4th International Conference on Accelerating Biopharmaceutical Development 2015

Scottsdale, Arizona, USA 1 – 4 March 2015

ISBN: 978-1-5108-1578-0

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© (2015) 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

<u>KEYNOTE</u>	
INCREASING NEED FOR RESPONSIVENESS AND FLEXIBILITY IN CLINICAL AND COMMERCIAL BIO-PHARMACEUTICAL SUPPLY CHAINS	1
WILL CHANGE IN THE PHARMACEUTICAL INDUSTRY ALSO CHANGE THE INDUSTRY'S PECKING ORDER?	14
Bernard Munos	
BIOLOGICS BEYOND TODAY'S MARKETS: THE CASE FOR INNOVATION IN BIOPROCESS R&D TO ENABLE GLOBAL ACCESS OF BIOLOGICS	21
SPEED	
AMGEN'S NEXT GENERATION BIOMANUFACTURING FACILITY	22
INTEGRATED STRATEGY TO ENABLE RAPID DELIVERY OF MATERIAL FOR IND ENABLING TOXICOLOGY STUDIES Scott Estes, Thomas Ryll	23
ACCELERATED DRUG DEVELOPMENT ENABLED BY VELOCIMAB® TECHNOLOGIES Darya Burakov	24
TOWARDS MAKING BIOLOGIC DRUGS ON DEMAND	37
DEVELOPMENT OF A DEVICE PLATFORM TO SPEED PRODUCTS TO CLINIC AND MARKET	38
COST	
CONTINUOUS VS. BATCH BIOPROCESSING	39
DOES PFIZER NEED A LOW COST LOW VOLUME MANUFACTURING OPTION?	50
Jeff Salm, Thomas Crowley, Tanya Shang, Anthony Barry, Kristin Murray	
ULTRA SCALE-DOWN (USD) TECHNOLOGIES FOR A SCALEABLE AND INFORMED	51
BIOMANUFACTURING	51
RAPID PROCESS DEVELOPMENT ENABLED BY AUTOMATED, SINGLE USE HIGH	
THROUGHPUT TECHNOLOGIES	71
Christopher Kistler IMPROVING MANUFACTURING NETWORK PRODUCTIVITY: OVERCOMING THE DOWNSTREAM BOTTLENECKS	72
Lynn Conley	12
QUALITY	
BEYOND NUMERICAL TOOLS: CONTROL STRATEGY PRINCIPLES THAT ASSURE PRODUCT QUALITY THROUGHOUT DEVELOPMENT	73
Margaret N. Ruesch	13
UNLOCKING THE POWER OF ANALYTICS IN SUPPORT OF QBD IN DEVELOPMENT Hanne Bak	
UNDERSTAND & CONTROL PRODUCT QUALITY ATTRIBUTES IN CELL CULTURE	75

Anli Ouyang

CLOSING THE GAP- ADDRESSING SIMILARITY CHALLENGES OF A BIOTHERAPEUTIC WITH THE INNOVATOR PRODUCT	76
Gargi Seth	
A CHINESE HAMSTER OVARY CELL HOST CELL PROTEIN THAT IMPACTS PS-80	
DEGRADATION	77
Kelvin H. Lee, Abraham M. Lenhoff, Nick Levy, Kristin N. Valente	
INTEGRATION	
CONTINUOUS PROCESSING FOR PRE-CLINICAL AND CLINICAL MANUFACTURING:	70
BALANCING SPEED, COST, AND QUALITY	/8
Jon Coffman, Henry Lin, Samantha Wang, Scott Godfrey, Raquel Orozco, Samet Yildirim, George Setiabuti, Jens Vogel	
DEVELOPING A LEADING OPEN-ACCESS INTEGRATED BIOLOGICS DISCOVERY,	
DEVELOPMENT AND MANUFACTURING PLATFORM TO EXPEDITE GLOBAL	
DEVELOPMENT	79
Chris Chen, Weichang Zhou	
SCALE-DOWN AND PROCESS INTENSIFICATION: TWO KEY OPPORTUNITIES FOR	
INTEGRATION AND COST REDUCTION	95
Guenter Jagschies, Karol M. Lacki	
A PROCESS DEVELOPMENT STRATEGY PROVIDING FLEXIBILITY WHILE BALANCING	
COST AND SPEED WITHOUT SACRIFICING QUALITY	105
Martin Allen	
Author Index	