

3rd International Conference on Accelerating Biopharmaceutical Development 2013

Coronado Island, California, USA
24-27 February 2013

ISBN: 978-1-5108-1598-8

Printed from e-media with permission by:

Curran Associates, Inc.
57 Morehouse Lane
Red Hook, NY 12571



Some format issues inherent in the e-media version may also appear in this print version.

Copyright© (2013) by AIChE
All rights reserved.

Printed by Curran Associates, Inc. (2015)

For permission requests, please contact AIChE
at the address below.

AIChE
120 Wall Street, FL 23
New York, NY 10005-4020

Phone: (800) 242-4363
Fax: (203) 775-5177

www.aiche.org

Additional copies of this publication are available from:

Curran Associates, Inc.
57 Morehouse Lane
Red Hook, NY 12571 USA
Phone: 845-758-0400
Fax: 845-758-2634
Email: curran@proceedings.com
Web: www.proceedings.com

TABLE OF CONTENTS

KEYNOTE

Optimizing the Speed and Throughput of Therapeutic Antibody Development.....	1
<i>Kevin Bailey</i>	

ACCELERATING BIOPHARMACEUTICAL DEVELOPMENT

Biotechnology for the Next Decade: Meeting Society's Expectation for Pharmaceutical Innovation	2
<i>Joe Miletich</i>	
Efficient Upstream Process Development Programs Generated Using Early Molecule Assessment and Culture of Continuous Improvement.....	8
<i>Arvia Morris</i>	
Past and Present Strategies, Challenges, and Benefits of Stable Cell Line Development at Genentech	9
<i>Amy Shen</i>	
Streamlining the Discovery to Development Transition.....	10
<i>Martin Allen</i>	
Integration of Cell Culture Process Platform and Cell Line Expression Systems to accelerate Biopharmaceutical Development.....	11
<i>Rashmi Kshirsagar</i>	

INTEGRATING PROCESS DEVELOPMENT: UPSTREAM AND DOWNSTREAM TECHNOLOGIES

Enhancing Efficiency and Control for a Biopharmaceutical Manufacturing Process	12
<i>Rohin Mahtre</i>	
Challenges and Innovative Approaches to Improving the Efficiencies of Process Development and Tech Transfer.....	13
<i>Gene Schaefer</i>	
Using Cell Culture Platform and High-Throughput Bioreactors to Streamline Upstream Process Development.....	28
<i>Albert Schmelzer</i>	
Speeding Whole Bioprocess Solutions: the Crucial Interface Linking the Bioreactor to Purification	29
<i>Mike Hoare</i>	
Upstream and Downstream Strategies to Actively Control Product Quality Attributes	30
<i>Dean Pettit</i>	

ANALYTICAL DEVELOPMENT AND PRODUCTION CHARACTERIZATION STRATEGIES

Analytical Strategies Enabling Expedited Development of Therapeutic mAbs.....	31
<i>Rob Dufield</i>	
Structural and Functional Analysis of Recombinant Virus-Like Particles (VLPs).....	32
<i>Qinjian Zhao</i>	
Development & Characterization of a Live Seasonal Vaccine	55
<i>Kuldip Sra</i>	

FORMULATION APPROACHES

High Throughput Formulation Development of Therapeutic Proteins.....	70
<i>Vladimir Razinkov</i>	
Utility of High-Throughput Biophysical Analysis of Protein Stability during Formulation Development and Comparability Assessments.....	71
<i>David Volkin</i>	

Application of QbD Principles in Demonstrating Formulation Robustness and Container Closure Compatibility of a Prefilled Syringe Drug Product	72
<i>Mark Brader</i>	
Phase Appropriate Approach for Formulation Development.....	73
<i>Robert Muller</i>	

APPROACHES TO QBD FOR EXTERNALLY SOURCED DELIVERABLES

QbD Across the Development Lifecycle: the CMO perspective.....	85
<i>John Crowley</i>	
Using a Statistical and Risk Based Approach to Improve Process Robustness and Control in a Late Stage Antibody Process	108
<i>Lynn Conley</i>	
QbD at a CMO.....	109
<i>Abhinav Shukla</i>	

USING PRIOR KNOWLEDGE AND PLATFORM MANUFACTURING

Accelerating Early Phase Development through Efficient Implementation of Molecular Design and Platform Knowledge	123
<i>Rick Caimi</i>	
Increasing Access to the Clinic with a Low Cost, Low Volume Manufacturing Process	133
<i>Jeff Salm</i>	
Accelerated Formulation Development for Antibody-Drug Conjugates (ADCs).....	134
<i>Heather Flores</i>	

APPROACHES TO RISK MANAGEMENT

Development of Effective Control Strategies Using Product Quality Risk Assessment.....	135
<i>Gregg Nyberg</i>	
The Appropriate Use of Risk Management Tools in Biopharmaceutical Development	146
<i>Ann Subashi</i>	
The Development of a Rational Testing Strategy using QbD: A Case Study.....	147
<i>Mary Cromwell</i>	
Practical Considerations to Risk Assessments for Efficient Use in Pharmaceutical Development and Production	148
<i>Christoph Stark</i>	

KEYNOTE

Complexity in biological products – Applications to QbD	159
<i>Ganesh Kaundinya</i>	

TRANSLATION TO OPERATIONAL PRACTICE

Assessing the Criticality of Product Quality Attributes	183
<i>Greg Flynn</i>	
Quality by Design Execution from a CMO Perspective	184
<i>Clinton Weber</i>	
Control Strategies for Antibody-Drug Conjugates Drug Product Manufacturing	191
<i>Shan Jiang</i>	

QBD ROUNDTABLE

MedImmune's Experience in the FDA QbD Pilot Program: The Story So Far...	192
<i>David Robbins</i>	
Quality by Design Implementation for Biologics: Lessons Learned from the FDA Pilot Program	201
<i>Lynne Krummen</i>	
FDA OBP QbD Pilot Program: Key Outcomes and Learnings	211
<i>Kris Barnthouse, Ranga Godavarti</i>	

KEYNOTE

Unique Challenges of Quality by Design (QbD) for Biotechnology Products: Lessons Learned from the OBP QbD Pilot Program	217
<i>Barbara Rellahan</i>	

POSTER SESSION

A Robust and Disposable Flow Through Purification Train For Post-ProteinA Mab Processing	232
<i>Narendra Bam , Matthew Stone, Bill Cataldo, Kevin Galipeau, Michael Phillips, Mikhail Kozlov</i>	
Accommodating Filter Variability in Process Design	233
<i>Herb Lutz</i>	
Bayesian Approach to Design Space for Drug Product Dilution and Fill	234
<i>Bruno Boulanger, Pierre Lebrun, Tara Scherder</i>	
Benchmarking Study to Evaluate Trends for Viral Barrier Implementation in Commercial Cell Culture Processes	235
<i>Sean Delfosse, Melissa Sathavipat, Nathan Hsu, Matt Croughan</i>	
Controlling High Mannose Glycan Level and Optimizing Titer Through a Balanced Modulation of Cell Culture Process and Medium Changes	236
<i>Nicole Le</i>	
Genome-scale metabolic reconstructions of Escherichia coli highlight strain-specific adaptations to environmental niches	237
<i>Jonathan Monk</i>	
Human and Cultural Factors in QbD - Risks and Opportunities	238
<i>Tara Scherder</i>	
Lessons Learned from a Scale-down Model Qualification Case Study	239
<i>Angela Meier</i>	
Manufacturing Incidents Investigation Involving Raw Materials Used For Biopharmaceutical Products	240
<i>Zai-Qing Wen</i>	
Monitoring of Multiple Product Quality Attributes of Biologics using Stable Isotope Labeled Internal Standard and Mass Spectrometry	241
<i>Jette Wypych</i>	
QbD Strategies for Managing Chromatography Resin Lot-to-Lot Variability Based On Design of Experiments and Monte Carlo Simulation	242
<i>Mattias Ahnfelt, Karol M. Lacki, Tryggve Bergander, Gunnar Malmquist</i>	
Single Use Centrifuge Clarification Of High Density CHO	243
<i>David Richardson</i>	
Use of Annotated Chinese Hamster Reference Genome and Transcriptome to Investigate Regulatory Mechanisms and Mutation Rates	244
<i>Nitya M. Jacob, Faraaz Yusufi, Kathryn C. Johnson, Andrew Yongky, Huong Le, Dong-Yup Lee, George Karypis, Miranda G. S. Yap, Wei-Shou Hu</i>	
Author Index	