Keynote Speakers

Michael Kopcha, PhD, RPh
Director,
Office of Pharmaceutical Quality
FDA/CDER
Honorary FDA Conference Chair

François Sallans, PharmD
Vice President, Quality and Compliance, Chief Quality Officer
Johnson & Johnson
Honorary Industry Conference Chair

Thomas Cosgrove, JD
Director,
Office of Manufacturing Quality
FDA/CDER/OC

Roger Nosal, PhD
Vice President and Head of Global Chemistry, Manufacturing and Controls
Pfizer Inc.

Linking Quality to Clinical Relevance

- **Susan Berlam,** Senior Director, Regulatory CMC, Pfizer Inc.
- **Shrinivas (Cheenu) Murti, PhD,** Senior Director Global CMC Regulatory Affairs, Merck & Co., Inc.
- **Daniel Peng, PhD,** Senior Principal Scientist/Director, Shire
- **Sarah Pope Miksinski, PhD,** Director, Office of New Drug Products; Director (Acting), Office of Surveillance, FDA/CDER/OPQ
- **Paul Seo, PhD,** Director (Acting), Division of Biopharmaceutics, FDA/CDER/OPQ/ONDP

Modernizing Pharmaceutical Manufacturing through Emerging Technology and Innovation

- **Gabriella Dahlgren, PhD,** Manager, Analytical Sciences and Technology, Advanced Analytics and Design to Value, Janssen Supply Group
- **John Lepore, PhD,** Senior Director Chemical Engineering, Merck & Co., Inc.
- **Frank Montgomery, PhD,** Global Head, Regulatory CMC, AstraZeneca
- **Mohan Sapru, PhD,** Quality Assessment Lead (Acting), Office of New Drug Products, and Emerging Technology Team Member, FDA/CDER/OPQ

Designing Proactive Approaches to Facility and Life Cycle Quality Management

- **James McGlade,** Science Market Leader, BHDP Architecture
- **Rakhi Shah, PhD,** Branch Chief (Acting), Office of Process & Facilities, FDA/CDER/OPQ
- **Jennifer Walsh,** Director of Robustness and Validation, Global Drug Product Manufacturing Science and Technology, Bristol-Myers Squibb

Implementing Next Steps for Quality Metrics

- **Betsy Fritschel,** Director, Quality and Compliance, Johnson & Johnson
- **Steven Greer,** Corporate Quality Assurance, External Engagement Leader, Procter & Gamble
- **Jennifer Maguire, PhD,** Division Director (Acting), Office of Surveillance, FDA/CDER/OPQ
- **Sarah Pope Miksinski, PhD,** Director, Office of New Drug Products; Director (Acting), Office of Surveillance, FDA/CDER/OPQ
- **Bryan Winship,** Senior Director Global Quality Risk Management, Mylan

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Top Priorities for 2017 From Industry and the FDA Office of Pharmaceutical Quality and Office of Compliance

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- Linking Quality to **Clinical Relevance**
- Modernizing Pharmaceutical Manufacturing through **Emerging Technology and Innovation**
- Designing Proactive Approaches to Facility and **Life Cycle Quality Management**
- Implementing Next Steps for **Quality Metrics**

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HONORARY CHAIRS

- **Michael Kopcha, PhD, RPh**
  Director, Office of Pharmaceutical Quality
  FDA
- **François Sallans, PharmD**
  Vice President Quality & Compliance, Chief Quality Officer
  Johnson & Johnson

REGULATORY AND INDUSTRY PLANNING TEAM

- **George Millili, PhD, Industry Chair**
  Senior Principal Technical Advisor
  Genentech (A Member of the Roche Group)
- **Timothy Watson, PhD, Industry Co-Chair**
  Research Fellow/CMC Advisory Office
  Pfizer Inc.
- **Rapti Madurawe, PhD, FDA Co-Chair**
  Director (Acting)
  Division of Process Assessment I, FDA/CDER/OPQ
- **Linda Evans O'Connor, PhD, PQRI Co-Chair**
  Director
  Lachman Consultant Services

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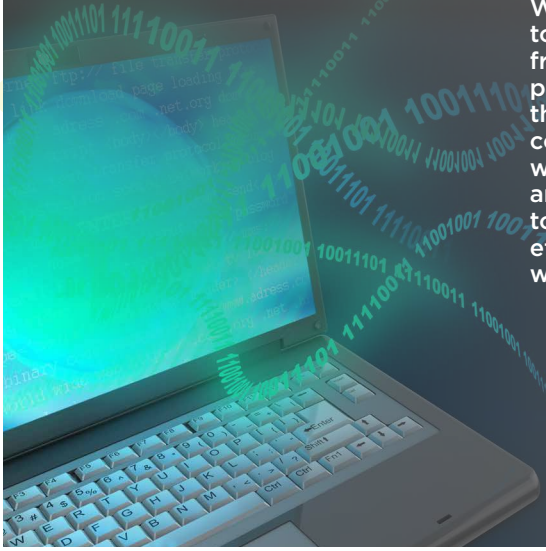

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Attend the ISPE Data Integrity Workshop on 4 June

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Want to know how to avoid 483s, warnings, import alerts, injunctions, seizures, Application Integrity Policy Invocations, and legal action from the FDA?

The 2017 ISPE Data Integrity Workshop will show you how to do just that, and more. Learn from practical, scenario-based problem solving and case studies that simulate real-world industry conditions. Engage and interact with pharmaceutical industry and regulatory thought leaders to grow your understanding of effective Data Integrity practices, with a special focus on:

- **Data Mapping/Flow**
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- **Data Integrity Governance**
- **NEW! *ISPE GAMP® Guide: Records and Data Integrity****

Separate purchase required

Monday, 5 June

Opening Keynote Session

Featured Speakers:

- **François Sallans, PharmD,** Vice President, Quality and Compliance, Chief Quality Officer, Johnson & Johnson
- **Michael Kopcha, PhD, RPh,** Director, Office of Pharmaceutical Quality, FDA/CDER

8 Workshop Sessions on 4 Core Topics Led by Regulatory and Industry Facilitators

Welcome Reception

Tuesday, 6 June

Keynote Session

Featured Speaker:

- **Roger Nosal, PhD,** Vice President, Pfizer Inc.

8 Workshop Sessions on 4 Core Topics Led by Regulatory and Industry Facilitators

Featured Sessions on Industry Initiatives

Facility Of The Year (FOYA) Reception

FOYA AWARDS BANQUET – Ticketed Event

Wednesday, 7 June

Keynote Session

Featured Speakers:

- **Helen Y. Saccone, PharmD,** Associate Director, Global Regulatory Policy, Office of Global Regulatory Operations and Policy, FDA/OC, *Invited*
- **Thomas Cosgrove, JD,** Director, Office of Manufacturing Quality, FDA/CDER/OC

Workshop Summary Presentations and Next Steps

Regulatory Round Table

FOYA 2018
Facility of the Year Awards

Facility of the Year Reception and Banquet

Tuesday, 6 June 2017

Join ISPE and prominent industry leaders as we recognize the 2017 Facility of the Year Awards (FOYA) Winners for their innovation and creativity in pharmaceutical and biotechnology facility design, construction, and operation. The FOYA Awards Reception and Banquet is the perfect opportunity to be seen by top pharmaceutical decision makers. Register as an individual or bring a group of your colleagues to honor and support these esteemed winners.

Individual tickets may be purchased during registration for $165.

For Exhibit and Onsite Branding Opportunities

Please contact Alisa Pachella, Sales Account Manager, at **apachella@ispe.org** or **+1-813-739-2274.**

Conference Fees

Type	On or Before 24 April	After 24 April
Member	US$2,145	US$2,345
Nonmember	US$2,525	US$2,725
Committee	US$1,610	US$1,760
Government	US$700	US$700
Young Professional	US$700	US$700
Student Member	US$75	US$75
Academia Member	US$1,610	US$1,760

Already registered for the Quality Manufacturing Conference? Add the Data Integrity Workshop to your itinerary. The workshop is a value-add and a must-attend event for anyone who wants to gain a comprehensive understanding of key data integrity issues over the pharmaceutical product life cycle. Save $100 when you register for both events.

Combined Registration Rates for Quality Manufacturing Conference and Data Integrity Workshop

Type	On or Before 24 April	After 24 April
Member	US$2,700	US$2,900
Nonmember	US$3,080	US$3,280
Committee and Academia	US$2,165	US$2,315
Government and Young Professional	US$850	US$850
Student Member	US$100	US$100

FOYA Reception and Banquet

Individual Ticket	US$165
Table for Eight	US$1,300

Group Discounts

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- Meet exhibitors dedicated to manufacturing software and equipment, validation and compliance services, and many other applications.

How to Register

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3. **Fax:** Complete the online registration form and fax it to: +1-813-264-2816
4. **Mail:** Complete the online registration form and mail it with payment to:

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