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Topical I: Comprehensive Quality by Design in Pharmaceutical Development and Manufacture

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Monday, October 17, 2011

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8:30 AM-11:00 AM

(#48) - [TI000 QbD Plenary](#)

Sponsored by: *Topical I: Comprehensive Quality by Design in Pharmaceutical Development and Manufacture*
Co-Sponsored by: *Pharmaceuticals (15b)*

12:30 PM-3:00 PM



(#68) - [TI012 Application of Quality by Design In Drug Product Process Development I](#)

Sponsored by: *Topical I: Comprehensive Quality by Design in Pharmaceutical Development and Manufacture*
Co-Sponsored by: *Pharmaceuticals (15b), Process Research and Innovation (12a)*

3:15 PM-5:45 PM

(#138) - [TI014 Application of Quality by Design In Drug Product Process Development II](#)

Sponsored by: *Topical I: Comprehensive Quality by Design in Pharmaceutical Development and Manufacture*

(#160) - [TI011 Implementation of the QbD Paradigm for Packaging Design and Estimation of Product Shelf Life](#)

Sponsored by: *Topical I: Comprehensive Quality by Design in Pharmaceutical Development and Manufacture*
Co-Sponsored by: *Pharmaceuticals (15b)*

Tuesday, October 18, 2011

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8:30 AM-11:00 AM



(#202) - [TI005 Application of Quality by Design In API Process Development](#)

Sponsored by: *Topical I: Comprehensive Quality by Design in Pharmaceutical Development and Manufacture*
Co-Sponsored by: *Pharmaceuticals (15b)*

12:30 PM-3:00 PM

(#332) - [TI006 QbD In Analytical Development](#)

Sponsored by: *Topical I: Comprehensive Quality by Design in Pharmaceutical Development and Manufacture*
Co-Sponsored by: *Pharmaceuticals (15b)*

3:15 PM-5:45 PM



(#407) - [TI002 Round Table Invited Session On QbD: QbD Filings](#)

Sponsored by: *Topical I: Comprehensive Quality by Design in Pharmaceutical Development and Manufacture*
Co-Sponsored by: *Pharmaceuticals (15b)*

6:30 PM-9:30 PM

(#422) - [TI015 Excellence In Integrated QbD Practice](#)

Sponsored by: *Topical I: Comprehensive Quality by Design in Pharmaceutical Development and Manufacture*
Co-Sponsored by: *Pharmaceuticals (15b)*

Wednesday, October 19, 2011

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8:30 AM-11:00 AM



(#432) - [TI008 Applications of PAT In a Manufacturing Setting](#)

Sponsored by: *Topical I: Comprehensive Quality by Design in Pharmaceutical Development and Manufacture*
Co-Sponsored by: *Pharmaceuticals (15b)*

12:30 PM-3:00 PM

(#497) - [TI009 Applications of Multivariate Data Analysis In Pharmaceutical Process Development: Traditional and Advanced Multivariate Methods](#)

Sponsored by: *Topical I: Comprehensive Quality by Design in Pharmaceutical Development and Manufacture*

3:15 PM-5:45 PM

(#607) - [TI007 QbD for Modified Release Dosage Forms](#)

Sponsored by: *Topical I: Comprehensive Quality by Design in Pharmaceutical Development and Manufacture*



Co-Sponsored by: *Pharmaceuticals (15b)*

Thursday, October 20, 2011

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8:30 AM-11:00 AM



(#655) - [TI001 Integrated QbD Approach for Design Space Development Including Real Time Release](#)

Sponsored by: *Topical I: Comprehensive Quality by Design in Pharmaceutical Development and Manufacture*

Co-Sponsored by: *Pharmaceuticals (15b)*

12:30 PM-3:00 PM



(#696) - [TI013 Innovations In Biopharmaceutical Processing: Factory of the Future](#)

Sponsored by: *Topical I: Comprehensive Quality by Design in Pharmaceutical Development and Manufacture*

Co-Sponsored by: *Pharmaceuticals (15b)*

(#701) - [TI003 Model Based QbD In Drug Substance or Drug Product Development](#)

Sponsored by: *Topical I: Comprehensive Quality by Design in Pharmaceutical Development and Manufacture*

Co-Sponsored by: *Pharmaceuticals (15b)*

3:15 PM-5:45 PM

(#752) - [TI004 QbD In Dry Powder Inhaler Development : Multifaceted Powder Characterization for Product Development](#)

Sponsored by: *Topical I: Comprehensive Quality by Design in Pharmaceutical Development and Manufacture*

Co-Sponsored by: *Pharmaceuticals (15b)*

(#754) - [TI010 Scale-up of Pharmaceutical Manufacturing Processes: Toward a QbD Approach](#)

Sponsored by: *Topical I: Comprehensive Quality by Design in Pharmaceutical Development and Manufacture*

Co-Sponsored by: *Pharmaceuticals (15b)*



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QbD Plenary

Monday, October 17, 2011: 8:30 AM

Symphony III (Hilton Minneapolis)

Description: As FDA continues to facilitate the implementation of Quality-by-Design (QbD) for pharmaceutical process/product development and manufacturing in the 21st Century, a great amount of challenges and opportunities are emerging from various aspects across industry, regulatory, and academia. This calls for collaborative efforts among various stakeholders. In this session, leaders and authority in various fields will be invited to present their views to address some of the critical issues and point out some of the future directions for QbD Implementation. Opportunities pertinent to the chemical engineering discipline will be highlighted.

Sponsor: Topical I: Comprehensive Quality by Design in Pharmaceutical Development and Manufacture
Co-Sponsor(s): Pharmaceuticals (15b)

Chair: Huiquan Wu
Email: huiquan.wu@fda.hhs.gov

Co-Chair: Christine Seymour
Email: christine.b.seymour@pfizer.com

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- | | |
|-----------------|--|
| 8:30 AM | Introductory Remarks |
| 8:35 AM | (48a) Quality by Design (QbD) Opportunities, Challenges and Future Direction
Moheb Nasr |
| 9:10 AM | (48b) QbD - It's Not Just for Breakfast Anymore
Paul C. Collins |
| 9:45 AM | (48c) Challenges and Opportunities for Process Systems Engineering Approaches to QbD and Design Space
G. V. Reklaitis |
| 10:20 AM | (48d) Evolution of QbD From a Drug Substance Scientist's Perspective
Timothy J. Watson |

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Application of Quality by Design In Drug Product Process Development I

Monday, October 17, 2011: 12:30 PM

Symphony III (Hilton Minneapolis)

Description: The application of Quality by Design principles is beginning to be well established in the pharmaceutical industry. In particular, the demonstration of the science and risk-based approaches being applied to specific subsets of the drug product design or processing has been discussed intensively during the past several years. Therefore, it is now time to widen the scope of QbD across multiple unit operations, including important aspects of the drug substance. This session invites presentations in which drug products have been designed and developed demonstrating a holistic QbD approach. Papers concerning small and large molecules, including biologics, are being considered. The goal of this session is to demonstrate QbD being applied across multiple unit operations and integrating aspects of the API.



Sponsor: Topical I: Comprehensive Quality by Design in Pharmaceutical Development and Manufacture

Co-Sponsor(s): Pharmaceuticals (15b), Process Research and Innovation (12a)

Chair: Mary T. Am Ende
Email: mary.t.am.ende@pfizer.com

Co-Chair: Johannes Khinast
Email: khinast@tugraz.at

 - indicates paper has an Extended Abstract file available on CD.

- | | | |
|---|-----------------|--|
|  | 12:30 PM | (68a) Practical Applications of QbD for a Parenteral Drug Product
Nancy J. Harper, Venkat Koganti and Gautam R. Ranade |
| | 12:50 PM | (68b) Rational Design and Scale-up of Batch Lubrication Processes for Immediate Release Formulations
Joseph Kushner IV, Daniel O. Blackwood, Bruce C. MacDonald, Mark Polizzi, Francis M. Moore and Bruno C. Hancock |
| | 1:10 PM | (68c) Automation and Control of Drug-On-Demand Technology
Laura Hirshfield, Arun Giridhar, Gintaras V. Reklaitis, Venkat Venkatasubramanian and Michael T. Harris |
|  | 1:30 PM | (68d) Dynamic Flowsheet Modeling and Sensitivity Analysis of Continuous Pharmaceutical Manufacturing
Fani Boukouvala, Vasilis Niotis, Lukasz Mioduszewski, Aditya U. Vanarase, Rohit Ramachandran, Fernando. J Muzzio and Marianthi G. Ierapetritou |
| | 1:50 PM | (68e) Innovative Techniques for Planning Experiments Across Multiple Unit Operations
Kelly Canter and Leonard Perry |
| | 2:10 PM | (68f) Real-Time Process Management and Knowledge Management for Continuous Pharmaceutical Manufacturing |

Girish Joglekar, Arun Giridhar, Gintaras V. Reklaitis and Venkat Venkatasubramanian

See more of this Group/Topical: [Topical I: Comprehensive Quality by Design in Pharmaceutical Development and Manufacture](#)

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Application of Quality by Design In Drug Product Process Development II

Monday, October 17, 2011: 3:15 PM

Conrad A (Hilton Minneapolis)

Description: The application of Quality by Design principles is beginning to be well established in the pharmaceutical industry. In particular, the demonstration of the science and risk-based approaches being applied to specific subsets of the drug product design or processing has been discussed intensively during the past several years. Therefore, it is now time to widen the scope of QbD across multiple unit operations, including important aspects of the drug substance. This session invites presentations in which drug products have been designed and developed demonstrating a holistic QbD approach. Papers concerning small and large molecules, including biologics, are being considered. The goal of this session is to demonstrate QbD being applied across multiple unit operations and integrating aspects of the API.

Sponsor: Topical I: Comprehensive Quality by Design in Pharmaceutical Development and Manufacture

Chair: Mary T. am Ende
Email: mary.t.am.ende@pfizer.com

Co-Chair: Johannes G. Khinast
Email: khinast@tugraz.at

-
- 3:15 PM** [\(138a\) Linkage of Critical Quality Attributes Across a Multi-Unit Operation Process Train Using a High-Shear Wet Granulation Design of Experiment](#)
Diana S. Hou, Julianne Farabaugh, Gina Thompson and David Lavrich
- 3:35 PM** [\(138b\) An Integrated Quality by Design \(QbD\) Approach towards Prediction of Protein Degradation In Heated Mixing Vessels by Computational Fluid Dynamics](#)
Marco Iannuccelli, Siegfried Adam, Daniele Suzzi and Johannes G. Khinast
- 3:55 PM** [\(138c\) Applications \(and Challenges\) of Utilizing QbD, DOE and Other Process Tools In the Transfer of a Sterile Lyophilized Product From One Site to Another - Practical Perspectives](#)
Daniel Kim, Manish Sharma, David Unger and Stelios Tsinontides
- 4:15 PM** [\(138d\) Dissolution of Disintegrating Solid Dosage Forms In a Modified Dissolution Testing Apparatus 2](#)
Shrutiben R. Parekh and Piero M. Armenante
- 4:35 PM** [\(138e\) QbD – More Than Just An Acronym](#)
Sean E. Mackey
- 4:55 PM** [\(138f\) Rethinking Assessment of Raw Material Variability In Drug Product Development Experiments](#)
Stephen L. Conway
- 5:15 PM** [Implementing Quality by Design in Pharmaceutical Salt Selection](#)

Jeremy Merritt, Shekhar Viswanath and Gregory Stephenson

See more of this Group/Topical: [Topical I: Comprehensive Quality by Design in Pharmaceutical Development and Manufacture](#)

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Implementation of the QbD Paradigm for Packaging Design and Estimation of Product Shelf Life

Monday, October 17, 2011: 3:15 PM

Symphony III (Hilton Minneapolis)

Description: Abstract: While drugs and delivery systems become more complex, QbD principles and modeling tools become more essential to be implemented early in the development process to maintain drug products' stability profile throughout the life cycle. These approaches are used to define packaging design parameters and attributes in order to choose appropriate packaging and sorbent options systematically for optimum shelf life stability. This session will include both invited talks as well as submitted papers on adoption of the QbD paradigm for packaging design for different dosage forms and for shelf life estimation while keeping in mind the patients who use its products and physicians who prescribe them. There will be discussions of how a design space can be defined by taking into account complex drug products and delivery systems, users, physicians and stability considerations. Other issues to be discussed include: - How can developers efficiently implement QbD based approaches in packaging design early in the process without extensive and expensive trial and error? - What are the tools that are available to predict and simulate drug formulation, manufacturing and packaging interaction with formulation throughout the life cycle of the product?

Sponsor: Topical I: Comprehensive Quality by Design in Pharmaceutical Development and Manufacture
Co-Sponsor(s): Pharmaceuticals (15b)

Chair: Nahed Mohsen
Email: nmohsen@exponent.com

Co-Chair: Sharmista Chatterjee
Email: sharmista.chatterjee@fda.hhs.gov

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- | | |
|----------------|---|
| 3:15 PM | (160a) QbD Principles for Packaging Design and Stability: A Regulatory Perspective
Sharmista Chatterjee |
| 3:40 PM | (160b) Stability In a QbD Framework
Theodora Kourti |
| 4:05 PM | (160c) Science-Based Stability and Packaging Development Under the Umbrella of QbD
Rey Chern |
| 4:30 PM | (160d) Using QbD to Asses the Factors That Affect Stability and Packaging
Stephanie Krogmeier and Kevin J. Bittorf |
| 4:55 PM | (160e) Designing Pharmaceutical Packaging Using a Product-Packaging Stability Modeling
Seung-yil Yoon |
| 5:20 PM | (160f) Implementation of QbD Paradigm In Sterile Dosage Form Packaging – Some Practical Considerations
Dr. Hemant N. Joshi |

See more of this Group/Topical: [Topical I: Comprehensive Quality by Design in Pharmaceutical Development and Manufacture](#)

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Application of Quality by Design In API Process Development

Tuesday, October 18, 2011: 8:30 AM

Symphony III (Hilton Minneapolis)

Description: Modernization of regulatory processes in the pharmaceutical industry has led to several innovative approaches to risk-based implementation of Quality by Design. Speakers for this session should include topics describing their application of QbD principles with examples of determination of critical process parameters (CPPs), mapping of design spaces (DS), real time process monitoring, and the determination of appropriate control strategies for small and large molecule drug substance processes.

Sponsor: Topical I: Comprehensive Quality by Design in Pharmaceutical Development and Manufacture
Co-Sponsor(s): Pharmaceuticals (15b)

Chair: Kevin D. Seibert
Email: seibertkd@lilly.com

Co-Chair: Sanjeev Katti
Email: sanjeev.katti@genzyme.com

 - indicates paper has an Extended Abstract file available on CD.

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|---|---|
| 8:30 AM | (202a) Application of Design Space Mapping Accounting for Model Uncertainty and Common Cause Variability In Drug Substance Development
Shankar Vaidyaraman, Isabel Figueroa, Sze Wing Wong and Shekhar Viswanath |
| 8:55 AM | (202b) Design Space Development for the Final Recrystallization Process for Axitinib, a Complex Solvating API
Steven M. Guinness, Brian P. Chekal and Gregory S. Steeno |
| 9:20 AM | (202c) Impurity Fate Mapping In the Development of Pazopanib
Michael A. McGuire |
| 9:45 AM | (202d) A Model-Centric Solution to Link Content Uniformity Targets with API Particle Size Specifications and Process for a QbD Exercise
Salvador García-Muñoz, Weili Yu, Mark A. Pinto and Sean K. Bermingham |
|  10:10 AM | (202e) Process QbD Case Study: An Integrated PAT Approach for a Dynamic Pharmaceutical Co-Precipitation Process Characterization and Process Design Space Development
Huiquan Wu and Mansoor A Khan |
| 10:35 AM | (202f) A QbD Approach to Improve Tablet Coating Uniformity
Atul Dubey, Fani Boukouvala, Golshid Keyvan, Richard Hsia, Kostas Saranteas, Dean Brone, Tushar Misra, Marianthi Ierapetritou and Fernando. J Muzzio |

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QbD In Analytical Development

Tuesday, October 18, 2011: 12:30 PM

Symphony III (Hilton Minneapolis)

Description: The same QbD concepts applied to the design and control of manufacturing processes can also be applied to analytical measurement systems. Advantages of doing so include better understanding of method capability, the development of more robust methods, facilitation of manufacturing process improvements, flexibility to make changes to certain operating conditions and the establishment of a framework for evaluating & implementing new technology. Authors are invited to share how they have applied QbD principles in their design and prosecution of measurement systems.

Sponsor: Topical I: Comprehensive Quality by Design in Pharmaceutical Development and Manufacture
Co-Sponsor(s): Pharmaceuticals (15b)

Chair: Jackson D. Pellett
Email: pellett.jackson@gene.com

Co-Chair: John Kauffman
Email: john.kauffman@fda.hhs.gov

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|-----------------|---|
| 12:30 PM | (332a) FDA Perspective On QbD for Analytical Methods
Elaine Morefield |
| 12:55 PM | (332b) Co-Operative Implementation of Quality-by-Design Based Experimentation Between Product Development and Analytical R&D Laboratories - A Recipe for Success!
Graham Shelver |
| 1:20 PM | (332c) Quality by Design for Analytical Methods In Early Development
Jackson Pellett |
| 1:45 PM | (332d) Examples of Applying Quality by Design Principles to Analytical Methods
Kimber Barnett, Timothy Graul and Melissa Hanna-Brown |
| 2:10 PM | (332e) Quality by Design for Particle Size Analysis
Zhigang Sun |
| 2:35 PM | (332f) Analytical QbD for Biologics
Amir Malek, Toby Reichenberg and Dell Farnan |

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Round Table Invited Session On QbD: QbD Filings

Tuesday, October 18, 2011: 3:15 PM

Symphony III (Hilton Minneapolis)

Description: Round Table Invited session on QbD: QbD filings As FDA continues to facilitate the modernization of regulatory processes related to pharmaceutical products in the 21st Century, Quality-by-Design (QbD) approaches for some of the pharmaceutical process/product development and manufacturing have been discussed intensively over the past few years in various forums. Some real-world case studies have been reported in the public literature. However, a risk-based and science-based approach for QbD filling based on the regulatory guidance and guidelines are barely shared and discussed in the public domain. As a first step, this round table discussion session is intended to address this information gap to the possible extent. Inputs from recognized experts and experienced practitioners in the community across academia, industry, and regulatory agencies in the world will be sought to identify commonality among QbD filing. An in-depth Q&A following the presentations should stimulate innovative research and development in the QbD area, and facilitate the QbD implementation in the pharmaceutical sector.

Sponsor: Topical I: Comprehensive Quality by Design in Pharmaceutical Development and Manufacture
Co-Sponsor(s): Pharmaceuticals (15b)

Chair: Christine Seymour
Email: christine.b.seymour@pfizer.com

Co-Chair: Huiquan Wu
Email: huiquan.wu@fda.hhs.gov

 - indicates paper has an Extended Abstract file available on CD.

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|--|---|
| 3:15 PM | (407a) Progress In Quality by Design Implementation In Fda's Office of New Drug Quality Assessment
Christine Moore |
| 3:30 PM | (407b) QbD Approaches for Continuous Manufacturing
Fernando J. Muzzio |
| 3:45 PM | (407c) Experiences with Quality by Design Filings and Prior Approval Inspections
Chris Balducci |
| 4:00 PM | (407d) Quality by Design for Generic Drugs
Yingxu Peng |
| 4:15 PM | (407e) To Be Updated
Stefanie Pluschkel |
|  4:30 PM | (407f) QUALITY by Design (QBD), Biopharmaceutical Manufacture
Kurt Brorson |

4:45 PM [Panel Discussion: Christine Seymour and Huiquan Wu](#)

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Excellence In Integrated QbD Practice

Tuesday, October 18, 2011: 6:30 PM

Symphony III (Hilton Minneapolis)

Description: This special QbD Awards evening session will feature presentations from industry and FDA on the state of integrated QbD practice applied to large or small molecules in development and supply. This session will introduce a new AIChE award on "Excellence in Integrated QbD Practice." This award will recognize the advancement of the practice of QbD including design space development, QRM, and innovative control strategies, including API and formulation. Candidates were nominated by the AIChE QbD community. Speakers will be asked to submit an extended abstract in advance of the meeting to facilitate judging by an awards committee of the best presentation in this session. Following the keynote presentations, the winners of the AIChE awards for Drug Substance, Drug Product, and Excellence in Integrated QbD Practice will be announced, followed by a networking session with light refreshments.

Sponsor: Topical I: Comprehensive Quality by Design in Pharmaceutical Development and Manufacture

Co-Sponsor(s): Pharmaceuticals (15b)

Chair: Eric Ahuja
Email: eric_ahuja@merck.com

Co-Chair: John Lepore
Email: lepore@merck.com

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Applications of PAT In a Manufacturing Setting

Wednesday, October 19, 2011: 8:30 AM

Symphony III (Hilton Minneapolis)

Description: This section focuses on the use of Process Analytical Technologies to monitor, control, and gain a better understanding of Pharmaceutical manufacturing processes at commercial scales (drug products and drug substances (APIs)). Authors are encouraged to submit papers discussing case studies, research, and value-added applications of PAT in manufacturing settings as well as challenges overcome and lessons learned while implementing PAT in pharmaceutical manufacturing operations.

Sponsor: Topical I: Comprehensive Quality by Design in Pharmaceutical Development and Manufacture
Co-Sponsor(s): Pharmaceuticals (15b)

Chair: David Unger
Email: dunger@cehalon.com

Co-Chair: Mark A. LaPack
Email: lapackma@lilly.com

 - indicates paper has an Extended Abstract file available on CD.

- | | |
|-----------------|--|
| 8:30 AM | Welcoming Remarks |
| 8:32 AM | (432a) Taking PAT From the Laboratory to Commercial Manufacturing
Mark A. LaPack, Stephen B. Jeffery, Steven J. Doherty, Joseph R. Martinelli and Christopher L. Burcham |
| 9:00 AM | (432b) Combining Microwave Resonance Technology to Multivariate Data Analysis As a Novel PAT Tool to Improve Process Understanding In Fluid Bed Granulation
Vera Lourenco, Thorsten Herdling, Gabriele Reich, Jose Cardoso Menezes, Dirk Lochmann and Jens Schewitz |
| 9:20 AM | (432c) PAT Application and Validation of Online Particle Sizing Measurement for Controlling a Critical Quality Attribute
Kevin J. Bittorf |
| 9:40 AM | (432d) Experimental and Theoretical Study of Lyophilization From a Packing of Vials: Using of Tunable Diode Laser Absorption Spectroscopy (TDLAS) for Process Monitoring and Model Calibration
Pavol Rajniak, Cassandra Mifkovich and Leon Farber |
| 10:00 AM | (432e) Optical Coherence Tomography: A New PAT-Tool for Fast and Non-Destructive Analysis of Tablet Coating Quality
Daniel M. Koller, Christoph Schinwald, Otto Scheibelhofer, Michael Leitner and Johannes G. Khinast |

- 10:20 AM** [\(432f\) QbD-Driven PAT Applications for Precision Spray-Coating Development and Control](#)
Charles Miller, Bruce T. Thompson, Fan Zhang-Plasket, Patrick T. Schilling, John Higgins, Gert Thureau, Mano Ramasamy and Eric Ahuja
-  **10:40 AM** [\(432g\) Process Analytical Technology for Recombinant Pandemic Flu Vaccines: Viral Ultrastructure, Aggregation, and Binding](#)
De-Hao Tsai, Daniel Lipin, Suvajyoti Guha, Jeremy Feldblyum, Kenneth D. Cole, Kurt A. Brorson, Michael Zachariah, Michael J. Tarlov, Anton P. J. Middelberg and Leonard F. Pease III
- 10:59 AM** [Concluding Remarks](#)

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Applications of Multivariate Data Analysis In Pharmaceutical Process Development: Traditional and Advanced Multivariate Methods

Wednesday, October 19, 2011: 12:30 PM

Symphony III (Hilton Minneapolis)

Description: The application of multivariate latent variable methods (PCA, PLS, LPLS, JYPLS, OPLS ..) has dramatically increased in the pharmaceutical sector after the introduction of concepts like Process Analytical Technology and Quality by Design . Early applications of these techniques were heavily concentrated on pure Chemometrics for the development of soft sensors or monitoring. Applications have since evolved from pure Chemometrics isolated from process engineering, to an integral usage of the data from analytical instruments combined with data and models from the process engineering perspective to derive fundamental process understanding from a system. This session seeks submissions where multivariate methods were used to understand analytical information (NIR, UV, HPLC, NMR, FBRM,...etc) in combination with process engineering principles to support or derive process understanding, ultimately seeking for a valid design space. Examples of this work include (but not limited to): Reaction kinetic studies supported by spectra; drug product and process performance and using intermediate complex analytical data; and scale-up.

Sponsor: Topical I: Comprehensive Quality by Design in Pharmaceutical Development and Manufacture

Chair: Salvador García-Muñoz
Email: Salvador.Garcia-Munoz@pfizer.com

Co-Chair: Jacob Albrecht
Email: jacob.albrecht@bms.com

-
- 12:30 PM** [\(497a\) Transferring Monitoring Models Between Different Scales Through Multivariate Statistical Techniques](#)
Emanuele Tomba, Pierantonio Facco, Fabrizio Bezzo, Salvador García-Muñoz and Massimiliano Barolo
- 12:55 PM** [\(497b\) Implementation of Genetic Algorithms In the Generation of High-Order Statistical Models](#)
Brendan C. Mack, Nathan Domagalski, Daniel Hallow, Michael Fenster, Lindsay Hobson and Jose Tabora
- 1:20 PM** [\(497c\) Understanding the Impact of the Properties of Raw Materials Onto Product Quality Using JR-PLS](#)
Salvador García-Muñoz
- 1:45 PM** [\(497d\) De-Risking Scale-up of a High Shear Wet Granulation Process Using Latent Variable Modeling and near Infrared Spectroscopy](#)
Koji Muteki, Ken Yamamoto, George L. Reid and Mahesh K. Krishnan
- 2:10 PM** [\(497e\) Advancing Quality by Design Through Diverse Uses of Latent Variable Methods In Vaccines and Biologics Manufacturing](#)
Charles Miller, Louis Obando, John Higgins, Gert Thurau and Eric Ahuja

2:35 PM

[\(497f\) Insights Into Lactate Metabolism Through Multivariate Analysis of Cell Culture Bioprocess Data](#)

Huong Le, Santosh Kabbur, Ziran Sun, Luciano Pollastrini, Kevin Johnson, Keri Mills, George Karypis and Wei-Shou Hu

See more of this Group/Topical: [Topical I: Comprehensive Quality by Design in Pharmaceutical Development and Manufacture](#)

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QbD for Modified Release Dosage Forms

Wednesday, October 19, 2011: 3:15 PM

Symphony III (Hilton Minneapolis)

Description: Modified release dosage forms are often designed to maximize a therapeutic effect or minimize side effects to achieve the Quality Target Product Profile (QTPP). Design and development of these dosage forms is focused on meeting the target product performance in the patient, and therefore they are well-suited to the science and risk-based approaches under Quality by Design paradigm. Papers concerning modified release dosage forms, including combination products, are being considered in this session. Submissions that address the unique challenges in designing and developing modified release dosage forms, including advances in measurement tools, and modeling, are welcome.

Sponsor: Topical I: Comprehensive Quality by Design in Pharmaceutical Development and Manufacture
Co-Sponsor(s): Pharmaceuticals (15b)

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 - indicates paper has an Extended Abstract file available on CD.

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|---|----------------|---|
| | 3:15 PM | (607a) CMC Reviewer Expectations for ANDAs Using QbD Approaches
Robert L. Iser |
|  | 3:35 PM | (607b) Mechanistic Models and Computer Software for Quality by Design In Formulation of Modified Release Dosage Forms
Xiao Yu Wu and Yousheng Zhou |
| | 3:55 PM | (607c) Mechanistic Investigation of Drug Release From Asymmetric Membrane Tablets
Mary T. am Ende |
| | 4:15 PM | (607d) QbD for Generic MR Drug Products
Yue (Helen) Teng |
|  | 4:35 PM | (607e) Fluid Bed Coating Process for Modified Release Applications
Orapin Rubino |
| | 4:55 PM | (607f) Implementation of QbD In the Development of a CR Dosage Form
Nancy E. Sever, Michael Brian Mackaplow and Didier LeFebvre |
| | 5:15 PM | (607g) Control Strategy for Manufacturing of Modified Release Capsules: A Regulatory Perspective
Zhigang Sun |

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Integrated QbD Approach for Design Space Development Including Real Time Release

Thursday, October 20, 2011: 8:30 AM

Symphony III (Hilton Minneapolis)


Description: Quality by design approach is best implemented if it is integrated as part of the development process. Case studies demonstrating the integration of QbD into development and the benefits gained from a manufacturing, regulatory, quality and financial perspective will be presented. Improvements or lessons learned from the integration of QbD should be highlighted. The session will also focus on the use of QbD principles as they relate to real time release regulatory applications and approvals.

Sponsor: Topical I: Comprehensive Quality by Design in Pharmaceutical Development and Manufacture
Co-Sponsor(s): Pharmaceuticals (15b)

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Co-Chair: Adam Siegfried
Email: siegfried.adam@rcpe.at

 - indicates paper has an Extended Abstract file available on CD.

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|---|-----------------|--|
|  | 8:30 AM | (655a) Managing Uncertainty In Design Space
Patrick J. Whitcomb and Mark Anderson |
| | 8:50 AM | (655b) An Integrated Design Space Involving All Unit Operations in Tablet Manufacturing
Theodora Kourti |
| | 9:10 AM | (655c) Design Space Definition Using a Variational Bayes' Approximation
Linus Mockus, José Miguel Laínez, Lee E. Kirsch and Gintaras V. Reklaitis |
| | 9:30 AM | (655d) A Data-Driven Modeling Approach Using the Design of Dynamic Experiments Methodology In Calculating the Design Space of Batch Pharmaceutical Processes
Christos Georgakis |
| | 9:50 AM | (655e) Dynamic Design Space As An Integrated Component of Quality by Design
Benoit Igne, Carl A. Anderson and James K. Drennen III |
| | 10:10 AM | (655g) Dissolution Testing of Prednisone and Salicylic Acid Calibrator Tablets At Different Tablet Locations
Anandhavalavan Arulmozhi and Piero M. Armenante |

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Model Based QbD In Drug Substance or Drug Product Development

Thursday, October 20, 2011: 12:30 PM

Symphony III (Hilton Minneapolis)

Description: Understanding the relationships between the manufacturing process and product quality attributes is essential to implementing Quality-by-Design (Qbd), leading to robust processes and improved performance through operation in an appropriate design space. Speakers are invited to present models based on first-principles, statistical (including multivariate), or semi-empirical methods, and their use to develop design spaces during API process and drug product development. Submissions that address model verification or application at scale are particularly welcome.

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Co-Sponsor(s): Pharmaceuticals (15b)

Chair: James Marek
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Co-Chair: Robert E. Yule
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-
- 12:30 PM** [\(701a\) Modeling a Reactive Crystallization with a Reduced Population Balance Equation for Dissolution and Growth to Control Critical Quality Attributes](#)
Daniel Patience, Linli He, Dale Mowrey, Partha Mudipalli, Michael Christie and Roger Bakale
- 12:50 PM** [\(701b\) Model-Based Characterisation of Organic and Aqueous Tablet Film Coating Processes: Parameter Estimation and Risk Management](#)
Salvador García Muñoz, Mary T. Am Ende, Mark A. Pinto and Sean K. Bermingham
- 1:10 PM** [\(701c\) Design Space Verification for Tablet Dosage Form Using Modeling](#)
Mary T. am Ende, Thomas P. Garcia, Kim Vukovinsky, Penelope Butterell, Alex Chueh, Bernd Schuemmelfeder, Vincent E. McCurdy and Daniel Gierer
- 1:30 PM** [\(701d\) New Model-Based Platform for Enhanced Content Uniformity Prediction of Oral Dosage Forms](#)
Salvador García-Muñoz and Weili Yu
- 1:50 PM** [Break](#)
- 1:55 PM** [\(701e\) Computation of Reliabilities for Extent of Reactant Conversion Incorporating Batch Effects with Applications to ICH Q8 Design Space](#)
Brian R. Crump, Rick Lewis, Zifang Guo and John Peterson
- 2:15 PM** [\(701f\) Estimating Reaction Model Uncertainty with Bayesian Markov Chain Monte Carlo](#)
Jacob Albrecht

2:35 PM

[\(701g\) Controllability Analysis of Protein Glycosylation In CHO Cells](#)

Melissa M. St. Amand, Kevin Tran, Devesh Radhakrishnan, Anne S. Robinson and Babatunde A. Ogunnaike

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Innovations In Biopharmaceutical Processing: Factory of the Future

Thursday, October 20, 2011: 12:30 PM

Conrad A (Hilton Minneapolis)

Description: The biopharmaceutical industry is experiencing tremendous change, challenges, and opportunities. These have been brought on by the advent of single use technologies, high titer processes, challenges to tradition by biosimilars, and new tools such as QbD/PAT. These innovations are changing the way biopharmaceuticals are developed, produced and characterized which can positively impact process development capabilities, timelines, cost structures, and even the entire manufacturing strategy. This session invites papers on the development and application of single use technologies in the upstream and downstream areas, advances in bioprocess monitoring and control, new approaches to harvest and downstream processes including considerations of high titer processing, and alternative manufacturing schemes such as continuous processes to bring about more efficient and cost effective therapeutics.

Sponsor: Topical I: Comprehensive Quality by Design in Pharmaceutical Development and Manufacture

Co-Sponsor(s): Pharmaceuticals (15b)

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Email: cardoso.menezes@ist.utl.pt

- indicates paper has an Extended Abstract file available on CD.

- 12:30 PM** [\(696a\) Use of Single-Use Technologies In Downstream Purification of Mabs - A Case Study](#)
Venkatesh Natarajan
- 12:51 PM** [\(696b\) Alternative Approaches to Cell Culture Harvests](#)
Gregory Frank
- 1:12 PM** [\(696c\) Scale and Bioreactor Design Translation for Rocking Bag Bioreactors](#)
John Bowers
- 1:33 PM** [\(696d\) Control of Virus Contamination In Cell Culture](#)
Gregory S. Stimpfl
- 1:54 PM** [\(696e\) PAT Applications In Recombinant Protein Production Cell Culture Processes](#)
Veronica Carvalhal
- 2:15 PM** [\(696f\) At-Line NIR Spectroscopy As a Simple and Effective PAT Monitoring Technique In Mab Cultivations During Process Development and Manufacturing](#)
Christian Hakemeyer, Silke Werz, Jose Cardoso Menezes, Francisca Folque, Gledson Jose and Ulrike Strauss



2:36 PM

(696g) Challenges, Opportunities, and Scientific Aspects of Implementing PAT In
Biopharmaceuticals

Huiquan Wu and Mansoor A Khan

See more of this Group/Topical: [Topical I: Comprehensive Quality by Design in Pharmaceutical Development and Manufacture](#)

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Innovations In Biopharmaceutical Processing: Factory of the Future

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Sponsor: Topical I: Comprehensive Quality by Design in Pharmaceutical Development and Manufacture

Co-Sponsor(s): Pharmaceuticals (15b)

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2:36 PM

(696g) Challenges, Opportunities, and Scientific Aspects of Implementing PAT In
Biopharmaceuticals
Huiquan Wu and Mansoor A Khan

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Scale-up of Pharmaceutical Manufacturing Processes: Toward a QbD Approach

Thursday, October 20, 2011: 3:15 PM

Symphony III (Hilton Minneapolis)

Description: Abstract: Scale-up of any pharmaceutical manufacturing process entails a skilful combination of art experience, science and engineering. Combination of a few well-established tools such as statistical methods (such as Design of Experiments (DOE)), PAT process monitoring tools, and quantitative modelling tools (such as CFD, DEM, PBE, etc.) may provide some advantages over the traditional methods of process scale-up in the pharmaceutical sector. Advancement in this direction could help to cause a paradigm shift from "Quality by Testing" to "Rational Process Design" within the spirit of the QbD initiative. Some open questions include but are not limited to: (1) how various tools aforementioned, if used individually, can be applied to or sustained for process scale-up; (2) how the pharmaceutical sector should develop a more innovative use of the existing tools. In this session, we seek papers that help to answer these two questions. Papers that focus on the use of quantitative tools (e.g. DOE, PAT, modelling, and theory) toward scaling-up pharmaceutical processes and linking to QbD implementation in the pharmaceutical sector are particularly encouraged. The session will provide a forum for open exchange of ideas or innovative use of tools for successful scale-up of the pharmaceutical processes. Papers concerning all areas of pharmaceutical scale-up, from small molecules to biologics, from drug substances to drug products, are being considered.

Sponsor: Topical I: Comprehensive Quality by Design in Pharmaceutical Development and Manufacture
Co-Sponsor(s): Pharmaceuticals (15b)

Chair: Huiquan Wu
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Co-Chair: Joe Hannon
Email: joe.hannon@scale-up.com

- 3:15 PM** [\(754a\) Application of a Joint Risk Assessment Platform to Identify Suitable Drug Substance and Drug Product Process Options](#)
 Joshua D. Engstrom, Jonathan Brown, Olav Lyngberg, Lindsay Hobson and San Kiang
- 3:35 PM** [\(754b\) Improved Process Understanding Through Implementation of QbD Methodologies](#)
 Shane T. Grosser, Aaron Moment, Angela Spartalis, George Zhou and Paul Fernandez
- 3:55 PM** [\(754c\) Harnessing Computational Fluid Dynamics \(CFD\) to Guide Reliable Scale-up of Pharmaceutical Processes](#)
 Ann M. Czyzewski, Hsien-Hsin Tung, Shailendra V. Bordawekar and Nandkishor K. Nere
- 4:15 PM** [\(754d\) Model-Guided Quality by Design: A Case Study On a Pharmaceutical Final Intermediate](#)
 Nathaniel D. Kopp, Zhongmin Xu, James S. Bergum, Thomas L. Laporte, Jose E. Tabora and Lori A. Spangler
- 4:35 PM** [Break](#)
- 4:45 PM** [\(754e\) Incorporating Computational Fluid Dynamics Methods for Quality by Design Framework for Exploring Design Space of a Fermentor](#)

Sravan Kumar Nallamothe and R. Muralikrishnan

5:05 PM [\(754f\) Scaling up Strategy for Continuous Powder Mixing Process](#)
Yijie Gao, Fernando. J Muzzio and Marianthi G. Ierapetritou

5:25 PM [\(754g\) Modified Application of Johanson's Model towards Roller Compaction](#)
Jasmine M. Rowe and John R. Crison

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