

# 2010 CONFERENCE SERIES



## Bethesda, Maryland

Conference co-sponsored by

THE  
UNIVERSITY  
OF RHODE ISLAND  
COLLEGE OF  
PHARMACY

## **FDA and PAT for Pharma Manufacturing FDA-Partnering with Industry**

...a joint FDA/URI College of Pharmacy conference

May 11 - 12, 2010

Hyatt Regency Bethesda

Conference produced by



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# ABOUT THE CONFERENCE

The Food and Drug Administration (FDA) is pleased to announce this joint conference with the University of Rhode Island (URI) College of Pharmacy. This 2-day conference is co-sponsored by FDA, the URI College of Pharmacy, and Pharma Conference Inc. The conference is intended to disseminate current and accurate information on Process Analytical Technology (PAT) to the pharmaceutical industry and create a venue for dialogue between the PAT users and FDA. The conference will feature FDA's perspective on where PAT will be applicable in the manufacturing process and FDA's current thinking on how PAT will be reviewed in new and abbreviated new drug applications, amendments, or supplements to an application.

Several top FDA officials will be on hand to present current and accurate information on PAT, as well answer your questions firsthand. These officials include Janet Woodcock, Director, Center for Drug Evaluation and Research; Helen Winkle, Director, Office of Pharmaceutical Science; and Jon Clark, Associate Director, Office of Pharmaceutical Science.

This is an important must-attend conference for anyone involved in PAT and manufacturing. Please visit our website today to register.

## WHO SHOULD ATTEND?

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

## WHY ATTEND?

- Because FDA initiated the planning and content of this conference in order to get the information out to you
- To get FDA's perspective on where PAT will be applicable in the manufacturing process



**Make sure to join us for these upcoming conferences.**

**Preparing for and Managing FDA and EU Inspections**  
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**15th Annual GMP By The Sea**  
Savannah, Georgia • August 16-18, 2010

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# THE PRESENTERS



**Ferdinando Aspesi, PhD** – Dr. Aspesi is the Senior Vice President, Quality & Compliance, Wyeth Pharmaceuticals – USA. He has more than 30 years of experience in Drug Substance and Drug Product Quality Assurance, Quality Control, Pharmaceutical Research and Development, Analytical Development and Manufacturing. He has been Senior Vice President for Global Quality and Compliance at two major pharmaceutical companies: Wyeth Pharmaceuticals Inc. and Aventis Pharmaceuticals Inc. In addition, Dr. Aspesi has been one of the global leaders who engaged the FDA on Process Analytical Technology and FDA 21st Century GMP's initiative and has contributed to the dialogue between Industry, FDA and EMEA.



**Terry Blevins, BS, MS** – Mr. Blevins is a principal technologist in DeltaV Product Engineering with a focus on basic and advanced control technology and has been actively involved in the application and design of process control systems throughout his career. In 1991 he established Emerson Process Management's Advanced Control Program that led to the development of DeltaV's self-tuning, model predictive, neural network, fuzzy logic control, and simulation products. Mr. Blevins coauthored ISA bestseller, *Advanced Control Unleashed*. He is the Fieldbus Foundation team leader for the Function Block Specification, the US expert to IEC TC65 WG6 and SC65C WG7 committees responsible of the IEC61499 and IEC61804 function block standards, and chairman of ISA SP104- EDDL (Electronic Device Description Language). In 2004, he was inducted into *Control Magazine's* Process Automation Hall of Fame.



**Kevin E. Cahill, BS** – Mr. Cahill is currently Vice President of The W. Edwards Deming Institute® and oversees general operations and development. Previously, he was the co-founder and CEO of ViewBridge, Inc. The company was founded in 1999 and through its operating division, AdConnections, implemented the first fully integrated internet based sales system for the media industry. Prior to that, he was Vice President Sales Manager for media rep firm, Katz Communications. As a member and chairman of the system oversight committee, he helped guide the design and implementation of various sales, technology, and management systems.



**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 has experience reviewing chemistry submissions, developing electronic submission technology, and helping to shape the future of drug product quality regulation in the FDA. 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.



**Neil Everall, PhD** – Dr. Everall has over 25 years experience in the development and application of infrared and Raman spectroscopic tools and techniques. He is currently employed by Intertek-MSG, providing contract analytical research and production support to a wide range of clients in the chemicals, materials, personal care, pharmaceuticals and medical device sectors. Dr. Everall's research interests center on the development and application of spectroscopic tools for characterizing materials and industrial processes in the laboratory and at the production line. Much of this work is directly relevant to PAT; he was one of the early adopters of Raman spectroscopy as a real-time process analysis and control tool. His work on the fundamentals of Raman microscopy has impacted how researchers acquire and interpret Raman maps and images. More recently, in collaboration with workers at the Rutherford Appleton Laboratory, his studies of Raman photon migration in opaque media stimulated a field of research that led to the commercialization of transmission Raman spectroscopy, which offers fast, accurate and non-destructive tablet analysis.

# THE PRESENTERS



**Richard L. Friedman, BS, MS** – Mr. Friedman is the Director of the Division of Manufacturing & Product Quality in the Center for Drug Evaluation and Research (CDER), Office of Compliance. In this position, he directs the interpretation and development of CGMP policy, review of inspectional recommendations, and determination of manufacturing site acceptability. He has been employed by FDA since 1990, including prior positions as New Jersey District Drug Specialist, CDER Senior Compliance Officer, and Team Leader of Guidance and Policy.



**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, where she was responsible for capital management, resource management, project manager training and development, project controls, project management standards, and the delivery performance of projects. She had previously worked for Hoffmann-La Roche, Exxon R&E, and Alabama Power Company.



**Ajaz Hussain, PhD** – Dr. Ajaz Hussain joined Philip Morris International R&D in 2008 as Vice President Biological Systems. In this role, Dr. Hussain is focused on innovation and developments in the field of alternative uses for the tobacco plant. Prior to this appointment Dr. Hussain served as Vice President and Global Head of Biopharmaceutical Development at Sandoz (a Novartis Company) and was responsible for the development and registration of Sandoz's biosimilars and follow-on-protein portfolio. Prior to joining Sandoz in 2005, he served as the Deputy Director of the Office of Pharmaceutical Science (OPS) in the Center for Drug Evaluation and Research (CDER), US FDA. At OPS/CDER/FDA he held a Senior Biomedical Research Scientist appointment. At the FDA he established a track record of developing and implementing science based global regulatory policies in the areas of clinical pharmacology (e.g., regulatory applications of the Biopharmaceutics Classification System) and Quality (CMC and CGMP requirements). He championed the FDA's Process Analytical Technology (PAT) Initiative and provided leadership for the development and implementation of the FDA's CGMP's for the 21st Century Initiative and its harmonization under ICH.



**Gawayne Mahboubian-Jones, PhD** – Dr. Mahboubian-Jones is a materials scientist and electronic control engineer who has worked in a wide variety of systems control environments both inside and outside the pharmaceutical industry. He has worked in a number of industry sectors specializing in development and control of processes using complex measurement systems (PAT-like systems) in both R&D and production environments, and in the application of control systems to support the implementation of lean manufacturing and 6-Sigma manufacturing. Over that period he published more than 20 papers and was credited with 5 patents. For the past seven years he has worked with Optimal Industrial Automation where he is responsible for a market-leading PAT data management suite and where he provides consulting services to pharmaceutical companies on implementation of PAT, PAT support systems, and the use of PAT to support QbD.



**Bonnie Norman, BS** – Ms. Norman is Director of Quality Assurance and Regulatory Affairs for Intel Corporation's Digital Health group. She is responsible for ensuring user safety, product quality, and compliance of sales and marketing, design and manufacturing activities for all Digital Health products. Ms. Norman joined Intel in May 2007. Prior to joining Intel, Ms. Norman held a variety of positions in the medical device, pharmaceutical, biotech, and technology industries. She has successfully assisted multiple companies with the many cultural changes necessary when transitioning into the medical device industry. She founded The Taregon Group, a consulting organization that assisted medical device, biotech, and pharmaceutical companies with a variety of design, manufacturing, quality, and regulatory issues. A key area of her consulting focus was in the area of application of industry controls to pharmaceutical bulk and fill/finish manufacturing operations. She has held a number of engineering management positions, specializing in complex software-driven electro-mechanical devices for both regulated and non-regulated industries.

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# THE PRESENTERS



**Babatunde A. Ogunnaike, PhD** – Dr. Ogunnaike is a professor at the University of Delaware and currently occupies the William L. Friend Chair of Chemical Engineering, a position he has held since 2002. From 1981 to 1982, he was a Research Engineer with the Process Control group of the Shell Development Corporation in Houston, Texas; and from 1982 to 1988, he was a professor at the University of Lagos with joint appointments in the Chemical Engineering and the Statistics Departments. He joined the Advanced Control and Optimization group of DuPont Central Science and Engineering in 1989, and was, from 1995 until September 2002, a Research Fellow in DuPont Chemical Sciences and Engineering. He is the author or co-author of four books, including a widely used textbook, *Process Dynamics, Modeling and Control*, published in 1994 by Oxford University Press, and the recent *Random Phenomena: Fundamentals of Probability and Statistics for Engineers*, published in 2009 by CRC Press. He is also an Associate Editor of the journal *Industrial and Engineering Chemistry Research*.



**Vilayat Sayeed, PhD** – Dr. Sayeed is the Division Director in the Office of Generic Drugs in FDA. He is responsible for the Chemistry Manufacturing Controls review (pre and post marketing) and approval of Abbreviated New Drugs Application (ANDA). Prior to joining the agency he worked in the industry for eight years as a principle investigator in the area of drug discovery and drug process development to support the National Cancer Institute investigational drugs program for the Phase II, Phase III clinical trials. He joined the Office of Generic Drugs, Center for Drug Evaluation and Research, in 1992 and assumed his current position in 2004. He has published extensively in peer-reviewed journals, has authored two book chapters, and has presented at national and international conferences on topics related to science and regulation.



**Michael Simeone, RPh, MBA** – Mr. Simeone is the Director of Continuing Education, College of Pharmacy, University of Rhode Island. He has an extensive background in developing and implementing continuing pharmaceutical education programs. Prior to joining the College of Pharmacy, he practiced hospital pharmacy for over twenty years. Mr. Simeone is also a Certified Diabetes Outpatient Educator in the state of Rhode Island.



**Martin Warman, BS** – Mr. Warman is a Scientific Fellow at Vertex Pharmaceuticals supporting the use of PAT during QbD. Prior to this he provided PAT consultancy services to the pharmaceutical sector. He has over 17 years experience in the field having worked in the pharmaceutical (Pfizer), the instrument sector (with Dionex), in petrochemical (Shell) and in academia (University of Westminster). During that time he has developed and implementing a variety of PAT solutions, from spectroscopic to chromatographic and including acoustic and particle characterization.



**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. Prior to joining CDER, Dr. Woodcock was director of the Office of Therapeutics Research and Review, Center for Biologics Evaluation and Research (CBER).

# AGENDA

## Tuesday, May 11, 2010

### Morning Session: Moderator – Helen Winkle, Director, OPS-IO, CDER, FDA

7:00 – 8:00	Registration
8:00 – 8:05	URI College of Pharmacy Welcome
8:05 – 8:15	FDA Welcome
8:15 – 9:00	21st Century Drug Product Quality
9:00 – 9:45	Quality Through Design and Manufacturing Control
9:45 – 10:05	Break
10:05 – 10:50	Industry Perspective on the Implementation of PAT
10:50 – 11:35	Process Analytical Technology: Process Understanding and Control
11:35 – 12:00	Question and Answer Session
12:00 – 1:15	Lunch

Michael Simeone on behalf of URI  
College of Pharmacy  
Helen Winkle  
Janet Woodcock, MD, FDA  
Ajaz Hussain, PhD

Ferdinando Aspesi, PhD  
Gawayne Mahboubian-Jones, PhD  
Morning Speakers

### Afternoon Session: Moderator – Helen Winkle, Director, OPS-IO, CDER, FDA

1:15 – 2:00	PAT in Biopharmaceutical Development and Manufacturing
2:00 – 2:45	Case Study: Application of PAT to the Production of Titanium Dioxide
2:45 – 3:30	FDA PAT Review Process
3:30 – 3:50	Break
3:50 – 4:35	FDA PAT Regulatory Inspection
4:35 – 5:20	FDA PAT Compliance Process
5:20 – 5:45	Question and Answer Session

Babatunde Ogunnaike, PhD  
Neil Overall, PhD  
Vilayat Sayeed, PhD, FDA

National Drug Expert Investigator,  
ORA, FDA  
Rick Friedman, FDA  
Afternoon Speakers

## Wednesday, May 12, 2010

### Morning Session: Moderator – Jon Clark, Associate Director, OPS-IO, CDER

8:00 – 8:05	Welcome
8:05 – 8:40	Introduction to the W. Edwards Deming Institute
8:40 – 9:25	Design and Control of Quality
9:25 – 9:45	Break
9:45 – 10:30	Use of Advanced Process Models in Biological Manufacturing
10:30 – 11:15	Applying Controls to Pharmaceutical Manufacturing While Enhancing Business Value

Jon Clark  
Kevin Cahill  
TBD

Terry Blevins, PhD  
Bonnie Norman

### Afternoon Session: Moderator – Jon Clark, Associate Director, OPS-IO, CDER

1:00 – 1:45	An Integrated Systems Approach: Quality Management System
1:45 – 2:30	Technology Challenges: A Partnership
2:30 – 2:50	Break
2:50 – 3:35	Efficient and Agile Pharmaceutical Manufacturing and Regulation: A Partnership
3:35 – 4:05	Question and Answer Session
4:05 – 4:15	Closing Remarks

Martin Warman, PhD  
Melissa Herkt

Helen Winkle, FDA  
FDA

CONTINUING  
EDUCATION



Participants will receive 1.4 CEUs (14.00 contact hours) for **FDA and PAT for Pharma Manufacturing** conference attendance. The University of Rhode Island College of Pharmacy is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This is a knowledge type of activity. Attendance and completion of evaluation forms and self-assessment tools at the conclusion of the program are required for issuance of a statement of credit. Statements will be mailed within six to eight weeks of program completion. ACPE universal program number 060-999-10-052-L04-P.

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### FEES

#### Payment Received By April 15, 2010

\$1795

#### Payment Received After April 15, 2010

\$1995

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

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):**

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#### NEW ADDRESSES!

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### HOTEL

**Hyatt Regency Bethesda**  
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Bethesda, MD 20814  
(301) 657-1234  
\$219 single/double

A limited number of rooms have been blocked at the special rate listed per night (single or double). Hotel reservations must be made on or before **April 9, 2010** in order to guarantee the special rate. Individuals are responsible for making their own hotel reservations. **You must mention the title of the conference and Pharma Conference Inc when making your reservation in order to obtain this special rate. 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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