

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 bed mode
- Ion-exchange follows flow-through CEX
- All unit and operations are connected without hold 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 Filter	Activated Carbon Filter	Activated Carbon Filter
Flow	100 L/min	100 L/min	100 L/min	100 L/min
Capacity	1000 g/L	1000 g/L	1000 g/L	1000 g/L
4 to 6 min	1000 g/L	1000 g/L	1000 g/L	1000 g/L
4 to 6 min	1000 g/L	1000 g/L	1000 g/L	1000 g/L

- Flow through polishing yields matched to baseline process
- Baseline process assumptions per 1000 L/min & assumptions
- Flow through polishing utilizes one dual as opposed to four for traditional polishing
- 4 operations per facility, 2000 L/min batch producing 1 g/L cells, 143 facilities per year

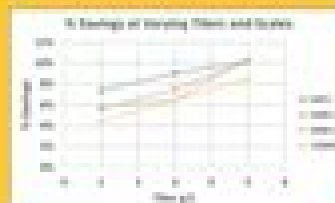


Process Time

- Implementing flow-through polishing can reduce polishing process time by 75%
- Total process time can be reduced by 14%
- Reduced process time can lead to higher productivity for existing manufacturing facilities

Sensitivity Analysis

- % Savings of CoG's was determined depending on dual and process scale. % Savings was calculated by comparing total CoG's of flow-through process and traditional process
- All modeled process scales displayed cost savings
- As dual increases, all process scales showed an increase in cost savings



Buffer Usage

- Less buffer and buffer volume is necessary due to converting to flow-through CEX as opposed to fixed-bed CEX. Also, less buffer is required for IEX due to less required flow
- Intermediate hold 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 consumables and also resulting 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

D Keegan



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U.S. MAB Bulletin, 1996 *A Supervisor's Guide to the Commissioned Personnel System* 1999 Department of Health & Human Services Program Support Center (U.S.). Division of Commissioned Personnel, 1999 **The Routledge History of Literature in English** Ronald Carter, John McRae, 2001 This is a guide to the main developments in the history of British and Irish literature charting some of the main features of literary language development and highlighting key language topics

Early Shelley Pamphlets Percy Vaughan, 1905 Language and literature (general) pamphlets, 1879 **Handbook of the Philosophy of Medicine** Thomas Schramme, Mary Jean Walker, 2025-09-30 This is the second edition of Springer's first wide ranging multi authored handbook on philosophy of medicine It covers the underlying conceptual issues of many important social political and ethical issues in health care and as such provides a single source of information for this far ranging and still developing field This new edition of this authoritative handbook includes topics that have gained momentum in the last couple of years This second edition introduces and develops nearly one hundred topics concepts and issues in the field It is written by distinguished specialists from multiple disciplines including philosophy health sciences nursing sociology political theory and medicine Many complicated social and ethical issues in health care are based on conceptual problems most prominently on the definitions of health and disease or on epistemological issues regarding causality or diagnosis Philosophy is the discipline that deals with such conceptual metaphysical epistemological methodological and axiological matters This handbook covers all the central concepts in medicine such as ageing death disease mental disorder and well being It is an invaluable resource for health care specialists who want to be informed and stay up to date with the relevant discussions as well as philosophers and ethicists with an interest in medicine and members of the general public with an interest in health care and related issues The text also advances these debates and sets the agenda for years to come

British Reform Writers, 1789-1832 Gary Kelly, Edd Applegate, 1996 Essays on literary figures during the period of intense political debates following the outbreak of the French Revolution to the passing of the Great Reform Bill of 1832 Provides information on reform writers that were important or unusual remarkable or representative in some way as a writer during this period **The Oxford Handbook of Percy Bysshe Shelley** Madeleine Callaghan, 2012-12-27 The Oxford Handbook of Percy Bysshe Shelley takes stock of current developments in the study of a major Romantic poet and prose writer and seeks to advance Shelley studies in new directions It consists of forty two chapters written by an international cast of established and emerging scholar critics This Handbook is divided into five thematic sections Biography and Relationships Prose Poetry Cultures Traditions Influences and Afterlives The first section reappraises Shelley's life and relationships including those with his publishers through whom he sought to reach an audience for the Ashes and sparks of his thought and with women creative collaborators as well as muse figures The second section gives his under investigated prose works detailed attention bringing multiple perspectives to bear on his conceptual positions and demonstrating the range of his

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- Chapter 5: Conclusion

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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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