## Conference Highlights

- Interactive Round Table Discussions with front-line District FDA leaders
- Case Studies presented by companies achieving successful turn-around
- FDA and Industry Session on implementing Sustainable Strategies
- Best-in-Class Tools for improving People-Process-Technology
- Successful communication and response strategies recommended by Legal and Industry experts

## Plenary Session

New Perspectives on GMP Quality and Compliance

#### **Speakers**



Moving from Quality Control to Quality Assurance Guv Wingate, Ph.D. VP & Compliance Officer, GlaxoSmithKline, UK



Sustainable Quality Claudio Pincus President, Quantic Group, USA



**Current FDA Perspectives on Proactive Compliance** 

Joseph McGinnis, R.Ph. New Jersey District Director, Compliance Branch, FDA Office of Regulatory Affairs, USA

#### Sponsorship Opportunities Available

Sponsoring an ISPE educational seminar or training program is a cost-effective way to gain competitive advantage, increase name recognition and create top-ofmind awareness in today's pharmaceutical science and biotechnology manufacturing industry. Sponsorships include pre-event exposure on the ISPE website, onsite exposure with exhibit opportunities, company logo on signage and mentions in print and electronic communication.

For more information or to secure your sponsorships, contact Daniel Murphy at dmurphy@ispe.org.



**TODAY!** 

www.ISPE.org/2014ProactiveComplianceConference

# Ahead

Go Beyond Basic Compliance.

## Proactive Compliance Conference

13 - 14 January 2014

Hilton East Brunswick Hotel & Executive Meeting Center East Brunswick, New Jersey USA





# Add Proven Proactive Tools To Your Resources From Regulatory And Industry Experts

PEOPLE: Reducing Human Error • PROCESS: Preventing Repeat Compliance Issues • TECHNOLOGY: Effective Measuring and Monitoring

FDA Leaders from the New Jersey and Philadelphia District Offices confirmed to participate in the full conference including interactive discussions.

## Monday, 13 January

09.00 - 12.00 PLENARY SESSION: New Perspectives on GMP Quality and Compliance

Paul D'Eramo, VP Pharmaceutical Regulatory Compliance, Johnson & Johnson, USA

Current FDA Perspectives on Proactive Compliance

Joseph McGinnis, R.Ph., Director of Compliance New Jersey District, FDA, USA

Moving from Quality Control to Quality Assurance

Guy Wingate, Ph.D., VP & Compliance Officer, GlaxoSmithKline, UK

Sustainable Quality

Claudio Pincus, President, Quantic Group, USA

10.30 - 11.00 Networking Break

12.00 - 13.00 Lunch with Exhibitors

13.00 – 14.30 Proactive Approaches to Current Regulatory Priorities

FDA regulators share their experience on current hot topics regarding cGMPs and pre-approvals. Hear proactive approaches to compliance, current regulatory priorities, and answers to your pressing questions.

Leader: Joseph McGinnis, R.Ph., Director of Compliance NJ District, FDA, USA

Karyn Campbell, Director, Investigations Branch, FDA, USA

Denise DiGiulio, Compliance Officer, GDMA Branch, FDA/CDER/OMPQ, USA

Erin McCaffery, Consumer Safety Officer, FDA, USA

14.30 – 15.30 Proactive Company Benchmarks—Interactive Round Table Discussions

FDA regulators and industry experts facilitate open discussion on

- Compliance Challenges
- Organizational Culture
- Training and Coaching
- Technology
- Pre and Post Inspections

**Leader: Paul D'Eramo,** VP Pharmaceutical Regulatory Compliance, Johnson & Johnson, USA

Karyn Campbell, Director, Investigations Branch, FDA, USA

Denise DiGiulio, Compliance Officer, GDMA Branch, FDA/CDER/OMPQ, USA

Erin McCaffery, Consumer Safety Officer, FDA, USA

Joseph McGinnis, R.Ph., Director of Compliance NJ District, FDA, USA

15.30 - 16.00 Networking Break with Exhibitors

16.00 – 17.00 Proactive Quality Assurance Model

Undergoing a Quality Remediation Plan: Key Challenges

Veronica Cruz, Vice President Quality & Compliance, Johnson & Johnson, USA

17.00 - 18.30 Networking Reception with Exhibitors

## Tuesday, 14 January

08.30 – 09.30 Proactive Quality Assurance Strategies

Consent Decrees: How to Think and Act

Roy Sturgeon, Ph.D., President, Lachman Consultant Services Inc., USA

09.30 – 14.45 Best-In-Class Proactive Tools and Strategies People-Process-Technology

Moderators: Stephen Mahoney, Senior Advisor Global Quality & Compliance,

Paul D'Eramo, VP Pharmaceutical Regulatory Compliance, Johnson & Johnson, USA

Proactive Responses to Regulatory Intervention

Jennifer Zachary, Associate, Covington & Burling LLP, USA

Driving Quality through People: A Sustainable Human Error Prevention Program

Wendy Kouba, Executive Director, Strategy Realization Office, Merck Global Vaccines & Sterile Manufacturing, USA

Reni Gorman, Sr. Director of Consulting, Performance Development Group, USA

**Quality Metrics: Achieving Standardization across Your Organization Sandra Omrod,** Global Quality Manager, Quality Standards & Compliance, AstraZeneca, USA

Making the Case for e-Production Records

Gregory Ruklic, Systems & Compliance Professional, Independent, USA

10.30 – 11.15 Networking Break with Exhibitors

12.30 - 13.30 Lunch with Exhibitors

14.45 – 15.00 Networking Break with Exhibitors

15.00 – 16.00 Implementing and Sustaining Proactive Strategies: Regulatory and Industry Perspectives

Moderator: Guy Wingate, Ph.D., VP & Compliance Officer, GlaxoSmithKline, UK

Karyn Campbell, Director, Investigations Branch, FDA, USA

Paul D'Eramo, VP Pharmaceutical Regulatory Compliance, Johnson & Johnson, USA

Denise DiGiulio, Compliance Officer, GDMA Branch, FDA/CDER/OMPQ, USA

Stephen Mahoney, Senior Advisor Global Quality & Compliance, Genentech Inc., USA

Erin McCaffery, Consumer Safety Officer, FDA, USA

Joseph McGinnis, R.Ph., Director of Compliance NJ District, FDA, USA

Please visit the conference website for more details at www.ISPE.org/2014ProactiveComplianceConference

### Conference Fees

	REGULAR / ONSITE (AFTER 16 DECEMBER)			
- 1	☐ Member ☐ New Member	\$ 1,745 \$ 2,014	□ Nonmember □ Committee	\$ 2,115 \$ 1,005
- 1	Government Academia/Emerging Economy Members	\$ 500 \$ 1,135	Student Members	\$ 200

#### GROUP DISCOUNT RATE OFF OF REGULAR REGISTRATION FEE:

3 - 5 participants Save 10%
6 - 10 participants Save 15%
11 or more participants Save 20%

To qualify, all registrant information must be submitted at the same time; only ONE payment to cover all registrations will be accepted. Registrations that arrive later will NOT be eligible for the group discount. To register as a group, please contact ISPE (tel: +1-813-960-2105).

#### How to Register

Online: www.ISPE.org/2014ProactiveComplianceConference

Via Fax: Complete the registration form online

and fax it to: +1-813-264-2816

Via Mail: Complete the registration form online and

mail it with payment to:

ISPE Headquarters 600 N. Westshore Blvd., Suite 900

Tampa, Florida 33609 USA

**Questions?** Call ISPE Member Services at tel: +1-813-960-2105, or email: ask@ispe.org. For more information visit the event website.

Written confirmation will be sent to you after your registration is processed (time permitting).

#### Hotel Information

Hilton East Brunswick Hotel
& Executive Meeting Center

East Brunswick, New Jersey USA

TEL: +1-732-828-2000

FAX: +1-732-828-6958



Upcoming

Driving Innovation.

Driving Effectiveness in

Intercontinental Frankfurt

Workshop

CMO Workshop

2-5 June 2014

Hilton Baltimore

Annual Meeting

Caesars Palace

Pharma EXPO

12-15 October 2014

2-5 November 2014

Chicago, Illinois USA

McCormick Place

Las Vegas, Nevada USA

Fall 2014 Europe

3rd Annual ISPE-FDA CGMP

Stratified Sampling Workshop

Baltimore, Maryland USA

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Pharmaceutical Operations within the New Quality Culture 28-30 April, 2014 Frankfurt, Germany

#### Reservations

For room reservations at the Conference venue, Hilton East Brunswick Hotel & Executive Meeting Center, East Brunswick, New Jersey USA, call +1-732-828-2000, FAX: +1-732-828-6958. When making your reservation by phone, mention ISPE for a discounted rate of \$149 single/double. This rate is good until 31 December 2013, 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. We thank you for staying at the Hilton East Brunswick as this enables ISPE to meet contract requirements.

#### Cancellations and Substitutions

Cancellations must be made in writing. If cancellations are received by 31 December 2013, a full refund, minus a 10% handling fee (maximum of \$100), will be issued. After that time, no refunds will be granted. If you are unable to attend, substitutions will be accepted. However, nonmembers substituting for a Member must pay difference in fees prior to the start of the event. ISPE is not responsible for lost airfare due to cancellations.

Schedule