphlet
 - Advantages of eBooks Over Traditional Books
2. Identifying Mab Through Time Pamphlet
 - Exploring Different Genres
 - Considering Fiction vs. Non-Fiction
 - Determining Your Reading Goals
3. Choosing the Right eBook Platform
 - Popular eBook Platforms
 - Features to Look for in an Mab Through Time Pamphlet
 - User-Friendly Interface
4. Exploring eBook Recommendations from Mab Through Time Pamphlet
 - Personalized Recommendations
 - Mab Through Time Pamphlet User Reviews and Ratings
 - Mab Through Time Pamphlet and Bestseller Lists
5. Accessing Mab Through Time Pamphlet Free and Paid eBooks
 - Mab Through Time Pamphlet Public Domain eBooks
 - Mab Through Time Pamphlet eBook Subscription Services
 - Mab Through Time Pamphlet Budget-Friendly Options

6. Navigating Mab Through Time Pamphlet eBook Formats
 - ePub, PDF, MOBI, and More
 - Mab Through Time Pamphlet Compatibility with Devices
 - Mab Through Time Pamphlet Enhanced eBook Features
7. Enhancing Your Reading Experience
 - Adjustable Fonts and Text Sizes of Mab Through Time Pamphlet
 - Highlighting and Note-Taking Mab Through Time Pamphlet
 - Interactive Elements Mab Through Time Pamphlet
8. Staying Engaged with Mab Through Time Pamphlet
 - Joining Online Reading Communities
 - Participating in Virtual Book Clubs
 - Following Authors and Publishers Mab Through Time Pamphlet
9. Balancing eBooks and Physical Books Mab Through Time Pamphlet
 - Benefits of a Digital Library
 - Creating a Diverse Reading Collection Mab Through Time Pamphlet
10. Overcoming Reading Challenges
 - Dealing with Digital Eye Strain
 - Minimizing Distractions
 - Managing Screen Time
11. Cultivating a Reading Routine Mab Through Time Pamphlet
 - Setting Reading Goals Mab Through Time Pamphlet
 - Carving Out Dedicated Reading Time
12. Sourcing Reliable Information of Mab Through Time Pamphlet
 - Fact-Checking eBook Content of Mab Through Time Pamphlet
 - Distinguishing Credible Sources
13. Promoting Lifelong Learning
 - Utilizing eBooks for Skill Development
 - Exploring Educational eBooks
14. Embracing eBook Trends
 - Integration of Multimedia Elements

- Interactive and Gamified eBooks

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