2011 CONFERENCE SERIES

Baltimore, Maryland

Plus Optional
One-Day Workshop:

Modeling of Unit Operations in Solid Dosage Product Manufacture

June 14, 2011

Critical Path Research for Process Scale-Up and Stability

June 15-16, 2011

University of Maryland Baltimore School of Pharmacy

Conference produced by

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NIPTE The National Institute for Pharmaceutical Technology and Education
Improving quality and lowering costs of pharmaceuticals

Conference co-sponsored by

aaps American Association of Pharmaceutical Scientists

ABOUT THE CONFERENCE

A goal of FDA's Center for Drug Evaluation and Research is to implement the International Conference on Harmonization (ICH) guidances Q8, Q9, and Q10 covering drug product development (through Quality by Design), risk management, and quality management systems. The ICH guidances are aligned with CDER's Critical Path Initiative, Moving Manufacturing into the 21st Century, to develop new manufacturing approaches that improve pharmaceutical manufacturers' ability to assess and improve product quality.

Quality by Design (QbD), a component of the ICH Q8 guidance, offers the possibility of improving product quality. Realization of the QbD paradigm requires a systematic framework for determining the design space for specific operations and their processes as a whole. Such a framework will facilitate process innovation, continuous quality improvement and reduce manufacturing costs. Further, the risks of ending up with an undesired and unstable product due to process scale-up will be addressed systematically.

To demonstrate the use of QbD principles in formulation design faculty and students from NIPTE member institutions and scientists from the FDA in collaboration with scientists from the pharmaceutical industry have developed two case studies that can guide similar QbD based development processes. One of the case studies involves a solid dosage product and the other a small molecule parenteral product.

The main objectives of these case studies were to:

1. To demonstrate a systematic process for QbD based process development;
2. Implement and/or refine existing models of critical unit operations to facilitate definition of design spaces and scale-up of pharmaceutical processes directly from the laboratory or pilot plant to the desired scale of manufacturing; and
3. Develop rigorous methodologies that can be used to generate a preliminary design that is compatible with the time frame of the development process, and refine the design during the post-approval phase.

At this conference, NIPTE faculty and their collaborators will:

1. Present short courses on model-based design of solid dosage formulations and lyophilized formulations based on the research findings;
2. Present the results of the two case studies;
3. Seek input from scientists and engineers from industry, regulatory agencies and academia on the research conducted so far;
4. Identify what works, what does not work and the gaps and issues in research and product development using QbD principles;
5. Develop a strategy for incorporating the input received and planning a path forward to advance QbD based process development in the pharmaceutical industry.

WHO SHOULD ATTEND?

All pharmaceutical personnel involved in process development and engineering, process improvement, process optimization, implementation of new technology, implementation of PAT and QbD and those who are interested in learning how to use state-of-the-art pharmaceutical science and technology to speed up process development and to develop robust manufacturing processes.

WHY ATTEND?

To get perspective on PAT and QbD application in the pharmaceutical development process

ABOUT THE PRESENTERS

Carl Anderson, PhD – Dr. Anderson is an assistant professor of pharmaceutical sciences in the Mylan School of Pharmacy and Graduate School of pharmaceutical sciences. At Duquesne University he leads a research group investigating industrial pharmaceutical applications of analytical technology, pharmaceutical applications of chemical imaging, and best practices in risk-based manufacturing. He is currently a member of ASTM E.55 Pharmaceutical Application of PAT.

Hamid Arastoopour, PhD – Dr. Arastoopour is the Max McGraw Professor of Energy/Environment/Economics (E3). He has served on the Editorial Board of the *Powder Technology Journal* since 1990.

Prabir Basu, PhD – Dr. Basu is the Executive Director of the National Institute for Pharmaceutical Technology and Education (NIPTE). Prior to joining Purdue University in 2004, Dr. Basu worked in the pharmaceutical industry (Searle, Pharmacia and Pfizer) for over 20 years in various capacities in research, development, manufacturing, and outsourcing. Dr. Basu is a Fellow of AIChE.

Robin Bogner, PhD – Dr. Bogner is an Associate Professor of Pharmaceutics at the University of Connecticut in its School of Pharmacy. Dr. Bogner is on the Editorial Boards of *Pharmaceutical Development and Technology, American Journal of Pharmaceutical Education*.

Jon Clark, BS, MS – Mr. Clark is the Associate Director for Policy Development and GMP in the CDER Office of Pharmaceutical Science. He joined the FDA in 1992 after 12 years experience working in industry. He is engaged in the Pharmaceutical Quality CGMPs for the 21st Century program, the Product Quality Research Institute (PQRI) and ICH. He frequently represents CDER's drug quality policy in public speaking engagements and working groups.

Alberto Cuitiño, PhD – Dr. Cuitiño is a Professor of Mechanical and Aerospace Engineering at Rutgers University. Professor Cuitiño is currently the editor of Mechanics (a publication of the American Academy of Mechanics) and also the applied mechanics subject editor for the Latin American Applied Research.

James K. Drennen, III, PhD – Dr. Drennen is presently Associate Dean for Research and Graduate Programs in the Mylan School of Pharmacy and Graduate School of Pharmaceutical Sciences at Duquesne University. He is also a co-founder and Director of the Duquesne University Center for Pharmaceutical Technology. In addition, Dr. Drennen is a founding partner in the consulting company Strategic Process Control Technologies, LLC and is Editor-in-Chief of the *Journal of Pharmaceutical Innovation*. Dr. Drennen was the recipient of the first Buchi NIR Award in September 2001.

Nancy Harper, PhD – Dr. Harper is a Research Fellow in the Pharmaceutical Development / Life Cycle Management group at Pfizer Global R&D in Groton, CT. During her 28-year career at Pfizer, she has been responsible for the overall product development of parenterals, inhalation products, oral liquids, and topical dosage forms for human or veterinary use. Her efforts have involved all aspects of development from early clinical phase to commercialization and post-launch support, including NCE's as well as product enhancements. Dr. Harper's current emphasis is on late-stage development and technical regulatory strategy, with particular focus on the application of QbD principles to product development.

ABOUT THE PRESENTERS

Mansoor A. Khan, PhD – Dr. Khan is the director of product quality research in the Center for Drug Evaluation and Research at the US Food and Drug Administration. Prior to joining FDA, Khan was a professor of pharmaceutics and director of graduate program in the School of Pharmacy at Texas Tech University Health Sciences Center. He is the chair-elect of Pharmaceutics and Drug Delivery section of the American Association of Pharmaceutical Scientists (AAPS), and has been recognized as an AAPS fellow. He serves on the editorial board of Pharmaceutical Technology, the *Journal of Clinical Research and Regulatory Affairs*, and the *Journal Critical Reviews in Therapeutic Drug Carrier Systems*.

Lee E. Kirsch, PhD – Dr. Kirsch is Professor of Pharmaceutics and Biochemical and Chemical Engineering at the University of Iowa. He was an industrial scientist and group leader for 12 years at Lilly Research Laboratories before joining the faculty at Iowa in 1995. He was the editor of the PDA *Journal of Pharmaceutical Science and Technology* from 2000 to 2008 and is currently the editor-in-chief of the AAPS *PharmSciTech*.

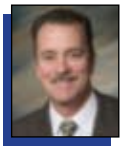
James Litster, PhD – Dr. Litster holds a joint appointment as Professor of Chemical Engineering and Professor of Industrial and Physical Pharmacy at Purdue University, USA. Prior to his appointment in 2007, he spent 20 years at The University of Queensland, most recently as Head of the School of Engineering (2005-2007) and Director of the Particle and Systems Design Centre (2001-2007).

Linas Mockus, PhD – Dr. Mockus is currently Senior Research Scientist at Purdue University where he is actively supporting QbD projects. From 2004 to 2008, he was with Allergan as Senior Project Engineer and in 1997 he was with Pfizer as Senior Development Engineer.

Christine Moore, PhD – Dr. Moore is the Deputy Director for Science and Policy in CDER's Office of New Drug Quality Assessment (ONDQA). She has been in the forefront of developing Quality by Design Topics within FDA and served as a member of the ICH Expert Work Group for Q8(R). Her background is in chemical and biochemical engineering with degrees from Northwestern University and Massachusetts Institute of Technology.

Eric Munson, PhD – Dr. Munson is the Patrick DeLuca Endowed Professor in Pharmaceutical Technology at the Department of Pharmaceutical Sciences, College of Pharmacy, University of Kentucky. Prior to joining the University of Kentucky, Dr. Munson was a Professor at the Pharmaceutical Chemistry Department at the University of Kansas.

Fernando Muzzio, PhD – Dr. Muzzio is Professor of Chemical Engineering at Rutgers University, New Jersey and Director of the Engineering Research Center at Rutgers on Structured Organic Particulate Systems.



Steven Nail, PhD – Dr. Nail is currently a Senior Baxter Research Scientist in the R&D organization of Baxter Pharmaceutical Solutions, Bloomington. Dr. Nail was a Professor in the School of Pharmacy at Purdue from 1999 to 2006 and is a Fellow of the American Association of Pharmaceutical Scientists. In 2007, he received the AAPS Research Achievement Award in Pharmaceutical Technology.

ABOUT THE PRESENTERS

Michael Pikal, PhD – Dr. Pikal is the Pfizer Distinguished Chair in Pharmaceutical Technology at the University of Connecticut. Dr. Pikal is a Fellow of the American Association of Pharmaceutical Scientists. He also received the AAPS Research Achievement Award in Pharmaceutical Technologies in 2001 and received the 2009 AAPS Distinguished Scientist Award.

G.V. Rex Reklaitis, PhD – Dr. Reklaitis is Edward W. Comings Professor of Chemical Engineering, Purdue University. He is editor in chief of the Elsevier journal, Computers & Chemical Engineering, and on the editorial boards of several computing and systems oriented publications. He is a fellow of AICHE and has received national awards from AICHE and ASEE for his contributions to process systems engineering.

Raj Suryanarayanan, PhD – Dr. Suryanarayanan is Professor of Pharmaceutics in the College of Pharmacy, University of Minnesota. He also holds the William and Mildred Peters Endowed Chair in Pharmaceutics. He is a fellow of the AAPS and is the past-chair of the Teachers of Pharmaceutics Section of the American Association of Colleges of Pharmacy.

Helen N. Winkle, BA – Ms. Winkle has been director of the Office of Pharmaceutical Science since 2000. In this role, she is responsible for overseeing the activities of the Office of Generic Drugs, the Office of New Drug Quality Assessment, and the Office of Biotech Products, all of which are responsible for the quality review of all market pharmaceutical products. Ms. Winkle also manages the laboratory activities of the Center for both small molecules and proteins. During her tenure as director, she has initiated a number of innovative changes in the process for regulating pharmaceutical product quality, including facilitating PAT (process analytical technologies), promoting the concept of quality by design, and streamlining the processes for regulatory decision-making. She has contributed significantly in influencing the scientific programs in the areas of CMC, microbiology and biopharmaceutics for brand, biotech and generic drugs, and has focused on revitalizing the Center's research programs, including ensuring that research projects are directed at those issues which are most relevant in meeting regulatory decision-making requirements.

Janet Woodcock, MD – Dr. Woodcock is the Director, Center for Drug Evaluation and Research. She previously held various positions within the Office of the Commissioner, FDA as Deputy Commissioner and Chief Medical Officer, and she shared responsibility and collaborated with the Commissioner in planning, organizing, directing, staffing, coordinating, controlling, and evaluating the agency's scientific and medical regulatory activities in order to achieve the mission of FDA. She also served as the Deputy Commissioner for Operations and Chief Operating Officer, FDA, where she was responsible for overseeing Agency operations and cross-cutting regulatory and scientific processes at FDA.

Lawrence Yu, PhD – Dr. Yu is the Director for Science at the Office of Generic Drugs, Food and Drug Administration. He is also adjunct Professor of Pharmaceutical Engineering at the University of Michigan and adjunct Professor of Pharmaceutical Sciences at the University of Maryland. Prior to joining the FDA, Dr. Yu had worked at Pfizer (Upjohn) and GlaxoWellcome for 8 years. Dr. Yu joined the FDA in 1999 and has served as Team Leader, Deputy Division Director, and Division Director.

CONTINUING EDUCATION

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Learning Objectives for Pre-Conference Workshop: Modeling of Unit Operations in Solid Dosage Product Manufacture

At the completion of this knowledge-based activity, the participant will be able to:

1. Describe techniques in the manufacture of typical solid oral dosage form products appropriate for modeling the principal unit operations, such as granulation, fluidized bed drying, milling, powder blending, roller compaction and tablet compression.
2. Discuss how well-planned modeling efforts can significantly reduce expensive and time-consuming experimental work while increasing process understanding.

Learning Objectives for Conference: Critical Path Research for Process Scale-up and Stability

At the completion of this knowledge-based activity, the participant will be able to:

1. State the benefits of implementation of Quality by Design (QbD) approach and role of fundamental research in successful implementation of QbD according to the Food and Drug Administration (FDA).
2. Describe what the FDA believes are the roadblocks and issues in the implementation of QbD.
3. State the reasons why the FDA believes that developing realistic case studies where QbD principles have been used to design a formulation can benefit the industry and the FDA.
4. Discuss what is FDA doing to make it easier to implement QbD for new drugs and for generics.
5. State how academic members and FDA scientists have gone about applying QbD principles to the design of solid dosage forms and small molecule parenteral formulations.
6. Evaluate what has worked well in QbD case studies and what these case studies might be lacking.
7. Discuss the ways to move forward with making QbD implementation easier for new and generic drug development?
8. Determine how to design formulations for solid dosage forms and small molecule parenterals early in development using a systematic approach and by using models wherever feasible to develop more robust manufacturing processes.

Keywords: Food and Drug Administration (FDA); Compounding; Regulation
Total credit hours: 12.75 hours (1.275 CEU) – knowledge

AGENDA

Pre-Conference Workshop: Modeling of Unit Operations in Solid Dosage Product Manufacture

Tuesday, June 14, 2011
Moderators: Robin Bogner, PhD • Rex Reklaitis, PhD • Lee Kirsch, PhD • James Drennen, Ph.D

9:00	Conference Commencement
12:00-1:00	Lunch
5:00	Conference Wrap-up

The Quality by Design approach to pharmaceutical development as stipulated in Q8(R2) is a "systematic process which relates mechanistic understanding of material attributes and process parameters to drug product CQAs." Mathematical modeling of unit operations is an essential part of this process. During the pre-conference workshop you will be learn state-of-the-art techniques appropriate for modeling the principal unit operations involved in the manufacture of typical solid oral dosage form products. The unit operations that will be covered include wet granulation, fluidized bed drying, milling, powder blending, roller compaction, and tablet compression. Examples of models considered will span the range from purely mechanistic such as Kunii-Levenspiel type models based on hydrodynamics and kinetics for fluidized bed drying to semi empirical such as Johanson's rolling theory for roller compaction. Hybrid models for milling, such as population balances coupled to breakage kernels that are determined empirically, will be included as well. Using real world examples, we will demonstrate how in-silico modeling efforts can significantly reduce experimental effort while at the same time increasing process understanding.

AGENDA

Critical Path Research for Process Scale-up and Stability

Wednesday, June 15, 2011

Morning Session: Moderator – Rex Reklaitis, PhD

8:30-9:00	Role of Academic Research in Science-Based Approach to Implementation of QbD	Janet Woodcock, MD
9:00-9:30	Roadblocks & Issues to implementation of QBD	Helen Winkle
9:30-10:00	Case Study Strategy – What the FDA Hopes to Accomplish	Jon Clark
10:00-10:30	NIPTE Organization and its Membership Status	Prabir Basu, PhD
10:30-11:00	Break*	
11:00-11:30	Implementation of Quality by Design for New Drugs	Christine Moore, PhD
11:30-12:00	Question-Based Review and the Updates from the Office of Generic Drugs	Lawrence Yu, PhD
12:00-1:00	Lunch*	

Afternoon Session: Track #1 Moderator – Robin Bogner, PhD

Presentations on Research Results and Conclusions of the Gabapentin Example

1:00-1:30	Background and Scientific Needs	Mansoor Khan, PhD
1:30-2:00	Integrating Stability Issues	Lee Kirsch, PhD
2:00-2:30	Panel Discussion on Stability Issues	Lee Kirsch, PhD Raj Surynarayanan, PhD Eric Munson, PhD
2:30-2:45	Break*	
2:45-3:30	Dynamic Risk Assessment	Carl Anderson, PhD
3:30-5:00	Unit Operations Modeling	Jim Litster, PhD Fernando Muzzio, PhD James Drennen, PhD Alberto Cuitiño, PhD Hamid Arastoopour, PhD
5:00-6:00	Networking Reception	

Afternoon Session: Track #2 Moderator – Prabir Basu, PhD

Short Course on Formulation Design and Process Development of Lyophilized Products

Mike Pikal and Steve Nail, two of the most distinguished scientists and researchers on the science of freeze drying will introduce the basics of the physics and process engineering aspects of Formulation Design and Process Development of Lyophilized product formulation aspects etc. along with their personal examples and anecdotes of more than 60 years of practical experience.

Thursday, June 16, 2011

Morning Session: Track #1 Moderator – Lee Kirsch, PhD

8:30-10:00	Design Space Models with Scaling and Stability	Rex Reklaitis, PhD Robin Bogner, PhD Linas Mockus, PhD
10:00-10:30	Break*	
10:30-12:00	**Breakout Sessions – lessons learned, unanswered questions, potential pitfalls** *Participants will be divided into two or more groups to provide feedback on the research being discussed, then report the results of their discussions during Breakout Session Presentations Thursday afternoon.*	
	Breakout Session # 1	Facilitators: Lee Kirsch, PhD James Drennen, PhD Robin Bogner, PhD
	Breakout Session # 2	Facilitators: Rex Reklaitis, PhD Eric Munson, PhD Carl Anderson, PhD
12:00-1:00	Lunch*	

AGENDA

Critical Path Research for Process Scale-up and Stability

Morning Session: Track #2 Moderator – Prabir Basu, PhD

8:30-10:00 **Presentations on Research Results and Conclusions on QbD for Small Molecule Parenteral Project**

Project Scope	Mike Pikal, PhD Steve Nail, PhD
Risk Analysis	Nancy Harper, PhD
Experimental Plan and Results	Steve Nail, PhD Mike Pikal, PhD

10:00-10:30 Break*

10:30-12:00 **Breakout Sessions – lessons learned, unanswered questions, potential pitfalls**

Participants will be divided into two or more groups to provide feedback on the research being discussed, then report the results of their discussions during Breakout Session Presentations Thursday afternoon.

Breakout Sessions #1 and #2	Facilitators: Steve Nail, PhD Mike Pikal, PhD Nancy Harper, PhD

12:00-1:00 Lunch*

Afternoon Session Track #1

1:00-2:30 Breakout Session Presentations — Track 1 Facilitators

Afternoon Session Track #2

1:00-2:30 Breakout Session Presentations — Track 2 Facilitators

Conference Wrap Up
Combined Session – NIPTE and FDA Representatives

2:30-3:30 Next Steps

3:30-4:00 Wrap-up

*Indicates non-educational activities

POSTER SESSION

Graduate and Post-Doctoral Students at the NIPTE universities who were involved in the two QbD case studies will present posters of their research at this conference. The posters will present detailed results of various aspects of the NIPTE/FDA QbD projects. Additional posters will feature other projects from NIPTE faculty that directly impact our advancements in QbD.

REGISTRATION

Critical Path Research for Process Scale-up and Stability

and

Pre-Conference Workshop – Modeling of Unit Operations in Solid Dosage Product Manufacture

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621 W. Lombard Street
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http://www.fincsvc.umaryland.edu/travel/hotels.cfm

For additional information, contact Pharma Conference Inc (830) 896-0027 Fax: (830) 896-0029 or e-mail: contactus@pharmaconference.com.
Our office hours are 8:00 a.m. to 4:00 p.m. Monday through Thursday and 8:00 a.m. to 1:00 p.m. Friday central USA time.

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