

Pharmaceutical Discovery, Development and Manufacturing Forum 2014

Core Programming Area at the 2014 AIChE Annual Meeting

Atlanta, Georgia, USA
16-21 November 2014

ISBN: 978-1-5108-1269-7

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© (2014) 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

(105a) Development of a Multistep Continuous Process and Manufacturing for a Key Pharmaceutical Intermediate of Dapagliflozin	1
<i>Chenchi Wang, Prashant Deshpande, Junying Fan, Laurent Lehmann</i>	
(105b) Process Intensification Using a Continuous Packed Bed Reactor for Enzymatic Hydrolysis	2
<i>Dimitri Skliar, Thomas L. Laporte, Sara Chuang, Amarjot Singh, Nicolas Cuniere, Animesh Goswami</i>	
(105c) Organic Solvent Nanofiltration in Continuous Catalytic Reactions	3
<i>Ludmila Peeva, Joao Da Silva Burgal, Andrew G. Livingston</i>	
(105d) Development of Continuous Antisolvent Nucleation Processes to Achieve Better Control over Crystalline Particle Attributes	4
<i>Anna Jawor-Baczynska, Ulrich Schacht, Naomi Briggs, Alastair J. Florence, Jan Sefcik</i>	
(105e) Avoiding Microreactor Clogging By Inorganic Solid Formation in Continuous Chemical Synthesis of Pharmaceutical Compounds	5
<i>Gaurav Giri, Klavs F. Jensen</i>	
(105f) Controlled Accumulation of Inorganic Salts in Microreactors for Palladium-Catalyzed Amination	6
<i>Yizheng Chen, Ryan L. Hartman</i>	
(158a) An Integrated Systematic Framework to Assist the Development of Pharmaceutical Processes	7
<i>Emmanouil Papadakis, Gürkan Sin, Krist V. Gernaey, Rafiqul Gani</i>	
(158b) Modeling of Disintegration and Dissolution of Formulated API	9
<i>Nikolay Zaborenko, David C. Sperry</i>	
(158c) A Practical Computational Tool to Predict Formulation and Process Variables during the Development of Spray-Dried Amorphous Solid Dispersions	10
<i>Iris Duarte, José Luís Santos, João F. Pinto, Márcio Temtem</i>	
(158d) Method for Prediction of Pharmaceutical Solubility for Solvent Selection	19
<i>Andrew Bird, Joe Hannon</i>	
(158e) Impact of Continuous Drug Product Processing on Formulation and Process Development Workflow	20
<i>Ian Leavesley, Salvador García-Muñoz, Ahmad Almayya, Xiaoyu Zhang</i>	
(158f) CFD-Predicted and PIV-Measured Velocity Profiles in a USP Dissolution Testing Apparatus 2 Equipped with an Arch-Shaped Fiber Optic Probe and Their Impact on Tablet Dissolution	21
<i>Bing Wang, Gerard Bredael, Piero M. Armenante</i>	
(166a) Reducing Powder Lubrication in an Encapsulation Process for Improved Dissolution Performance	22
<i>William R. Ketterhagen, Daniel O. Blackwood</i>	
(166b) Residence Time Distribution Measurement Via Video Analysis for Design of Experiment Characterization of Melt Extrusion	23
<i>Patrick R. Wahl, Gudrun Hörl, Daniel Kaiser, Stephan Sacher, Johannes G. Khinast</i>	
(166c) Tracking the Fate of Agglomerated API in the Drug Product Process with NIR Chemical Imaging	24
<i>Megerle Scherholz, Gary McGeorge, Boyong Wan</i>	
(166d) Behaviour of HPMC and Microcrystalline Cellulose during a Roller Compaction Process	25
<i>Graham O'Mahony, Mary Ellen Crowley, Rakesh Dontireddy, Michael McAuliffe, Abina Crean</i>	
(166e) Impact of Material and Source Variability on the Performance of Roller-Compacted Formulation and Critical Drug Product Attributes	26
<i>Junshu Zhao, Otilia Koo, Yongmei Wu, Tejas Shah, Sandeep Rana, Dinesh Morkhade, Hubert Alby, Vishwas Nesarikar, Kevin Macias, Ruiling Hartley, Arturo Marin</i>	
(207a) The Synergistic Nature of Chemistry & Chemical Engineering Technology Teams Working Together in the Development of Post-Launch “2nd Generation” API Processes	27
<i>Brian Dennehy, Adam Burrell</i>	
(207b) Platform Chemical Engineering Approaches to Support Manufacturing Optimisation	28
<i>Jessica Whelan, Miriam Carr, Brian Glennon, Mark Barrett</i>	
(207c) Leveraging Development Knowledge Post-Validation to Control Form and Improve Operational Consistency for a Pharmaceutical Intermediate with Multiple Polymorphs	29
<i>Eric M. Saurer, Nathaniel D. Kopp, Peng Geng, Chester E. Markwalter, Jason Sweeney, Shawn Pack</i>	
(207d) Commercialisation of API Processes in Manufacturing at Eli Lilly	30
<i>Paul Malone</i>	
(207f) Integration and Application of Multiple Platform Technologies into a Drug Substance Validation Program	31
<i>Marc O'Donoghue, Daire Osborne, Tim O'Sullivan</i>	
(211a) Novel In Situ Methods for Floc Size Determination in Cell Culture Separations	32
<i>Des O'Grady, Terry P. Redman</i>	
(211b) Progress on a Mixed-Mode Hydrogel Membrane – A New Tool for Mab Purification	33
<i>Xiaoqiao Shang, Jim Stout, Renaud Jacquemart, Dharmesh Kanani</i>	
(211c) Rapid Characterization of HCP Removal on Adsorptive Membranes Using Protein Surrogate Biomarkers	34
<i>Alpana Naresh, Roel Lievrouw, Marty Siwak</i>	
(211d) Optimization of Tangential Flow Ultrafiltration Processing Step with High Concentration Self-Buffering Proteins	35
<i>Jessica R. Molek, Mark Lankford, Bruno F. Marques, Kent E. Goklen</i>	

(211e) Purification of Adenovirus Serotype 5 By Two-Column, Open-Loop, Size-Exclusion, Simulated Counter-current Chromatography.....	36
<i>José P. B. Mota, Piergiuseppe Nestola, Ricardo J. S. Silva, Cristina Peixoto, Manuel J. T. Carrondo, Paula M. Alves</i>	
(211f) Centrifugal Separation of Disk Centrifuge in Downstream Processing.....	38
<i>Wallace Woon-Fong Leung</i>	
(238a) Managing Residual Risk Via the Control Strategy: A Case Study	39
<i>Luke Schenck, Shane T. Grosser, Marguerite Mohan, Brett Duersch, John Lepore</i>	
(238b) Estimation of Product Robustness: Prediction of Manufacturing Variability	40
<i>Jose E. Tabora, Nathan Domagalski, Jacob Albrecht, Ronald Behling, Jun Li, Gerard Sentveld, John R. Crison, Jennifer Walsh</i>	
(238c) Digital Determination of Pairs for the Synthesis of a Pharmaceutical Intermediate	41
<i>Carla Luciani, Michael Kobierski, Allison Fields, Kevin Seibert, David Varie, Salvador García-Muñoz</i>	
(238d) Model-Based Process Control in API Manufacturing: A QbD-Vantage!	42
<i>Samrat Mukherjee, Marc Greenfield</i>	
(238e) Ensuring Consumption of a Genotoxic Starting Material in API Manufacture through the Use of Kinetics and Mixing Studies	43
<i>Christopher Pink</i>	
(265a) Efficacious Polyanhydride Nanovaccines Against White Spot Syndrome Virus in Shrimp	44
<i>Yashdeep Phanse, Supraja Puttamreddy, Duan Loy, Julia Vela Ramirez, Kathleen Ross, Balaji Narasimhan, Lyric Bartholomay</i>	
(265b) Understanding What Is Still Patentable in the Life Science Industry	45
<i>Jennifer Roscetti</i>	
(265c) Negatively Charged Carbon Nanohorn Supported Cationic Liposome Nanoparticles: A Novel Delivery Vehicle for Anti-Nicotine Vaccine	46
<i>Yun Hu, Hong Zheng, Wei Huang, Sabina De Villiers, Paul Pentel, Jianfei Zhang, Harry Dorn, Marion Ehrlich, Chenneng Zhang</i>	
(265d) Protein Pegylation Using Micro-Reactors	46
<i>Pedram Madakdar, P. Ravi Selvaganapathy, Raja Ghosh</i>	
(265e) Optimization of Valuable Intermediates By 11-Alpha-Hydroxylation of Steroid DHEA By Solvent-Enhanced Beauveria Bassiana	87
<i>Richard González, Tonya L Peeples</i>	
(265f) Corrosion Protection Properties of Polybenzoxazine/Organoclay Nanocomposite Coatings on Mild Steel.....	88
<i>Changlu Zhou, Zhong Xin</i>	
(265g) Viscosity and Short Time Dynamics of Concentrated Solutions of Proteins Interacting with a Short Range Attractive and Long Range Repulsive Interaction	89
<i>P. Douglas Godfrin, Steven D. Hudson, Kunlun Hong, Lionel Porcar, Peter Falus, Norman J. Wagner, Yun Liu</i>	
(277a) Ensuring Success of Broad Industrial/Academic Collaboration	90
<i>Brian Glennon, Jon O Halloran</i>	
(277b) Exploring Opportunities for Information Exchange and Mutual Development of Enabling Technologies	91
<i>Srinivas Tummala, Kevin D. Seibert, Margaret Faul</i>	
(277c) The Center for Pharmaceutical Development (CPD) – An I/U CRC for Late-Stage Pharmaceutical Development.....	92
<i>Andreas S. Bommarius</i>	
(277d) Collaborative Development of an Auto-Sampling Probe for HPLC	93
<i>Joel M. Hawkins, Daniel Hallow, Leen Schellekens</i>	
(277e) Systems-based Pharmaceutics - An Industrial Pre-competitive Alliance	94
<i>Salvador García-Muñoz</i>	
(299b) A Novel and Universal Method for High Mannose Fc Glycan Modulation in Recombinant Therapeutic Antibodies.....	95
<i>Jack Huang, Henry Lin, Jerry Yang</i>	
(299c) Towards Controlling the Glycoform: Bridging the Gap from the Extracellular Environment to Antibody Glycosylation.....	96
<i>Philip M Jedrzejewski, Ioscani Jimenez Del Val, Antony Constantinou, Anne Dell, Stuart Haslam, Karen M. Polizzi, Cleo Kontoravdi</i>	
(299a) Optimization of a Novel CHO Cell Bank Production Method	97
<i>Angela Meier</i>	
(299e) Developing a High Titer Defined Medium and Feed for <i>E. coli</i> Fermentation Systems.....	98
<i>Mark Berge, Shushil Machhi, Jaclyn Brennan, Varnika Roy</i>	
(299f) Directional Oscillating Shear in Conventional and Novel Culture Dishes.....	99
<i>Jonathan Jones, Amlan Chakraborty, M. Keith Sharp, R. Eric Berson</i>	
(305a) A Materials Science Approach to Bilayer Tablet Compaction.....	100
<i>Jasmine M. Rowe, Keirnan Lamarche, Brian Delancy, Brian Carroll, Preetanshu Pandey, Faranak Nikfar</i>	
(305b) Design of Component Particle Attributes to Optimize the Processibility of Pharmaceutical Blends	101
<i>Stephen L. Conway, Hirotaka Nakagawa, David Goldfarb</i>	
(305c) Development of a Novel Method for the Solubilization of Poorly Water-Soluble Drugs.....	102
<i>Atsushi Hoyano, Masanori Kobayashi, Yuichiro Shimada, Daisuke Kobayashi, Atsushi Shono, Katsuto Otake</i>	
(305d) Experimental & Numerical Investigation of Bipolar Charging in a Hopper-Chute Assembly.....	103
<i>Vipul Gupta, Saurabh Sarkar, Shivangi S. Naik, Raj Mukherjee, Vinit Sharma, Prasad Peri, Bodhisattwa Chaudhuri</i>	
(305e) The Effect of Process Parameters Including Blend Shearing and Compaction Pressure on Pharmaceutical Tablet Properties	104
<i>Pallavi Pawar, Yifan Wang, Hee Joo, Alberto Cuitino, Fernando Muzzio</i>	

(305f) Investigating the Influence of Carrier Morphology and Dosator Capsule Filling Process on the Performance of Dry Powder Inhalers (DPIs)	105
<i>Sarah Zellnitz, Eva Faulhammer, Verena Wahl, Hartmuth Schroettner, Johannes G. Khinast</i>	
(333a) Design and Administration of Dissolving Microneedle Patches in Human Subjects	107
<i>Jaya Arya, Haripriya Kalluri, Devin McAllister, Winston Pewin, Xin Dong Guo, Mark Prausnitz</i>	
(333b) pH-Sensitive P(IA-co-NVP) Hydrogels As Oral Delivery Vehicles for High Isoelectric Point-Exhibiting Therapeutic Proteins	108
<i>Michael C. Koetting, Annie Zhang, Nicholas A. Peppas</i>	
(333c) Self-Assembled Peptide Amphiphile Micelles Improve Group a Streptococcal Vaccination	109
<i>John C. Barrett, Bret D. Ulery, Simon Liang, Amanda M. Trent, Reid V. Wilkening, Laura C. Cook, Michael J. Federle, Matthew V. Tirrell</i>	
(333e) Advanced Structuring of Lipids for Controlled Drug Release; Polymorphic Crystallizations and Curing Effects	110
<i>Diogo Gomes Lopes, Katrin Becker, Eva Faulhammer, Detlev Haack, Dirk Lochmann, Johannes G. Khinast, Andreas Zimmer, Sharareh Salar-Behzadi</i>	
(361a) Optimal Startup of a Continuous Pharmaceutical Process	111
<i>Ali M. Sahlodin, Paul Barton</i>	
(361b) Operation Strategy Development for Grignard Reaction in a Continuous Stirred Tank Reactor	113
<i>Sze Wing Wong, Shujauddin M. Changi, Richard Shields, Willis V. Bell III, Bernard M. McGarvey</i>	
(361c) A Computational Analysis of a Combined Cooling Anti-Solvent Continuous Crystallization Cascade: A Paracetamol/Methanol/Water Case Study	114
<i>K. Hutton, P. J. Frawley</i>	
(361d) Obtaining Pure Enantiomers and Co-Crystals Using Continuous Preferential Crystallization: A Process Development Investigation Using Population Balance Models	126
<i>Thomas Vetter, Christopher L. Burcham, Michael F. Doherty</i>	
(361e) Process Modeling, Simulation and Optimization for Continuous Pharmaceutical Manufacturing (CPM) of Ibuprofen	128
<i>Hikaru G. Jolliffe, Dimitrios I. Gerogiorgis</i>	
(361f) Continuous Purification of Active Pharmaceutical Ingredients Using Multistage Organic Solvent Nanofiltration Membrane Cascade	129
<i>Ludmila Peeva, Joao Da Silva Burgal, Andrew G. Livingston</i>	
(386a) Drug Encapsulated Aerosolized Microspheres As a Localized, Degradable Cancer Therapy	130
<i>J. Alaina Floyd, Anna Galperin, Buddy Ratner</i>	
(386b) Polymer Strip Films As a Robust, Surfactant-Free Platform for Delivery of BCS Class II Drug Nanoparticles	132
<i>Scott Krull, Ramana Susarla, Afolawemi Afolabi, Meng Li, Ecevit Bilgili, Rajesh Dave</i>	
(386c) Enhanced Bioavailability of Poorly Soluble Pharmaceuticals By Means of Free Surface Electrospinning	134
<i>Jeffrey T. Miller, Alexis Goebel, Matthew P. Lee, Keith M. Forward</i>	
(386d) Improved Spray Drying Capability with Affinisol™ High Productivity Polymers	135
<i>William Porter III, Robert Schmitt, Oliver Petermann, Meinolf Brackhagen, Matthias Sprehe, Matthias Knarr, Wes Spaulding</i>	
(386e) Inhalation Characteristics of Polyanhidride Nanoparticle-Based Pulmonary Delivery Vehicles	136
<i>Timothy Brenza, Mai Tu, Jennifer Fiegel, Timothy Sullivan, Balaji Narasimhan</i>	
(386f) Tablet Design and the Potential Impact on Oral Drug Delivery	137
<i>Luke E. K. Achenie, Naresh Pavurala</i>	
(428a) Twin Screw Wet Granulation Development of a Model Compound	138
<i>Mark Apicella, Brendon G. Ricart, Mehrdad Kheirpour Langroudi, Seth Forster</i>	
(428b) Continuous High Shear Wet Granulation: Impact of Process and Design Parameters on Granule Properties	140
<i>Wei Meng, Xue Liu, Fernando Muzzio</i>	
(428c) Inter-Particle Coating Variability in a Continuous Coater	141
<i>Rahul Kumar, Carl R. Wassgren</i>	
(428d) Evaluation of Different Combinations of Continuous Mixing Operations Across a Range of Formulations	142
<i>Ian Leavesley, Carla Luciani, Ahmad Almaya, Jeremy Merritt, Wyatt Roth</i>	
(428e) Implementing a Robust PAT Solution and Closed Loop Control on a Continuous Manufacturing Plant for the Production of Pharmaceutical Tablets at UPRM	143
<i>Leonel Quiñones, Elvin Almodovar, Carlos Velazquez</i>	
(428f) Model-Aided Development of a Continuous Drug Product Manufacturing Process	144
<i>Salvador García-Muñoz, Carla Luciani, Zhenqi Shi, Wyatt Roth, Adam S. Butterbaugh, Joshua Hanson, Leo Manley, Lukas Barnes, Ian Leavesley, Ahmad Almaya</i>	
(451a) The Use of CFD Modeling to Understand Variability in Particle Agglomeration in an API Crystallization	145
<i>Chester E. Markwalter, Brenda Remy, Jason Sweeney, Shawn Pack, Tarang Bulchandani, Gopal Kasat, Damodaran Vedapuri</i>	
(451b) Large Bioreactor Simulation with Graphic Processors	146
<i>Christian Witz, Akshay Prakash, Johannes G. Khinast</i>	
(451c) On the Use of Periodically Inverted Assay Tubes As a Screening Platform for Recombinant Escherichia Coli Cultures	147
<i>Mario M. Alvarez, Roberto Pérez</i>	
(451d) Characterization of Oxygen Availability Measured As Oxygen Transfer RATE and Dissolved Oxygen Tension in Shake Flasks for the Production of O-Mannosylated Proteins in Streptomyces Lividans	148
<i>Ramsés Gamboa-Suárez, Luz Marín-Palacio, Luis Servín-González, Norma Valdez-Cruz, Wolf Kloekner, Jochen Buchs, Mauricio Trujillo-Roldán</i>	

(456a) Preparation and Preliminary Antitumor Activity Evaluation of a New Targeted Nanoparticle System.....	150
<i>Eva M. Martín Del Valle, Jose Roman, Jesus Rodriguez-Rodriguez, Miguel A. Galan</i>	
(456b) Osteotropic Therapy Via LbL Nanoparticles.....	151
<i>Stephen Morton, Nisarg Shah, Mohiuddin Quadir, Jason Deng, Zhiyong Poon, Paula T. Hammond</i>	
(456d) Biodegradable Nanoparticle-Based Delivery System for Enhanced Blood-Brain Barrier Transport Utilizing Macrophage Carriage	152
<i>Timothy Brenza, Sangya Singh, Julia Vela-Ramirez, Howard E. Gendelman, Georgette Kamogne, Balaji Narasimhan</i>	
(456e) Stabilities of Exosomes Derived from Mammalian Cells: Nanoparticle Morphology and Functional RNAs.....	153
<i>Yuetong Wu, Vanessa Cuppett, David J. Klinke</i>	
(456f) Engineering an Effective Immune Adjuvant By Designed Control of Shape and Crystallinity of Aluminum Oxyhydroxide Nanoparticles.....	154
<i>Bingbing Sun</i>	
(456g) Novel Chemoradiotherapeutic Magnetic Nanoparticles for Targeted Treatment of Non-Small Cell Lung Cancer.....	155
<i>Imalka Munaweera, Yi Shi, Bhuvaneswari Koneru, Ruben Saez, Russell Coyle, Ali Aliev, Anthony J. Pasqua, Kenneth J. Balkus Jr.</i>	
(456h) Uptake, Co-Localization, Cytotoxicity and Transepithelial Transport of Acid-Labile Doxorubicin-Dendrimer Conjugates in an <i>in Vitro</i> Model of the Lung Adenocarcinoma Epithelium	156
<i>Qian Zhong, Bruno Hemia, Alisha Punjabi, Sandro R. P. Da Rocha</i>	
(486a) Crystallinity Detection Methods for Polymer-Stabilized Solid Dispersion Formulations.....	157
<i>Stephen L. Conway, Eugene Park, Itzia Arroyo, Jun-Hong Chou, Rory Sargeant, Kenneth Rosenberg</i>	
(486b) In Vitro and in Vivo Validation of a New Drug Delivery System for Human LUNG Cancer.....	158
<i>Eva M. Martín Del Valle, Jose Roman, Miguel A. Galan</i>	
(486c) Screening Microneedle Formulations for Influenza Vaccine Stabilization.....	159
<i>Matt Mistilis, Andreas S. Bommarius, Mark Prausnitz</i>	
(486d) Tablet Press Weight Control Model.....	160
<i>Leo Manley, Bernard M. McGarvey, Genevieve Sullivan</i>	
(486e) Quality-By-Design Evaluation of an Immediate Release Tablet Platform.....	161
<i>Joseph Kushner Iv, Beth A. Langdon, Fasheng Li, Gautam R. Ranade, Daniel Song, Anil Kane, Ian Hicks, Lalji Kathiria, Kam Agarwal</i>	
(486f) Excipient-Process Interactions and Their Effects on Tablet Compaction and Film Coating.....	162
<i>Preetanshu Pandey, Shruti Gour, Dilbir Bindra, Jade Trinh, David Buckley, Sherif Badawy</i>	
(418ci) Investigation of the Effect of Ethylcellulose Viscosity Variation on Slightly Soluble and Freely Soluble Drugs from Extended Release Multiparticulates.....	163
<i>Cody A. Schoener, Shari Workentine, Raxit Mehta, Jason Teckoe, Ali Rajabi-Siahboomi</i>	
(524a) The Virtual Product-Process Design Lab	165
<i>Sawitree Kalakul, Georgios Kontogeorgis, Rafiqul Gani</i>	
(524b) Oscillatory Amplitudes Regulation Method in 1,3-PD Production By Klebsiella Pneumoniae	166
<i>Hangzhou Wang, Tong Qiu, Jinsong Zhao, Bingzhen Chen</i>	
(524c) Molecular Design of Optimum CO₂ Capture Solvents: From Conceptual Screening to SAFT-Based Validation	168
<i>Athanassios I. Papadopoulos, Sara Badr, Alexandros Chremos, Esther Forte, Theodoros Zarogiannis, Panos Seferlis, Stavros Papadokonstantakis, Claire S. Adjiman, Amparo Galindo, George Jackson</i>	
(524d) Structure Generation of Optimal Reactants and Products Using Signature Descriptors.....	170
<i>Vikrant Dev, Nishanth G. Chemmangattuvalappil, Mario Richard Eden</i>	
(524e) An Application of Computer-Aided Molecular Design (CAMD) Using the Signature Molecular Descriptor: Designing New Water-Reducing Admixtures for Cement through Cement Paste Rheology Evaluation	171
<i>Hamed Kayello, Donald P. Visco Jr., Joseph Biernacki</i>	
(524f) Graph Based Database Development for Gasoil Reactive Systems	172
<i>Charles C. Solvason, Jorge M. Martinis</i>	
(524g) Determining Optimal Groups for Group Contribution Methods	174
<i>Nick Austin, Nick Sahinidis, Daniel W. Trahan</i>	
(527a) Mathematical Modeling of Macromolecular Release of Stimuli-Responsive Polyelectrolyte Multilayer Films.....	175
<i>Jouha Min, Paula T. Hammond, Richard D. Braatz</i>	
(527b) Formulation Design Evaluation for a Single Layer Osmotic Capsule.....	176
<i>Ting Wang, Gregory Goeken, Fasheng Li, Joseph Kushner Iv</i>	
(527c) Process Control of Modified-Release Matrix Tablet Manufacturing Operations and Key Excipient Enablers.....	177
<i>True Rogers, Kathryn Hewlett, Karen Balwinski, Joerg Theuerkauf, Louis Ruocco</i>	
(527e) QbD in Development of Film Coated Tablets: A Risk Assessment Based Doe Towards a Robust Product and Process	181
<i>Ganeshkumar Subramanian</i>	
(580a) Wavenumber Selection for NIR Calibration Modeling: Application to Water and Drug Content Estimation	182
<i>Taku Uchimaru, Takuya Miyano, Koichi Fujiwara, Manabu Kano, Hideaki Tanabe, Hiroshi Nakagawa, Tomoyuki Watanabe, Naoki Wakiyama</i>	
(580b) Improvement of Iterative Optimization Technology (Calibration-Free/ Minimum Approach) with Dimensionality Reduction of Spectra.....	184
<i>Hiromasa Kaneko, Koji Muteki, Daniel O. Blackwood, Yang A. Liu, Sonja Sekulic, Kimito Funatsu</i>	
(580c) Application of Multivariate Data Analysis to Cell Culture Development	185
<i>John Bowers, Balrina Gupta, T. Craig Seamans, Louis Obando</i>	
(580d) Model Development for NIR-Based Real-Time Monitoring of Ingredient Concentration	186
<i>Hiroshi Nakagawa, Manabu Kano, Shinji Hasebe, Takuya Miyano, Tomoyuki Watanabe, Naoki Wakiyama</i>	

(580e) Detection of Process Fingerprints Applying Multivariate Analysis Methods to Monoclonal Antibody Cell Culture Data	188
<i>Michael Sokolov, Alessandro Butté, Miroslav Soos, Massimo Morbidelli</i>	
(585a) In-Process Particle Size Analysis for Commercial Pharmaceutical Manufacturing	189
<i>Zhigang Sun</i>	
(585b) On-Line Reaction Profiling in Pharmaceutical Process Development	190
<i>Sarah Pulicari, Elie Chaaya, Paul Oram, Zhihao Lin, Ralph Calabria, Sherry Song, Jeonghan Park, Feng Xu, Azzeddine Lekhal</i>	
(585c) Applying PAT for Pharmaceutical Powder Blending Process: Challenges and Opportunities	191
<i>Huiquan Wu, Mansoor A. Khan</i>	
(585d) PAT Implementation and QbD Control Strategy for Commercial Production of a Drug Substance	192
<i>Elie Chaaya, Zhihao Lin, George Zhou, Sun Lei, Tseng-En Hu, Busolo Wabuyele, Cindy Starbuck</i>	
(585e) Always the Same? Location of Segregation Via Spectroscopy	193
<i>Roland Hohl, Otto Scheibelhofer, Patrick Wahl, Stephan Sacher, Johannes G. Khinast</i>	
(585f) PAT Data Management As a Tool to Support Continuous Production in Secondary Manufacturing	194
<i>Kjell Francois, Pamela Bruen Docherty</i>	
(593a) The Use of Mobius® Mix Vessels with Protein Solutions: Impact of Impeller Flow and Particle Shedding on Protein Turbidity and Aggregation	195
<i>Dana Kinzmaier, Elizabeth Goodrich</i>	
(593b) Practical Implementation of Single Use Filtration Assemblies in the Final Filling Operation	207
<i>Terri Love, Sue Walker</i>	
(593c) Selecting Single-Use Components for the Fill/Finish Operation	208
<i>Pietro Perrone</i>	
(593d) Clarification of CHO Bioreactor (2-6 lpm) with Single Use Centrifuge-Unifuge®	209
<i>David R. Richardson</i>	
(593e) A Method for Pre-Use Integrity Assurance with Large Volume Single-Use Bin and Mixer Bags	214
<i>Adam Sokolnicki, Takao Ito, Alexandra Steele</i>	
(603a) A Mathematical Model for Drug Delivery and Dose Optimization for Solid Tumors	215
<i>Daniel Lepak, Andrew Baik</i>	
(603b) Characterization of a Continuous Granulator	216
<i>Madeline Candelaria, Carlos Velazquez</i>	
(603c) Preparation of Structured Meso-Macroporous Silica Materials: Application As Delivery System	217
<i>Esther Santamaría, Alicia Maestro, Jose M. Gutierrez, Carmen Gonzalez</i>	
(603d) Process Control of the Continuous Tumbler Mixer	219
<i>Elvin Almodovar, Carlos Velazquez, Leonel Quinones</i>	
(603e) Investigation of the Applicability and Properties of Date Stone Extracts As Pharmaceutical Excipients	220
<i>Ahmad Albadarin, David Egan, Mark Davis, Collins John, Gavin Walker</i>	
(603f) CHO Cell Line Stability: Impact of Cell Banking	222
<i>Jayashree Subramanian, Abigail Pynn, Rigzen Aulakh, Parry Grewal, Mark Sanford, Inn Yuk</i>	
(603g) A Simple Process Transfer Method for Roller Compaction	223
<i>Weixian Shi, Omar L. Sprockel</i>	
(603h) Investigation of Impact of Roller Compaction Process Parameters on Critical Product Attributes	224
<i>Rakesh C. Dontireddy, Mary E. Crowley, Graham O'Mahony, Raghu Peddipatia, Michael A. McAuliffe, Abina M. Crean</i>	
(603i) Novel Antifungal Fusion Proteins	225
<i>Rudra Palash Mukherjee, Srinivas Jayanthi, David McNabb, T. K. S. Kumar, Bob Beitle</i>	
(603j) Microfluidic Platform for Crystallization Optimization and Structure Determination of Pharmaceutical Solid Forms	226
<i>Elizabeth M. Horstman, Sachit Goyal, Yuchuan Gong, Geoff G. Z. Zhang, Paul J. A. Kenis</i>	
(603k) Protein Disaggregation By Thermal Cycling	227
<i>Rahul Sadavarte, Raja Ghosh</i>	
(603l) The Ion Exchange Proteome of Pseudomonas Fluorescens	228
<i>Ahmed El Mashiete, Bob Beitle</i>	
(603m) Development of a Reverse Phase HPLC Assay to Characterize a Monoclonal Antibody	229
<i>Xianwen Chen</i>	
(603n) Characterization and Modeling of Continuous Processing Unit Operations with Experimentally Measured Residence Time Distributions (RTD)	230
<i>William E. Engisch Jr., Fernando J. Muzzio</i>	
(603o) Rapid Prediction of Facility Fit and Debottlenecking of Antibody Purification Facilities	231
<i>Yang Yang, Nina F. Thornhill, Suzanne S. Farid</i>	
(603p) Scale-up Strategies of High Shear Wet Granulation of a 50% Drug Load Compound: From 60L Bottom-Driven Granulator to 600L Top-Driven Granulator	232
<i>Jennifer (Ho) Sun, Mehrdad Kheiripour Langroudi, W. Mark Eickhoff</i>	
(603q) The Application of Novel Characterization Techniques to Understand Formulation-Process-Performance Interplay in Spray Dried Pharmaceutical Product Development	233
<i>Hannmi Xi</i>	
(603r) Fluidized-Bed Impregnation of Active Pharmaceutical Ingredients Onto Porous Carriers	234
<i>Thamer Omar, Xue Liu, Fernando J Muzzio, Benjamin J. Glasser</i>	
(603s) Development of an E .coli Recombinant Protein Fermentation Process	235
<i>Nitya Krishnan, Jane Gunson</i>	

(603t) Development of a Scale-Down Plate Model for Raw Material Variability Analysis in Mammalian Cell Culture	236
<i>Hedieh Rahimi, David Kolwyck, Gary Rogers, Jack Huang, Chetan T. Goudar</i>	
(603u) A Media Screening Engine for Live Viral Vaccine Process Development: Bridging High-Throughput DoE Screening and Upstream Process Development	237
<i>Jason Rodriguez, Esther Lim, Chris Daniels, Kent Hamaker</i>	
(603v) Design of a Large Scale Manufacturing Process and Site for Neural Stem Cells for Spinal Cord Injury Treatment	238
<i>Luqman Ahmad Mahir, Siti Nur Aishah Mohd Zain, Amulya Pervaje, Elaine Qian, Madeline Williams, Tiffany Rau</i>	
(641a) Simulation of Stirred Tank Hydrodynamics Using Mesh and Meshless Methods	239
<i>P. J. Frawley, Dragan Nikolic, Brian De Souza, Giuseppe Cogoni, Brian Hogan</i>	
(641b) Understanding of pMDI-Spacer Interactions through CFD Simulations	251
<i>Saurabh Sarkar, Maziar Kakhi, Prasad Peri, Bodhisattwa Chaudhuri</i>	
(641c) Applying Poisson-Boltzmann Theory to Predict Excipient Concentration in Ultrafiltered Therapeutic Protein Formulations	252
<i>John Robinson, Roger A. Hart</i>	
(641d) Fluid Bed Granulation: Towards a Comprehensive Process Model	253
<i>Robert Claudius Schardmüller, Markus Pieber, Gregor Toschkoff, Simon D. Fraser, Daniela Steigmiller, Bruno Chilian, Alfred Fetscher, Martin Maus, Michael Braun, Sean Bermingham, Johannes G. Khinast, Pavol Rajniak</i>	
(641e) The Simulation of Mixing and Free Surface Flows in Co-Rotating Twin-Screw Extruders	255
<i>Andreas Eitzlmayr, István Kondor, Josip Matic, Gerold Koscher, Johannes G. Khinast</i>	
(641f) Case Study: Simulation-Based Process Optimization for a Monoclonal Antibody Cation Exchange Step	268
<i>Trent Larsen, Stephen Hunt, Ashish Sharma, Robert Todd</i>	
(641g) Optimization of the Protein Pegylation Process	269
<i>Xiaojiao Shang, Brandon Corbett, Prashant Mhaskar, Raja Ghosh</i>	
(648a) Development of a Scalable Friedel-Crafts Acylation: A Mechanistic Approach	270
<i>Jacob Albrecht, Greg Beutner, Dayna Fanfair, Junying Fan, Michael Lawler, Jonathan Tripp, Jason Sweeney, David Conlon</i>	
(648b) Multiphase Transport Modeling for Vacuum Drying of Pharmaceutical Products	271
<i>Aditya G. Dodda, Kostas Saranteas, Michael A. Henson</i>	
(648c) Die Face Pelletizing of Sticky HME Formulations	272
<i>Daniel Treffer, Gerold Koscher, Johannes G. Khinast</i>	
(648d) Continuous Purification of Artemisinin and Artesunate	273
<i>Andreas Seidel-Morgenstern, Ju Weon Lee, Zoltan Horvath, Elena Horosanskaia, Heike Lorenze, Kerry Gilmore, Daniel Kopetzki, D. Tyler McQuade, Peter H. Seeberger</i>	
(650a) Tablet Coating Scale-up Based on DEM Simulations: Going from Lab- to Industry-Scale	275
<i>Gregor Toschkoff, Rok Dreu, Klaus Knop, Peter Kleinebudde, Andreas Altmeyer, Adrian Funke, Georg Scharrer, Johannes G. Khinast, Ydalisa Mercado-Delgado</i>	
(650b) Scalability and Impact of Freeze/Thaw Conditions on the Drug Substance Quality of Monoclonal Antibody Formulations	277
<i>William Rayfield, Heera Khan, Sunitha Kandula, Matthew H. Flamm, Nihal Tugcu</i>	
(650c) Scale-up of Agitated Drying: Effect of Shear Stress and Hydrostatic Pressure on API Powder Properties	278
<i>Brenda Remy, Weston K. Kightlinger, Eric M. Sauer, Nathan Domagalski, Benjamin J. Glasser</i>	
(650d) Mass Transfer Effects in a Nitro Reduction	279
<i>Steve Richter, Brian Kotecki</i>	
(650e) Kinetics Model for Designing Grignard Reactions in Batch or Flow Operations	280
<i>Shujauddin M. Changi, Sze Wing (Candice) Wong</i>	
(650f) Mixing Modeling Applied to a Mass Transfer Limited Heterogeneous Reaction with Lithium Hydroxide to Scale Between Plant and Lab Which Was Used to Reduce Cycle Time and Solve Issues with Reaction Time Variation	281
<i>Christopher J. Morrison, Qunying Dai</i>	
(668a) A Drop-on-Demand Manufacturing System for the Production of Melt-Based Pharmaceutical Dosage Forms	287
<i>Elçin İçten, Arun V. Giridhar, Zoltan K. Nagy, Gintaras V. Reklaitis</i>	
(668b) Sensor Network Design and Value of Information Analysis for Continuous Pharmaceutical Manufacturing	288
<i>Anshu Gupta, Arun Giridhar, Zoltan K. Nagy, Gintaras V. Reklaitis</i>	
(668c) Modeling of Residence Time Distribution in Continuous Solid Oral Dose Pharmaceutical Manufacturing Processes	290
<i>M. Sebastian Escotet-Espinoza, Amanda Rogers, Fernando J. Muzzio, Marianthi Ierapetritou</i>	
(668d) Determination of Design Space for Oral Pharmaceutical Drugs	292
<i>Kaliopi Chatzizacharia, Dimitris Hatzivramidis</i>	
(668e) Integrated Dynamic Real Time Optimization and Advanced Feedback Control of Continuous Tablet Manufacturing Process	305
<i>Ravendra Singh, Maitraye Sen, Fernando Muzzio, Marianthi Ierapetritou, Rohit Ramachandran</i>	
(680b) Influence of Controlled Fluid Shear on Nucleation Kinetics in Glycine Aqueous Solutions	306
<i>Carol Forsyth, Paul Mulheran, Claire Forsyth, Jan Sefcik</i>	
(680c) Analysis of Crystallization Kinetics Based on CSD Estimates from PAT Tools	307
<i>Huayu Li, Ronald W. Rousseau, Yoshiaki Kawajiri, Martha Grover</i>	
(680f) Heterogeneous Nucleation of APIs on Engineered Biocompatible Polymer Surfaces	308
<i>Li Tan, Rachel M. Davis, Allan S. Myerson, Bernhardt L. Trout</i>	

(680e) Impact of Surface Chemistry on Crystallization of Acetaminophen	309
<i>Hsin-Yun Hsu, M T Harris, Lynne Taylor</i>	
(680d) Development of a Robust API Crystallization in a Multi-Component Solvent Mixture: Using High Throughput Automation As an Enabling Technology to Develop Comprehensive Solubility Maps.....	310
<i>Benjamin Cohen, Michelle Mahoney, Brenda Remy, Jun Qiu, Chris Sfouggarakis, Zhongping Shi, Chenchi Wang</i>	
(739a) The Role of Excipient in Maintaining Process Control and Productivity of Direct Compression Tableting from Laboratory- to Pilot-Scale	311
<i>True Rogers, Kathryn Hewlett, Tejas Gunjikar, Karen Balwinski, Louis Ruocco, Joerg Theuerkauf</i>	
(739b) Scale-up of Wet-Granulation Process: Case Study of a Risk Assessment Based Technology Transfer to Manufacturing Site.....	313
<i>Ganeshkumar Subramanian, Sherif Badawy, Judy Lin, Keirnan Lamarche, Ajit Narang, Timothy Stevens</i>	
(739c) Plant-Wide Hybrid MPC-PID Control of a Continuous Direct Compaction Tablet Manufacturing Pilot-Plant for QbD Based Pharmaceutical Manufacturing	314
<i>Ravendra Singh, Abhishek Sahay, Fernando Muzzio, Marianthi Ierapetritou, Rohit Ramachandran</i>	
(739d) Scaling up a Capsule Filling Process for Inhalation Dosage Forms	316
<i>Marcos Llusá, Johannes G. Khinast, Simon Lawrence, Vittorio Calzolari, Stefano Biserni, Eva Faulhammer</i>	
(739e) A Computational Approach to Predict Lyophilizaiton Performance and Monitor Process Robustness for Biologics.....	320
<i>Xiaodong Chen, Vikram Sadineni, Mita Maity, Venkatramana Rao, Matthew Enterline</i>	
Author Index	