ISPE/FDA/PQRI Quality Manufacturing Conference

Formerly the ISPE/FDA CGMP Conference

1–3 June 2015
The Mayflower Renaissance
Washington, DC

Register Now!
www.ISPE.org/Quality-Manufacturing-Conference
Join leaders of the pharmaceutical industry and FDA for three days of open dialogue across the spectrum of modernization in manufacturing, regulatory insights and quality systems.

**At the Conference:**
- Take away solution-based approaches for facility operations, drug shortages prevention, continuous manufacturing, foundations for quality, Lifecycle knowledge management and data integrity.
- Discuss global harmonization and Q7, Q11 and Q12, inspection trends, ANVISA and MHRA regulatory perspectives.
- Discover cutting-edge technologies from 40+ exhibiting companies that can improve your processes and bottom line.
- Receive an update on the ISPE Quality Metrics Pilot Program and the outcomes of the ISPE Quality Metrics Summit.

**Expand Your Knowledge:**
- Best Practices in Delivering a Safe, Consistent Global Drug Supply
- Breakthrough Therapy
- Common Misconceptions of Compliance
- Continuous Manufacturing
- Corporate Governance and Executive Responsibility
- Data Integrity Compliance, Audits and Legal Implications
- Inspection Trends and Enforcement
- International Perspective from ANVISA and MHRA
- Lifecycle Knowledge Management
- Manufacturing Excellence
- Process Capability and Innovation
- Quality Assurance, Culture and Metrics
- Robust Change Management Systems

**Keynote Speakers:**
- **Juan Andres**
  Head of Global Technical Operations, Novartis AG
- **Andy Skibo**
  Regional Vice President, Supply Biologics, MedImmune/AstraZeneca
- **Janet Woodcock, MD**
  Director, FDA CDER

Attend one full day dedicated to regulatory topics. FDA will discuss the CDER reorganization and their new roles and priorities.
BREAKFAST WITH THE INVESTIGATORS
Milind Ganjawala, Branch Chief, Office of Manufacturing Quality, CDER/OC/OMQ, Invited
Jonathan Chapman, Consumer Safety Officer, ORA/OGROP, Invited
Brooke Higgins, Senior Policy Analyst, CDER/OC/OMQ, Invited
Nancy Rolli, Director, Investigations Branch, ORA/CE-FO/NWJ-DO, Invited

UNDERSTANDING THE CHANGES AT FDA
Cynthia Schnedar, JD, Director, Office of Compliance, CDER/OC
Tom Cosgrove, JD, Director, Office of Manufacturing Quality, CDER/OC/OMQ
Alonza Cruse, District Director, ORA/LOS-DO, Invited
Christine Moore, PhD, Acting Director, Office of Process and Facilities, CDER/OPQ/OPF

INTERNATIONAL REGULATORY PERSPECTIVE
EU Update: Inspection Trends and Enforcement
Gerald Hedden, Director, Inspection Enforcement and Standards Division, MHRA, Invited

ANVISA Outlook
Ana Paula Barreto, Office of the Chief Executive Officer-GADIP, National Health Surveillance Agency-ANVISA, Invited

GLOBAL HARMONIZATION
Q7 Alicia Mozzachio, RPh, Director, Regulatory, CDER/OPQ/OPPO/DRGS, Invited
Q11 Tim Watson, PhD, Research Fellow/CMC Advisory Office, Pfizer Inc.
Q12 Mary Oates, PhD, VP, Global Quality Operations, Pfizer Inc.

UPDATE ON QUALITY METRICS PILOT PROGRAM
Russ Wesdyk, Scientific Coordinator, FDA/CDER/OPS/IO, Invited
Diane Hagerty, Vice President, Genentech (A Member of the Roche Group)
Chris Potter, PhD, CMC Pharmaceutical Consultant and ISPE Advisor

Modernization in Manufacturing Track
Track Leaders:
Francis Godwin, Division Director, Division of Drug Quality 2, CDER/OC/OMQ/DDQ2
David Clark, Senior Director, Manufacturing Sciences & Technology, MedImmune/AstraZeneca
Dora Kourtis, PhD, Senior Technical Director, GlaxoSmithKline
Lance Minor, VP of Operations Strategy & Network Performance, MedImmune/AstraZeneca

Continuous Manufacturing

PAT – 15 Years Later
Dora Kourtis, PhD, Senior Technical Director, GlaxoSmithKline

Modernization and Production Efficiency: Key Elements in Drug Shortages Prevention

Drug Shortage’s Perspective on Modernization of Legacy Facilities
Capt. Val Jensen, RPh, Associate Director, Drug Shortage Staff, CDER/OCD/DSS, Invited

Drug Shortages Team Update
Frances Zipp, President, Lachman Consultant Services Inc. and Steering Committee Member, ISPE Drug Shortages Team

Panel Discussion with the Drug Shortages Team

Advanced Applications for Contamination Control — Drug Substance and Drug Product

Contamination Control in Aseptic Processing: Microorganisms and Macro-Particles
Stephen Langille, PhD, Acting Branch Chief – Office of Process and Facilities, Division of Microbiology Assessment, FDA/CDER/OPQ/OPF, Invited

Engineering HTST Skids
Marcella Goodnight, Associate Director, Process Engineering, Global Technical Operations, Medimmune/AstraZeneca

Closed Systems: Risk Mitigation for Contamination Control and Product Quality
Paul Smock, Biotechnology Quality & Technical Consultant, Meridian BioGroup

Adapting Legacy Facilities to Improve Biomanufacturing Flexibility

Manufacturing Modernization: Old Facilities + New Tech
Dave Marks, Principle, DME Engineering

Vertical Integration of Disposables in Biopharmaceutical Manufacturing
Sigma S. Mostafa, PhD, Director, Process Development, KBI Biopharma, Inc.

Maintaining Your Manufacturing Facilities in “Current” State
Younok Dumortier Shin, Director, Large Molecule Technology, Janssen
Regulatory Insights Track

Track Leaders:
- Mahesh Ramanadham, PharmD, Regulatory Operations Officer, CDER/OPQ/OPF/DIA/IABI
- Rose Mary Dillard, Director, Regulatory Compliance, Johnson & Johnson
- Steve Mahoney, Senior Director, Global Quality & Compliance, Genentech (A Member of the Roche Group)
- Tim Watson, PhD, Research Fellow/CMC Advisory Office, Pfizer Inc.

Process Capability

Get Up and Dance: Launching a Process Capability Program in a Global Manufacturing Network
- Aaron Goerke, GBMSAT Purification Senior Group Leader, Genentech (A Member of the Roche Group)

Process Capability and Technology Transfer
- Peter Millili, PhD, Principal Engineer, Bristol-Myers Squibb

Monitoring and Reducing Variability During the Lifecycle

FDA Perspective on Monitoring and Reducing Variability
- Daniel Peng, PhD, Senior Product Quality Reviewer, CDER/OPQ/OPF, Invited

PQLI/Process Validation Team Update
- Tara Scherder, Managing Director, Arlenda Inc.

Driving Process Performance through Awareness and Proactive Response
- Jenn Walsh, Associate Director Technical Services, Bristol-Myers Squibb

Risk Management

Risk Management Workshop Overview
- Chuck Hoiberg, PhD, Executive Director, Pfizer Inc.
- Vince McCurdy, PhD, Head, Operational Excellence, Pfizer Inc.

How OPF Utilizes Risk Assessment during Application Review
- Naiqi Ya, PhD, Supervisory Chemist, CDER/OPQ/OPF/DPAII, Invited

Breakthrough Therapy

Advancing Risk Management Concepts in Accelerated Drug Applications
- Eric Thostesen, Senior Director, Regulatory Compliance, Janssen Pharmaceutical Company Inc.

Accelerated Development Quality Management System Application and Deferrals Strategy
- Kate Waters, Principal Engineer, Genentech (A Member of the Roche Group)

Lifecycle Knowledge Management

Utilizing QRM to Improve Manufacturing Over the Lifecycle
- Christina Capacci-Daniel, Consumer Safety Officer, CDER/OPQ/OPF/DIA/IABI, Invited

Managing What We Know — A Lifecycle Approach
- Paige Kane, Director of Knowledge Management, Pfizer Global Supply
- Nuala Calnan, PhD, Regulatory Science Researcher, Dublin Institute of Technology and ISPE Quality Culture Team Lead

Quality Systems Track

Track Leaders:
- Rick Friedman, Deputy Director, Science and Regulatory Policy, CDER/OC/OMQ
- Lorraine McClain, Senior Director, Quality Risk Management, Teva Pharmaceuticals
- Stephen Tyler, Director Quality Assurance, AbbVie

Corporate Responsibility for Quality

Corporate Governance in the 21st Century
- Vivian Arencibia, Vice President of Group Compliance & Audit, Novartis Pharmaceuticals

Business Across Borders: The Impact of Culture on Quality
- Dana Blobner, Director, Quality Assurance, Ultragenyx Pharmaceutical Inc.

The Executive Role: Overseeing Both System and Process Health
- Johna Norton, Vice President, Quality, Global API, Puerto Rico, and Product Research and Development, Eli Lilly & Co.

Using Operational Excellence as a Foundation for Quality

FDA District Perspective
- Nancy Rolli, Director, Investigations Branch, ORA/CE-FO/NWJ-DO, Invited

OpEx Themes from St. Gallen
- Thomas Friedli, Vice Director, Institute of Technology Management, University of St. Gallen

OpEx Program Implementation: An Industry Perspective
- Mark Swatling, Senior Director, Operational Excellence, AstraZeneca

Robust Change Management

Across the Lifecycle
- Nigel Hamilton, Head of Global Quality External Affairs, Global Quality Strategy and Systems, Sanofi

When Change is Imperative
- Cathy Burgess, Partner, Alston & Bird LLP

Compliance and Enforcement

What is “Compliance”? Some Common Misconceptions
- Rick Friedman, Deputy Director, Science and Regulatory Policy, CDER/OC/OMQ

US Expectations for Good Distribution Practices
- Connie Jung, Pharmacologist, CDER/OC/ODS/IR, Invited

Why Companies Drift Out of Compliance
- Veronica Cruz, PhD, Executive VP/COO, ReComS Group

Lifecycle Data Integrity

FDA Perspective and Current Findings
- Karen Takahashi, Consumer Safety Officer, CDER/OPQ/OPPQ/DRGS/CO, Invited

Holistic Approach to Strengthen Data Integrity
- Peter Carbone, Vice President, Global Head External Relations, Group Quality, Novartis Services, Inc.

Business Reliability Built upon Data Integrity
- Cormac Dalton, Director, Quality & Compliance, AbbVie

Panel Discussion
- Elaine Eborall, Senior Director, Genentech (A Member of the Roche Group) and Session Speakers

Agendas are subject to change without notice. Every precaution is taken to ensure accuracy, but ISPE cannot accept responsibility for information distributed or contained in these programs, or personal opinions expressed during the presentations.
### Upcoming Classroom Training

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<th>4 — 6 May • Brussels, Belgium</th>
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For more information visit: www.ISPE.org/Training

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ISPE Europe Annual Conference  
4 — 6 May  
Steigenberger Airport Hotel  
Frankfurt, Germany

Pharma EXPO  
28 — 30 September  
Las Vegas Convention Center  
Las Vegas, NV  
*A joint venture with PMMI

Process Validation Conference  
7 — 8 October  
DoubleTree Hotel  
Silver Spring, MD

ISPE Annual Meeting  
8 — 11 November  
Philadelphia Marriott Downtown  
Philadelphia, PA

ISPE China Annual Fall Conference  
October  
Shanghai, China

For more information visit: www.ISPE.org/Events
Exhibit Hall

Explore new-to-market technologies and state-of-the art products designed to increase revenue and reduce costs while maintaining quality. More than 40+ exhibitors from around the world offer you the opportunity to:

- Find solutions to your most pressing quality challenges
- Negotiate with senior decision makers for new business opportunities
- Develop international contacts and improve your industry knowledge

Facility of the Year Awards Banquet

Tuesday, 2 June

Join ISPE for an evening of celebration to honor innovation and creativity in manufacturing facilities serving the regulated healthcare industry.

Tables are available for purchase, contact Alisa Pachella for details.

Interested in exhibiting or sponsoring?

Contact Alisa Pachella at apachella@ispe.org or +1-813-739-2274.

Conference Program Committee

FDA Co-Chair: Christine Moore, PhD, Acting Director, Office of Process and Facilities, OPQ

Industry Co-Chair: Joe Famulare, VP, Global Compliance and External Collaboration, Pharma Technical Quality, Genentech (A Member of the Roche Group)

PQRI Co-Chair: Louis Yu, PhD, Executive Vice President, Perrigo

Tom Cosgrove, JD, Director, Office of Manufacturing Quality, FDA

Rose Mary Dollard, Director, Regulatory Compliance, Johnson & Johnson

Rick Friedman, Deputy Director, Science and Regulatory Policy, Office of Manufacturing Quality, FDA

Diane Hagerty, Vice President, Genentech (A Member of the Roche Group)

Dora Kourtis, PhD, Senior Technical Director, GlaxoSmithKline

George Millili, PhD, Senior Principal Technical Advisor, Genentech (A Member of the Roche Group)

Hotel Information

Mayflower Renaissance Hotel
1127 Connecticut Avenue NW
Washington, DC 20036 USA

To make your reservation call +1-877-212-5752 or +1-202-347-3000

When making your reservation, mention ISPE for the discounted rate of $239 single/double. This rate is good until 8 May 2015, or until the room block is full, whichever comes first. Please contact the hotel as early as possible to make your reservations to ensure you are in the headquarters hotel.
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