Quality Manufacturing Conference

6 – 8 June 2016
Bethesda North Marriott
Bethesda, MD

New Tracks This Year!
- Frontiers in Manufacturing Science and Quality
- Manufacturing and Operational Excellence
- Transformation of Quality Oversight

Keynote Speakers:

Howard Sklamberg, JD
Deputy Commissioner for Global Regulatory Operations and Policy, FDA, Invited

Steven Solomon, PhD
Deputy Associate Commissioner for Regulatory Affairs, FDA/ORA/OACRA, Invited

Ann L. Lee, PhD
Senior Vice President, Genentech and Head of Global Technical Development, Roche

Michael Kopcha, PhD
Director, Office of Pharmaceutical Quality Offices and Leadership, FDA

Register Now!
www.ISPE.org/2016-Quality-Manufacturing-Conference
Featured Sessions:

**CLINICAL IMPLICATIONS OF DRUG SHORTAGES**
When Drugs Are Short, but the Ethical Challenges Are Long: The Absurdity of Having to Choose Which Children Receive Scarce Life-Saving Chemotherapy
Yoram Unguru, MD, Pediatric Hematology/Oncology, The Herman & Walter Samuelson Children’s Hospital at Sinai
Douglas Throckmorton, MD, Deputy Director, Center for Drug Evaluation and Research, FDA

**BREAKFAST WITH THE INVESTIGATORS**
Moderator: Karen Hirshfield, RPh, Senior Compliance Specialist, Genentech Inc., A Member of the Roche Group
Hear first-hand experiences, challenges, and recommendations faced by investigators visiting your sites.

**INDUSTRY AND GLOBAL REGULATORY DISCUSSION FORUM**
Leaders:
Stephen Tyler, Director Quality Assurance, AbbVie
Lawrence Yu, PhD, Deputy Director, FDA/CDER/OPQ
Theodora Kourtli, PhD, Senior Vice President Global Regulatory Affairs, ISPE
Panelists:
Alonza Cruse, Pharmaceutical Quality Program Director, FDA/ORA – Office of Operations
David Doleski, Deputy Director (Acting), Office of Process and Facilities, FDA/CDER/OPQ/OPF
Richard Friedman, Deputy Director, Science and Regulatory Policy, FDA/CDER/OC/OMQ
Robert Iser, Director (Acting), Office of Process and Facilities, FDA/CDER/OPQ/OPF
Sau (Larry) Lee, PhD, Associate Director for Science, Chair for OPQ Emerging Technology Team, OPQ
Neil Stiber, PhD, Deputy Director (Acting), Office of Surveillance, FDA/CDER/OPQ/OS
Industry Leaders Invited from Genentech/Roche, Novartis, Perrigo, Proctor & Gamble, and Teva Pharmaceuticals

**QUALITY METRICS – WAVE 2 AND IMPLEMENTING YOUR METRICS**
Leaders:
Peggy Speight, Executive Director, Bristol-Myers Squibb
Steven Greer, Quality Assurance External Engagement, Proctor & Gamble

At the Conference

- Gain insight into the FDA’s new focus on “One Quality Voice” through the integration of multiple review and inspection units
- Explore cutting-edge developments and revolutionary approaches in drug product and delivery, and their implications on quality
- Understand the impact of developing regulations on company program implementation and investment
- Investigate practices that improve manufacturing and prevent drug shortages

**ISPE FACILITY OF THE YEAR RECEPTION & AWARDS BANQUET**
Tuesday, 7 June, 18.30 – 22.30
Separate Registration Required
For more information, see page 8 or contact Alisa Pachella – apachella@ISPE.org

**ISPE Data Integrity Workshop**
Sunday, 5 June
Separate Registration Required
For more information, see page 7 or contact Rameeza Shaikh – rshaikh@ISPE.org
Manufacturing and Operational Excellence
Strategies to Improve Manufacturing and Prevent Drug Shortages

Track Leaders:
- David Doleski, Deputy Director (Acting), Office of Process and Facilities, FDA/CDER/OPQ/OPF
- Richard Friedman, Deputy Director, Science and Regulatory Policy, FDA/CDER/OC/OMQ
- Louis Yu, PhD, Executive Vice President (Retired), Perrigo; PQRI Board Treasurer
- Cynthia Harris, Head of Manufacturing Science and Technology, Novartis-Alcon

Driving a Culture of Continuous Improvement

Building and Sustaining a Culture of Continuous Improvement in a Global Pharmaceutical Company
- Conrad Mutschler, Vice President, Product Planning, Perrigo

The Importance of Quality Assurance Throughout the Lifecycle
- Richard Friedman, Deputy Director, Science and Regulatory Policy, FDA/CDER/OC/OMQ

Impact of Critical Utilities on Product Quality
- Critical Utilities Community of Practice

Drug Shortages Prevention

Mini-Training on the ISPE Gap Tool
- François Sallans, Vice President and Chief Quality Officer, Johnson & Johnson

Supply Chain Robustness
- Maria Phillips, PhD, Director, Xavier Health, Xavier Leadership Center, Xavier University

Drug Shortages Due to Manufacturing Issues – FDA Perspective
- David Doleski, Deputy Director (Acting), Office of Process and Facilities, FDA/CDER/OPQ/OPF

Update on the Pew/ISPE Project on Drug Shortages
- Stephen Mahoney, JD, Senior Director, Global Quality and Compliance, Genentech Inc., A Member of the Roche Group

Lifecycle Management

ISPE Process Validation Working Group Update
- Shawn R. Gould, Sr. Manager, Global Large Molecule Compliance, Johnson & Johnson Regulatory Compliance – Pharma Sector

ICH Q12 on Currently Marketed Products
- Keith Webber, PhD, Senior Director, Rx Regulatory Affairs, Perrigo

Managing Risk to Quality: The Good and the Bad
- David Jaworski, Senior Policy Advisor, FDA/CDER/OC/OMQ/MGPS

Advancements in Process Capability

Process Robustness to Assure Quality Products
- Akm Khairuzzaman, PhD, Acting Branch Chief, FDA/CDER/OPQ

Controversies and Contradictions in Process Capability and Performance Assessment
- Abe Germansderfer, Global Manufacturing Science and Technology Lead, Statistics Technology Lead, Novartis AG

The Role of Process Capability in Monitoring Product Quality
- Peter Millili, PhD, Manager, Commercial Process Characterization Group for Biologics Drug Product Manufacturing Science and Technology, Bristol-Myers Squibb

Process Capability Maturity Model
- Process Capability Maturity Team Member

Cautions in Capability: Avoiding Common Pitfalls in Calculating Process Capability
- Michael Reske, Quality Engineering Manager, Perrigo
Transformation of Quality Oversight
“One Quality Voice” – Integration of Review and Inspection

Track Leaders:
- Robert Iser, Director (Acting), Office of Process and Facilities, FDA/CDER/OPQ/OPF
- Alonza Cruse, Pharmaceutical Quality Program Director, FDA/ORA – Office of Operations
- Rose Mary Dollard, Director, Regulatory Compliance, Johnson & Johnson
- Lorraine McClain, Senior Director, Quality Risk Management, Teva Pharmaceuticals
- Karen Hirshfield, RPh, Senior Compliance Specialist, Genentech Inc., A Member of the Roche Group

Global GMPs and Compliance

Program Alignment Update
- Alonza Cruse, Pharmaceutical Quality Program Director, FDA/ORA – Office of Operations

Update and Trends from the EU
- MHRA, Invited

Inspections and Combination Products
- James Dunnie, Consumer Safety Officer, FDA/ORA/OO/OMPTO/DMPTPO

Hot Topics in Manufacturing

Combination Products Case Study
- Eric Thostesen, Senior Director, Regulatory Compliance, Johnson & Johnson

Q-11 Development and Manufacturing of Drug Substance
- Stephen Miller, Chemist, FDA/CDER/OPQ/ONDPI/DNDPI

Serialization and Product Traceability Perspectives
- James Rolley, Director, Serialization Program Management, Teva Pharmaceuticals

Data Integrity

Update from the Office of Compliance
- Thomas Cosgrove, JD, Director, Office of Manufacturing Quality, FDA/CDER/OC/OMQ

Global Data Integrity Issues
- MHRA, Invited

Data Integrity Workshop – Lessons Learned

Quality Risk Management

Quality Risk Modeling and Management
- Crystal Mersh, President, Quality Executive Partners, Inc.

Risk-Based Review – OPQ
- Andre Raw, Supervisory Chemist, FDA/CDER/OPQ/OLDP

Implementation of EU FMD Excipient Risk Assessment Guidance
- Eva Urban, Manager, Global Quality Risk Management, Celgene

Knowledge Management

Exploring the Link between Quality Risk Management and Knowledge Management
- Mariah Deguara-Pagan, Senior Manager, Right First Time Program Office, Pfizer Inc.

The Relationship between Data Integrity and Knowledge Management
- Paige Kane, Director Knowledge Management, Pfizer Global Supply

Q12 – Knowledge Management over the Product Lifecycle
- Ingrid Markovic, PhD, Biologist, FDA/CBER/OD/ADRM
Frontiers in Manufacturing Science and Quality
Cutting-Edge Developments and Futuristic Products

Track Leaders:
- Sau (Larry) Lee, PhD, Associate Director for Science, Chair for OPQ Emerging Technology Team, FDA/CDER/OPQ
- Neil Stiber, PhD, Deputy Director (Acting), Office of Surveillance, FDA/CDER/OPQ/OS
- Thomas Garcia, PhD, Research Fellow, Pfizer Inc.
- Theodora Kourti, PhD, Senior Vice President, Global Regulatory Affairs, ISPE

FDA New Technology Initiative – Part 1

Industry and Regulatory Perspectives on Implementation of Innovative Technologies
- Sau (Larry) Lee, PhD, Associate Director for Science, Chair for OPQ Emerging Technology Team, FDA/CDER/OPQ

Planning for Innovation Across the Lifecycle
- Michael O’Brien, Vice President Technology and Innovation, Pfizer Inc., Invited
- Geoffrey Wu, PhD, Associate for Science and Communication, Office of Lifecycle Drug Products, FDA/CDER/OPQ/OLDP

FDA New Technology Initiative – Part 2

Collaborations in Innovation – FDA Emerging Technologies Team
- Celia Cruz, PhD, Acting Director of Division of Product Quality Research at the Office of Testing and Research, FDA/CDER/OPQ/OTR/DPQR

Moving New Technologies Forward – A Case Study
- Diane Zezza, PhD, Vice President and Global Head, Regulatory CMC, Novartis

Emerging Technologies – Part 1

Impact on Manufacturing Development Case Study – Modular
- Richard Steiner, Business Development Manager, GEA Pharma Systems

Future of Quality Metrics
- Diane Hagerty, Vice President, South San Francisco Quality Operations, Genentech Inc., A Member of the Roche Group

Quality Manufacturing Standards for New Products – Discussion Forum
- Session Speakers with FDA
  - Neil Stiber, PhD, Deputy Director (Acting), Office of Surveillance, FDA/CDER/OPQ/OS
  - Daniel Peng, PhD, Quality Assessment Lead, FDA/CDER/OPQ/OPF

Emerging Technologies – Part 2: Familiar Concepts – New Developments

Nanotechnology: Process Development for Nanomaterial Drugs
- Peng Zou, PhD, Chemist, FDA/CDER/OPQ/SS
- Lawrence Mayer, PhD, President and Chief Scientific Officer, Celator Pharmaceuticals, Invited

Closed System Transfer Technology with INTACT™ – A Case Study
- Andreas Toba, PhD, Director, Product and Technology Performance, MedInstill
- Debasish Sahoo, PhD, Director, Engineering, MedInstill, Invited

Emerging Technologies – Part 3

3-D Printing – Technical and Lifecycle Management Considerations
- Adam Procopio, PhD, Senior Principal Scientist, Merck, Invited
- Sanjay Sehgal, PhD, VP and Head, Regulatory Affairs and Conformance, Aprecia, Invited

Digital Medicine
- Timothy Peters Strickland, MD, Senior Director, Global Clinical Development, Otsuka
- Michael Fahmy, Director, Global Regulatory Affairs, Otsuka
Quality Metrics

**Track Leaders:**
- Peggy Speight, Executive Director, Bristol-Myers Squibb
- Steven Greer, Quality Assurance External Engagement, Proctor & Gamble

**Learnings from ISPE Quality Metrics Pilot Program, Wave 2**
- Máiréad Goetz, Head of Compliance, Novartis Pharmaceuticals Corporation

**Introduction to ISPE Quality Metrics Wave 2 Data Collection**
- Paul Rutten, Partner, McKinsey & Company

**Insights on Quality Metrics and Culture Indicators from the Industry Quality Metrics Pilot**
- Vanya Telpis, Director of Knowledge, McKinsey & Company

**Shaping Excellence Leader Interviews – Understanding Leader Behaviors, Actions, and Attributes Most Influential to Quality Culture Excellence**
- Matthew Pearson, Head of Global Quality Risk Management, Knowledge Management, Operational Excellence and Learning, F. Hoffmann La-Roche
- Erika Ballman, ISPE Cultural Excellence Leadership and Vision Sub-team Lead; Site Quality and Regulatory Manager, Albemarle Corporation

**FDA Perspectives on Quality Metrics**
- Tara Gooen Bizjak, Senior Science Policy Advisor, FDA/CDER/OPQ, Invited

**Quality Metrics Panel Discussion**
- Moderator: Steven Greer, Quality Assurance External Engagement, Proctor & Gamble
- Máiréad Goetz, Head of Compliance, Novartis Pharmaceuticals Corporation
- Paul Rutten, Partner, McKinsey & Company
- Vanya Telpis, Director of Knowledge, McKinsey & Company
- Matthew Pearson, Head of Global Quality Risk Management, Knowledge Management, Operational Excellence and Learning, F. Hoffmann La-Roche
- Tara Gooen Bizjak, Senior Science Policy Advisor, FDA/CDER/OPQ, Invited
- Russell Wesdyk, OPS Scientific Coordinator, FDA/CDER/OPS/IO, Invited

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.
ISPE Data Integrity Workshop

Data Integrity in the Full Product Lifecycle, from Development to Post-Commercialization

Sunday, 5 June 2016
12.30 – 17.30
Separate Registration Required

Overview
ISPE is proud to introduce its first workshop on Data Integrity. The workshop will focus on key data integrity issues faced over the pharmaceutical product lifecycle. The half-day workshop will be held on 5 June in conjunction with the ISPE Quality Manufacturing Conference and is a value-added learning opportunity for attendees who are looking for a hands-on approach to identify, mitigate, and remediate potential causes of data integrity breaches.

The workshop will also bring forth the regulatory actions impacting key data integrity issues and will answer questions surrounding current expectations and guidance, including an overview of the Application Integrity Policy.

Learning Objectives
- Learn from industry and regulatory thought leaders about key issues in data integrity, including contributors, risks, and the regulatory impacts on your business
- Engage and interact with peers in practical scenario-based problem solving simulating real-world industry conditions and case studies
- Identify and deepen your understanding of effective data integrity practices and case studies
- Interact with peers in breakout sessions creating hypothetical fact patterns to identify key data integrity issues within your industry and business
Exhibit Hall

Explore exhibitors from around the world showcasing new-to-market technologies and state-of-the-art products designed to increase revenue and reduce costs while maintaining quality.

- Participate in meaningful conversations with exhibitors during networking breaks and lunches
- Find solutions to your most pressing quality challenges
- Negotiate new business opportunities with senior decision makers
- Develop international contacts and improve your industry knowledge

Interested in exhibiting or sponsoring?
Contact Alisa Pachella at apachella@ISPE.org or +1-813-739-2274

ISPE Facility of the Year Awards Banquet
Tuesday, 7 June, 18.30 – 22.30

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

The FOYA Awards Banquet is a perfect opportunity to be seen by top pharmaceutical decision makers. Become a sponsor or bring a group of your colleagues to honor and support these esteemed winners.

For details on how to become a sponsor or purchase tables, contact Alisa Pachella at apachella@ISPE.org or +1-813-739-2274.

Conference Program Committee

FDA Co-Chair: Lawrence Yu, PhD, Deputy Director, FDA/CDER/OPQ
Industry Co-Chair: Peter Carbone, Vice President, Novartis Pharmaceuticals
PQRI Co-Chair: Louis Yu, PhD, Executive Vice President (Retired), Perrigo
Industry Honorary Chair: Ann L. Lee, PhD, Senior Vice President, Genentech and Head of Global Technical Development, Roche
Paul D’Eramo, Vice President Regulatory Compliance, Johnson & Johnson
Joseph Famulare, VP, Global Compliance and External Collaboration, Pharma Technical Quality, Genentech Inc., A Member of the Roche Group; Chair, ISPE Board of Directors
Charles Hoiberg, PhD, Executive Director, Pfizer Inc.
Robert Iser, Acting Director Office of Process and Facilities, OPQ
Sau (Larry) Lee, PhD, Associate Director for Science, Chair for OPQ Emerging Technology Team, OPQ
Richard T. Lostritto, Acting Associate Director for Science, OPQ
George Millili, PhD, Senior Principal Technical Advisor, Genentech Inc., A Member of the Roche Group
Suzanne Pattee, Acting Associate Director for Regulatory Affairs, OPQ
Neil Stiber, Acting Deputy Director Office of Surveillance, OPQ
Eric Thostesen, Sr. Director Compliance, Strategic Business Support, Johnson & Johnson
Russell Wesdyk, Acting Director Office of Surveillance, OPQ
Conference Fees
and Registration Information

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<tr>
<th>QUALITY MANUFACTURING CONFERENCE &amp; ISPE DATA INTEGRITY WORKSHOP PACKAGE</th>
<th>2016 EARLY BIRD RATE</th>
<th>2016 REGULAR RATE</th>
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<td></td>
<td>ON OR BEFORE 9 MAY</td>
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*Save $100 when you add the ISPE Data Integrity Workshop to your registration.

**Includes a 1-year membership to ISPE.

Group discounts available. Please contact ISPE (tel: +1-813-960-2105) for more details.

How to Register

Online: www.ISPE.org/2016-Quality-Manufacturing-Conference
Via Fax or Email: Complete the registration form online and fax it to: +1-813-264-2816
or email to ask@ISPE.org.
Questions? Call ISPE at +1-813-960-2105, or email ask@ISPE.org.
Please see the conference website for information about cancellations and substitutions.

Hotel Information

Bethesda North Marriott
5701 Marinelli Rd
North Bethesda, MD 20852 USA

To make your reservation, call +1-800-859-8003 or +1-301-822-9200

When making your reservation, mention ISPE for the discounted rate of $209 single/double. This rate is good until 16 May 2016, 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.
ISPE Conferences

- ISPE Data Integrity Workshop
  5 June
  Bethesda, MD

- ISPE/FDA/PQRI Quality Manufacturing Conference
  6 – 8 June
  Bethesda, MD

- ISPE Annual Meeting & Expo
  18 – 21 September
  Atlanta, GA

- ISPE GAMP EU Regional Conference
  4 – 6 October
  Copenhagen, Denmark

- ISPE Europe Conference on Biotechnology
  24 – 25 October
  Frankfurt, Germany

- ISPE Process Validation Conference
  24 – 26 October
  Bethesda, MD

- ISPE Process Validation Statistics Conference
  25 – 27 October
  Bethesda, MD

- Pharma EXPO 2016
  6 – 9 November
  Chicago, IL

- ISPE Facilities of the Future Conference
  14 – 15 November
  Bethesda, MD

- ISPE Biopharmaceutical Manufacturing Conference
  5 – 7 December
  San Francisco, CA

www.ISPE.org/Events
# 2016 ISPE Training Schedule

## MAY

**ISPE Training Institute, Tampa, FL**
- Cross Contamination (T41), 12 – 13 May
- C&Q (T40), 16 – 17 May
- GAMP® 5 Data Integrity (T50), 9 – 10 May
- QbD (T43), 23 – 24 May

### Brussels, Belgium
- Basic GAMP® 5, Annex 11/Part 11 (T45), 23 – 25 May
- Bio Manufacturing (T31), 23 – 24 May
- Cleaning Validation (T17), 23 – 24 May
- C&Q (T40), 24 – 25 May
- Process Validation (T46), 23 – 25 May
- Project Management* (T26), 24 – 25 May

## JUNE

**ISPE Training Institute, Tampa, FL**
- Auditing (G07), 27 – 28 Jun.
- Sterile (T12), 6 – 7 Jun.
- Q7A (T30), 20 – 21 Jun.

## JULY

**ISPE Training Institute, Tampa, FL**
- Basic GAMP® 5 Annex 11/Part 11 (T45), 11 – 13 Jul.
- Cleaning Validation (T17), 25 – 26 Jul.
- HVAC (T14), 18 – 20 Jul.

## AUGUST

**ISPE Training Institute, Tampa, FL**
- C&Q (T40), 11 – 12 Aug.
- OSD (T10), 8 – 9 Aug.

## SEPTEMBER

**Barcelona, Spain**
- GAMP® 5 Data Integrity (T50), 26 – 27 Sept.
- GAMP® 5 Process Control (T21), 27 – 28 Sept.
- HVAC (T14), 26 – 28 Sept.
- Technology Transfer (T19), 27 – 28 Sept.
- QRM (T42), 26 – 27 Sept.

## OCTOBER

**ISPE Training Institute, Tampa, FL**
- Application of GAMP® 5 (T11), 12 – 13 Sept.
- QbD (T40), 29 – 30 Sept.

**Atlanta, GA**
- Technology Transfer (T19), 22 – 23 Sept.

## NOVEMBER

**ISPE Training Institute, Tampa, FL**
- Auditing (G07), 17 – 18 Nov.
- HVAC (T14), 7 – 9 Nov.
- Facilities, Systems and Equipment Workshop (T48), 10 – 11 Nov.
- GAMP® 5 Process Control (T21), 14 – 15 Nov.

## DECEMBER

**ISPE Training Institute, Tampa, FL**
- Cleaning Validation (T17), 12 – 13 Dec.
- OSD (T10), 8 – 9 Dec.
- Sterile (T12), 15 – 16 Dec.
Register Now!
Early Bird Deadline: 9 May 2016
www.ISPE.org/2016-Quality-Manufacturing-Conference

ISPE/FDA/PQRI
Quality Manufacturing Conference

6 – 8 June 2016
Bethesda North Marriott
Bethesda, MD

ISPE
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Tampa, Florida 33609-1114 USA