

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

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**MERCK**

## 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

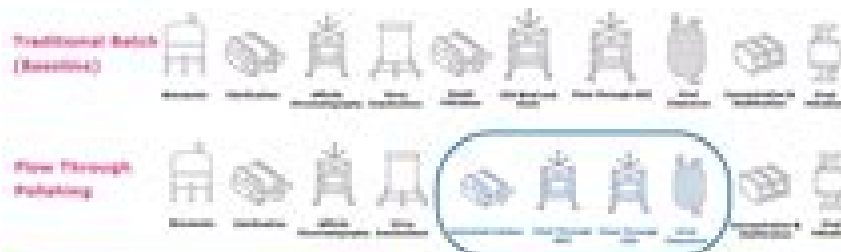
- Polish stream is substituted with activated carbon
- Ion-exchange chromatography (IEX) and cation exchange chromatography (CEX) are modified
- Experimental data suggests 40% capacity can be increased following activated carbon
- CEX is run in a flow-through mode, instead of fixed & elute
- Ion-exchange follows flow-through CEX
- All feed and product streams 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 Filter	Activated Carbon Filter	Activated Carbon Filter
Flow	100	100	100	100
Capacity	1000 gal	1000 gal	1000 gal	1000 gal
4 to run	1000 gal	1000 gal	1000 gal	1000 gal
4 to run	1000 gal	1000 gal	1000 gal	1000 gal

- Flow through polishing yields matched to baseline process
- Baseline process assumptions per 1000 units & assumptions
- Flow through polishing utilizes one dual as opposed to four for traditional polishing
- 4 operations per facility, 2000 x full batch producing 1 gal units, 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 were 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 size 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/flow CEX. Also, less buffer is required for IEX due to less required flow
- 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 rates
- Significantly less buffer required for polishing (80% less), which means material costs but also translates to footprint reduction

# Mab Through Time Pamphlet

**Rod Preece**



## **Mab Through Time Pamphlet:**

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**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 achievement in prose works from novels to political and poetic treatises The third section explores Shelley s creativity and gift as a poet emphasizing his capacity to excel in many different poetic genres The fourth section looks at Shelley s response to past and present literary cultures both English and international and at his immersion in science music theatre the visual arts and travel The fifth section concludes the volume by analysing Shelley s literary and cultural afterlife from his influence on Victorians and Moderns to his status as the exemplary poet for Deconstruction Packed with stimulating insights and readings The Oxford Handbook of Percy Bysshe Shelley brings out the relevance to Shelley s own work of his dictum that All high poetry is infinite      *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      **Pamphlets** ,1759      **Pamphlets in Philology and the Humanities** ,1912      *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      [Info MAB](#) ,1986      **The Complete Works of Percy Bysshe Shelley: Prose [ed. by Roger Ingpen** Percy Bysshe Shelley,1928 *Catalog of Copyright Entries. Part 1. [B] Group 2. Pamphlets, Etc. New Series* Library of Congress. Copyright Office,1937 **Fortitudine** ,1986      **Commissioned Corps Bulletin** United States. Public Health Service. Commissioned Corps,1997 [Early Shelley Pamphlets](#) Percy Vaughan,      *British Bee Journal, and Bee Keeper's Adviser* ,1894      **The Athenaeum** ,1894      **Sins of the Flesh** Rod Preece,2009-07-01 Unlike previous books on the history of vegetarianism *Sins of the Flesh* examines the history of vegetarianism in its ethical dimensions from the origins of humanity through to the present Full ethical consideration for animals resulting in the eschewing of flesh arose after the Aristotelian period in Greece and recurred in Ancient Rome but then mostly disappeared for centuries It was not until the turn of the nineteenth century that vegetarian thought was revived and enjoyed some success it subsequently went into another period of decline that lasted through much of the twentieth century The authority questioning cultural revolution of the 1960s brought a fresh resurgence of vegetarian ethics that continues to the present day      [The Connoisseur](#) ,1908

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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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