

# 2011 CONFERENCE SERIES



## Bethesda, Maryland

### **Operational Excellence: A Lifecycle Approach to Assuring Drug Quality**

**April 5-6, 2011**

**Hyatt Regency Bethesda**

Conference produced by



Conference sponsored by



# ABOUT THE CONFERENCE

The pharmaceutical industry is undergoing some of the most dramatic changes in its history. Market forces now demand greater efficiency and attention to product quality at every point in the drug life cycle.

Recent failures, consent decrees and product recalls have shown the danger of separating quality from efficiency in managing and running pharmaceutical R&D and manufacturing operations.

Learn how your peers are using the tools of operational excellence, process analytical technology (PAT) and Quality by Design (QbD) to address both efficiency and quality, thereby minimizing cost, increasing efficiency and improving product quality throughout the R&D and manufacturing phases.

***At this conference, you will hear from:***

- Leaders from FDA's review and inspection arms, who will discuss evolving regulator expectations and how to anticipate requirements to eliminate noncompliance and reduce delays;
- Top managers from leading pharmaceutical companies, who will demonstrate the ROI and financial benefits of embracing new technologies and methods and establishing a continuous improvement culture;
- Experts who are leading pharmaceutical operational excellence programs in R&D and manufacturing, who will share lessons learned and best practices;
- Experts from other industries that have surpassed six sigma in their quality processes, who will share concrete lessons that can be applied to pharmaceutical operations, blazing a trail for pharmaceutical op ex programs;
- Independent experts who are benchmarking the drug industry's current operational excellence efforts in both research and manufacturing, on areas that need improvement and lessons from ongoing pharma op ex programs.

Unlike many programs, this one will break away from theory, offering practical and actionable lessons for anyone who wants to advance professionally and achieve measurable improvements in short- and long-term financial performance within their team, department, facility, or company.

## WHO SHOULD ATTEND?

All pharmaceutical personnel involved in PAT or QbD or with the desire to improve their knowledge of the manufacturing process

All Quality Assurance Personnel from technicians to VPs

## WHY ATTEND?

To get FDA's perspective on where PAT or QbD will be applicable in the manufacturing process.

Register online at [www.pharmaconference.com](http://www.pharmaconference.com)

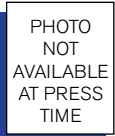
# ABOUT THE PRESENTERS



**Michalle Adkins, BS, ME** – Ms. Adkins, a Senior Industry Consultant at Emerson Process Management, has 20 years of pharmaceutical industry related experience including 13 years with Merck & Co. Inc. In her consulting engagements, Ms. Adkins uses her varied experiences including project management, planning, manufacturing, automation, and engineering. She has worked with several top pharmaceutical and biotech companies providing consulting services in project justification and definition, system planning, operations improvement and front end engineering and design definition.



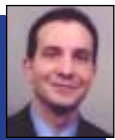
**Ali Afnan, PhD** – Dr Afnan, is the president of Step Change Pharma, Inc. which offers a range of consultancy services targeting the development and delivery of Pharmaceutical Manufacturing Excellence. Dr. Afnan was recruited in May 2003 by CDER, FDA to join the Agency's PAT and Drug Product Quality initiatives. He was a member of the PAT steering team and a co-author of the PAT Guidance. He had also been a member of the core team responsible for drafting, and finalizing, the most recent Guidance from FDA on process Validation. He left the FDA in March 2010.



**David Estell** – Biographical information not available at press time. Check back for updates.



**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.



**Thomas Friedli, PhD** – Dr. Friedli has been a member of the Faculty of the Institute of Technology Management at the University of St. Gallen (HSG) in Switzerland since 2000. In 2004, he became Privatdozent and Assistant Professor at the Institute of Technology Management. Dr. Friedli's main focus is the management of Manufacturing Enterprises. His area of expertise is in Operational Excellence in the Pharmaceutical Industry, Collaboration Management, Management of Industrial Services, and Quality and Process Management.



**Ted Fuhr, BS, MBA** – Mr. Fuhr is an Associate Principal in McKinsey & Company's Operations Strategy Practice with a focus on operations, quality, product development and strategy in the pharmaceutical and medical device industries. He works with clients to help them benefit from the application of world-class operations and product development principles. Prior to joining McKinsey, Mr. Fuhr was employed by Pfizer in various product development and supply chain management leadership roles. Prior to Pfizer, he managed the operations of an OTC pharmaceutical company, Murad, and was a nuclear trained submarine officer in the U.S. Navy.

# ABOUT THE PRESENTERS



**Brian Hasselbalch, BS** – Mr. Hasselbalch leads the development of CGMP guidance and policy as well as overseeing the development of guidance, procedural, and policy documents that define the CGMP regulations and other anti-adulteration provisions of the Federal Food, Drug, and Cosmetic Act in CDER's Office of Compliance. Mr. Hasselbalch began his FDA career as a field investigator specializing in drug manufacturing inspections in California and overseas. He joined the Center for Drug Evaluation and Research in 1995 as a compliance officer and, in addition to guidance work, evaluates regulatory cases and trains FDA field and center personnel on the CGMP regulations and related guidance.



**Melissa B. Herkt, BS** – Ms. Herkt is President and COO of the PlantWeb Solutions Group of Emerson Process Management. In this role, she leads the team providing operations support to the Group comprising Process Systems and Solutions, Power and Water Solutions, and Asset Optimization. Herkt is the former President of Process Systems and Solutions, where her responsibility included the management of all aspects of the division that provides process improvement solutions to the power, pulp and paper, chemical, hydrocarbon and energy, life sciences, and food and beverage industries. Before coming to Emerson in 2004, Ms. Herkt was Vice President of Global Project Management for GlaxoSmithKline.



**Peter Martin, PhD** – Dr. Martin is Vice President and Invensys Fellow, Invensys Operations Management. He joined The Foxboro Company in the 1970's and has worked in a variety of positions in training, engineering, product planning, marketing and strategic planning. Dr. Martin left Foxboro to become Vice President at Intech Controls and also at Automation Research Corporation before returning to Invensys in 1996. Since his return he had been Vice President of Marketing for Foxboro and Chief Marketing Officer for Invensys Manufacturing and Process Systems prior to moving into his current position.



**Justin McCue, PhD** – Dr. McCue is a Principal Engineer in the Process Biochemistry Department at Biogen Idec, Inc. For the past seven years, he has been involved in purification process development, process technology transfer, CMC team leadership, and new technology assessments for the production of recombinant biopharmaceuticals. Dr. McCue has led the downstream process development activities for the clinical manufacture of several recombinant monoclonal antibodies, Fc-fusion proteins and an Adenovirus. He is currently in charge of the downstream process development and process validation efforts for two programs in late stage clinical studies. During his time at Biogen Idec, Dr. McCue has managed a group of two to five Scientists, Associate Scientists and Engineers, and served as leader for interdepartmental CMC teams. Prior to joining Biogen Idec, Inc., Dr. McCue worked at Millipore Corporation.



**Paul McKenzie, PhD** – Dr. McKenzie leads the Pharmaceutical Development & Manufacturing Sciences (PDMS) organization. PDMS is responsible for the development, clinical supply, marketed product support, and technical life-cycle management of chemical and biologic pharmaceutical products. He has both R&D and supply chain experience working with both large and small molecules. Prior to this role, Dr. McKenzie led the BIO PD & MPS organization as Vice President, Biologics Pharmaceutical Development and Marketed Product Support. He came to Johnson & Johnson from Bristol-Myers Squibb (BMS), where he was Vice President and General Manager of the BMS large-scale cell culture facility in Massachusetts. Dr. McKenzie was previously Vice President, Technical Transfer Governance Committee, at BMS, and before that, Executive Director of Process Research & Development & Technology Transfer; and Director, Pilot Plant Operations, with BMS.



**Grace E. McNally, BS** – Ms. McNally is a Compliance Officer in CDER's Office of Compliance, Division of Manufacturing and Product Quality, Case Management Team. She reviews domestic cGMP cases and is active on several Guidance working groups dealing with process validation, cGMPs, combination products and manufacturing science. Ms. McNally began her FDA career in Philadelphia as a field investigator. In 1991, she assumed the Recall and Complaint Coordinator position in the Denver District. She later returned to inspectional work specializing in the pharmaceutical and medical device industries.



**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.

# ABOUT THE PRESENTERS



**Barbara Paldus, PhD** – Dr. Paldus is currently a partner at Skymoon Ventures. Prior to that, she was the CTO of Picarro, a company she founded in 1998. At Picarro, she was responsible for technology strategy, research, and business development, which led to a solid-state Cyan laser product in 2003 and cavity ring-down spectroscopy products in 2004.



**Alain Pralong, PhD** – Dr. Pralong is Vice President at Crucell, where he leads the Global Process Development Department. Prior to that, he worked at Merck-Serono in the manufacturing of hormones used in treatment of infertility. He also worked on manufacturing Adenovaccine clinical trial material at Schering-Plough. Following a move to Roche in 2004, he managed their transfer of Avastin process manufacturing from Genentech. He obtained his doctorate in molecular and cellular biology at the University of Berne.



**Eda Ross Montgomery, PhD** – Dr. Ross Montgomery is currently Senior Director, Quality: CMC and QbD for Vertex. In this role, she is responsible for the implementation of Quality by Design, including development of a strategy for the CMC filing, implementation at manufacturing sites, launch, and continuous improvement of Vertex's commercial products, as well as for ongoing support of commercial product. Dr. Ross Montgomery has over 20 years experience in the pharmaceutical industry, where she has led CMC teams for all Chemistry, Manufacturing, and Control activities and Analytical Development activities for four NDA filings and headed Analytical Development, Lifecycle Management, and Commercial Support departments.



**D. Christopher Watts, PhD** – Dr. Watts is currently a Partner in Consulting with NNE Pharmaplan, where he is responsible for developing Quality and Regulatory projects in addition to leading various strategic efforts related to the development and manufacture of pharmaceuticals. Prior to joining NNE Pharmaplan, he was with the FDA in the Office of Pharmaceutical Science at the Center for Drug Evaluation and Research, where his responsibilities included developing Agency policy and training programs, managing standards efforts, and collaborating in research ventures with industry and academia. Prior to joining the FDA, his industrial experience involved product and process development, as well as the scale-up and manufacture of inhalation and oral drug products.



**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.

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## Learning Objectives for Operational Excellence: A Lifecycle Approach to Assuring Drug Quality

*At the completion of this activity, the participant should be able to:*

1. Discuss the current state of the FDA's Quality by Design (QbD) implementation, lessons learned and the hurdles being faced in its implementation.
2. Explain and demonstrate how embracing new technologies such as continuous manufacturing and establishing a culture of continuous improvement can have a positive financial impact on pharmaceutical companies' bottom line.
3. Describe what the FDA's review and inspection teams expect of the pharmaceutical companies in the area of implementation of new technologies and operational excellence.
4. Implement a successful "Lean" and operational excellence program in manufacturing units.
5. Prepare for inspections by anticipating the issues that can lead to non compliance.
6. Benchmark one's own operation with other similar pharmaceutical operations around the world.

Keywords: Drug Manufacturing; Food and Drug Administration (FDA); Regulation

Total credit hours: 11.75 hours (1.175 CEU) - knowledge

**CONTINUING  
EDUCATION**



The University of Maryland School of Pharmacy is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This program meets the ACPE criteria for eleven and three quarter contact hour (1.175 CEU) of continuing education credit. Statements of credit will be mailed within 60 days to those participants who successfully complete the program. Successful completion requires participation at the entire program and completion of a program evaluation form. This program is cosponsored by NIPTE. UAN 0025-9999-11-003-L04-P.

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### Tuesday, April 5, 2011

#### Morning Session: Moderator – Ali Afnan, PhD

##### WHAT

8:00 – 9:00	Registration*	
9:00 – 9:10	Welcome	
9:10 – 9:40	FDA Perspective on Pharmaceutical Quality Opportunities and Challenges	Helen Winkle, FDA
9:40 – 10:10	Quality Management Through Design and Control	Deming Institute
10:10 – 10:30	Break*	
10:30 – 11:00	Adapting Industry Practice for Rapid Large Scale Manufacture	David Estell
11:00 – 11:30	Quality : Lab to Patient	Paul McKenzie
11:30 – 12:00	Vision for OpEx/Lean Manufacture and Six Sigma	Michalle Adkins
12:00 – 1:15	Lunch*	

#### Afternoon Session: Moderator – Christine Moore, PhD, FDA

##### WHY

1:15 – 1:55	State of QbD Implementation	Ted Fuhr
1:55 – 2:35	Economic Benefit of “Lean Quality”	James Drennen, PhD
2:35 – 2:55	Break*	
2:55 – 3:35	Establishing a Culture of Quality	Thomas Friedli
3:35 – 4:15	Science Based Quality	Christine Moore, PhD, FDA
4:15 – 5:15	Question and Answer Session	Afternoon Speakers
6:00 – 7:30	Reception – Provided by Emerson Life Science*	

### Wednesday, April 6, 2011

#### Morning Session: Moderator – Ali Afnan, PhD

##### HOW

8:30 – 8:40	Welcome	
8:40 – 9:20	Managing Quality within a Network of Partners	Eda Ross Montgomery, PhD
9:20 – 10:00	Mitigating Raw Material Variability in Downstream Protein Purification Process Operations	Justin McCue, PhD
10:00 – 10:20	Break *	
10:20 – 11:00	Quality: A Management View of Integrating Process Knowledge and Understanding	Melissa Herkt
11:00 – 11:40	An Integrated Quality Approach	Barbara Paldus, PhD
11:40 – 12:20	A Leap Forward in Bio-Manufacturing	Alain Pralong, PhD
12:20 – 1:35	Lunch*	

#### Afternoon Session: Moderator – Christopher Watts, PhD

##### BENEFITS

1:35 – 2:25	Real Time Release, and Supply Chain Efficiencies	Christopher Watts, PhD
2:25 – 3:05	Managing the Cost of Quality	Peter Martin, PhD
3:05 – 3:25	Break*	
3:25 – 4:05	Continuous Process Verification	Grace McNally, FDA
4:05 – 4:55	Quality System for Innovative Manufacturing	Brian Hasselbalch, FDA
4:55 – 5:30	Question and Answer Session	Afternoon Speakers

\*Non-Educational Activity

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## FEES

Includes conference materials, continental breakfast, breaks and lunches per agenda

Payment Received By February 11, 2011  
Payment Received After February 11, 2011

Industry  
\$1795  
\$1895

FDA/Academia  
\$995  
\$995

Cancellation Policy: 30 days or more for a full refund less \$150 cancellation fee; under 30 days, no refund, but attendee substitutions may be made at any time. Cancellations and substitutions must be made in writing to Pharma Conference (email [registration@pharmaconference.com](mailto:registration@pharmaconference.com)). In the event of any civil disorder, extremely adverse weather conditions, or other Acts of God, Pharma Conference reserves the right to reschedule the meeting dates in the interest of attendee safety.

## PAYMENT

**Full payment may be made by credit card or company check**

- Checks must be received within 15 days of receipt of registration form.
- Checks should be made payable to Pharma Conference Inc, in U.S. dollars and drawn on a U.S. bank.
- Registrations will be confirmed when full payment has been received. Taxpayer ID #27-1438344.
- **Registrations made within 15 days of conference start date must be accompanied by full payment.**

**Checks should be sent to Pharma Conference Inc at the following addresses (see check instructions above):**

**Airmail to:** P.O. Box 291386, Kerrville, Texas 78029 USA

**Express to:** 819 Water Street, Suite 350, Kerrville, Texas 78028 USA

## HOTEL

**Hyatt Regency Bethesda**  
One Bethesda Metro Center  
Bethesda, MD 20814  
(301) 657-1234  
\$226 single/double

A limited number of rooms have been blocked at the special rates per night (single or double). **Hotel reservations must be made on or before March 7, 2011** in order to guarantee the special rate. Individuals are responsible for making their own hotel reservations. Be sure to mention the name of the program when making your reservation in order to be properly identified with the program. Please do not use travel agents for reservations.

For additional information, contact Pharma Conference Inc (830) 896-0027 Fax: (830) 896-0029 or e-mail: [contactus@pharmaconference.com](mailto: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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