NOVEMBER 1-3, 2017  |  DOUBLETREE BETHESDA
BETHESDA, MD (WASHINGTON, DC)

2017 SUMMIT HIGHLIGHTS

NEW FOR 2017!

- FDA’s ORA Reorg and What it Means for Inspections
- Preparing for the MDSAP Audit Process: A Case Study from the Manufacturer’s Perspective
- Building Your Best Internal Audit Team for Quality Results

Plus twin tracks for drug/biologics and device manufacturers and two pre-conference workshops, focusing on FDA Inspection Management and QSIT Secrets.

Expert panels featuring current and former FDA officials and industry professionals:

- FDA Field Investigators: What They Look For, What Problems are Emerging and AMA (Ask Me Anything)
- The US/EU Mutual Recognition of Drug GMP Inspections: Practical Consequences for Manufacturers
- European Medical Device Regulations — Preparing for the Storm

FEATURED EXPERT SPEAKERS:

- JOHN AVELLANET, Managing Director and Principal, Cerulean Associates LLC
- KATLIN BACKFIELD, Attorney at Law, Consultant, Backfield PLLC
- MARK BROWN, Partner, King & Spalding
- CONNIE HOY, Executive Vice President of RA/QA, Cynosure
- IBIM TARIAH, Ph.D., Technical Director, BSI Americas Inc.
- DAN O’LEARY, President, Ombu Enterprises LLC
- SUSAN SCHNIEPP, Fellow, Regulatory Compliance Associates, Inc.
- CYNTHIA SCHNEDAR, Executive Vice President, Regulatory Compliance, Greenleaf; former Director of the Office of Compliance, CDER, FDA
- VICKY STOAKES, President, IntegRx, Inc.; former FDA Chemist, ACNA and Investigator, Atlanta District Office Drug Cadre
- KARL VAHEY, Vice President Manufacturing Quality, Patient Monitoring and Recovery, MITG, Medtronic
- STEVE NIEDELMAN, Lead Quality Systems and Compliance Consultant, King and Spalding, former FDA Deputy Associate Commissioner for Regulatory Operations
- DAVID CHESNEY, Principal and General Manager, DL Chesney Consulting, LLC
- JULIE LARSEN, Senior Partner, Director Inspection Readiness Services, BioTeknica
- CAROL BENNETT, J.D., Deputy Director, Office of Regulatory Policy, CDER, FDA (Invited)
- ROBIN NEWMAN, Director, Office of Compliance CDHR, FDA (Invited)
- DANA CORRIGAN, J.D., Associate Commissioner, Office of Global Regulatory Operations and Policy, OC, FDA (Invited)
- DOUGLAS STEARNS, Director, Office of Enforcement and Import Operations, ORA (Invited)

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Thursday, Nov. 2

8:00 a.m. – 8:30 a.m. | REGISTRATION & CONTINENTAL BREAKFAST

8:30 a.m. – 8:45 a.m.

Opening Comments by Chairperson Steve Niedelman, Lead Quality Systems and Compliance Consultant, King and Spalding, former FDA Deputy Associate Commissioner for Regulatory Operations

8:45 a.m. – 9:30 a.m.

FDA’s ORA Reorg and What It Means for Inspections

The FDA reorganized its Office of Regulatory Affairs inspectorate to more closely align inspection efforts with the myriad types of products it regulates — essentially organizing staff by area of expertise instead of geographic region. Will inspections happen more frequently? Does this make inspection outcomes more predictable or less? Will inspections be conducted faster if they are done by experts, or will they take longer to go through more detail? Associate Commissioner Ellen Morrison will discuss the latest developments and talk about what to expect from the changes.

Ellen Morrison, Associate Commissioner, OMPTO, ORA, FDA

9:30 a.m. – 10:15 a.m.

The World of FDA Quality Metrics: Yesterday, Today and Tomorrow

CDER and CBER have the Quality Metrics Submission guidance. CDRH has the Case for Quality initiative. All centers are driving towards a culture of quality within the life sciences industry. Marla Phillips has a unique perspective that comes from working on both sides of the line. With the FDA, she co-led the CDRH metrics initiative, and with PricewaterhouseCoopers, she co-led the pharmaceutical metrics initiative. Her presentation will examine the difference between the two initiatives, their progress, the differences and the similarities in their metrics. From her industry experience, she will examine the potential impacts, the unintended outcomes and how to protect everyone’s time from doing busy work that does not achieve the end goal. She will also share her thoughts of where these initiatives are headed.

Marla A. Phillips, Ph.D., Director, Xavier Health, Xavier University

10:15 a.m. – 11:00 a.m.

Postmarket Adverse Event Reporting and cGMP: What You Absolutely Need to Know

The FDA issued two final rules that set forth the postmarket safety reporting and current good manufacturing practices (cGMP) requirements for combination product and constituent part sponsors. This session summarizes key concepts and provides insightful case studies about how the rules work in the real world.
Day 1 Agenda (cont.)
THURS., NOV. 2

Katlin Backfield, Attorney at Law, Consultant, Backfield PLLC; former Associate Chief Council for Drugs, OCC, FDA

12:15 p.m. – 1:00 p.m.
Cautionary Tales: Words to the Wise on Compliance
Those who fail to learn from the mistakes of others are destined to repeat them. Using real situations encountered by pharmaceutical and biologics firms, discover strategies for staying up-to-date with FDA cGMP regulations. Examples of non-compliance are presented with suggestions for applying these lessons and improving your regulatory compliance strategies.

Vicky Stoakes, President, IntegRx, Inc.; former FDA Chemist, AGNA and Investigator, Atlanta District Office Drug Cadre

1:00 p.m. – 2:00 p.m. | LUNCH

2:00 p.m. – 3:30 p.m.
The US/EU Mutual Recognition of Drug GMP Inspections: Practical Consequences for Manufacturers
In March, the US and European Union signed a mutual recognition agreement (MRA) to recognize each other’s drug GMP inspections. This is good news for the industry that should see fewer inspections. However, it doesn’t come without some concerns. First, each inspection now has greater consequences as any third-party inspector that proves compliance in the US, Canada, Australia, Brazil, the EU and Japan. The audit process is not what you’re used to compared to an FDA or ISO audit. Cynosure has successfully certified two manufacturing sites in the last year. The Cynosure facility in MA (1,000 people) was audited as part of the MDSAP Program undergo an assessment performed by a single third-party inspector that proves compliance in the US, Canada, Australia, Brazil, the EU and Japan. The audit process is not what you’re used to compared to an FDA or ISO audit. Cynosure has successfully certified two manufacturing sites in the last year. The Cynosure facility in MA (1,000 people) was audited as part of the MDSAP Program undergo an assessment performed by a single third-party inspector that proves compliance in the US, Canada, Australia, Brazil, the EU and Japan. The audit process is not what you’re used to compared to an FDA or ISO audit. Cynosure has successfully certified two manufacturing sites in the last year. The Cynosure facility in MA (1,000 people) was audited as part of the MDSAP Program undergo an assessment performed by a single third-party inspector that proves compliance in the US, Canada, Australia, Brazil, the EU and Japan. The audit process is not what you’re used to compared to an FDA or ISO audit. Cynosure has successfully certified two manufacturing sites in the last year. The Cynosure facility in MA (1,000 people) was audited as part of the MDSAP Program undergo an assessment performed by a single third-party inspector that proves compliance in the US, Canada, Australia, Brazil, the EU and Japan. The audit process is not what you’re used to compared to an FDA or ISO audit. Cynosure has successfully certified two manufacturing sites in the last year. The Cynosure facility in MA (1,000 people) was audited as part of the MDSAP Program undertake

Moderator: David Chesney, Principal and General Manager, DL Chesney Consulting, LLC; former FDA District Director for the San Francisco office

Dara Corrigan, J.D., Associate Commissioner, Office of Global Regulatory Operations and Policy, OC, FDA (Invited)

Cynthia Schnedar, Executive Vice President, Regulatory Compliance, Greenleaf; former Director of the Office of Compliance, CDER, FDA

Katlin Backfield, Attorney at Law, Consultant, Backfield PLLC

Mark Brown, Partner, King & Spalding

3:30 p.m. – 3:50 p.m. | BREAK

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before, during and after an inspection. During an inspection? This presentation will give you a framework they follow, and what affects their thinking they receive their next inspection assignment? What problems are emerging and AMA (Ask Me Anything)?

Karl Vahey, Vice President Manufacturing Quality, Ibim Tariah, Technical Director, BSI Americas Inc. Dan O’Leary, President, Ombu Enterprises LLC Inspection Readiness Services, BioTeknica

Moderator: Julie Larsen, Principal/Director, Inspection Readiness Services, BioTeknica

Dan O’Leary, President, Ombu Enterprises LLC

Ibim Tariah, Technical Director, BSI Americas Inc.

Karl Vahey, Vice President Manufacturing Quality, Patient Monitoring and Recovery, Medtronic

3:30 p.m. – 3:50 p.m. | BREAK

Plenary Session Panel Discussion

3:50 p.m. – 5:15 p.m.

FDA Field Investigators Panel: What They Look For, What Problems are Emerging and AMA (Ask Me Anything)

Ever wonder what an investigator is thinking when they receive their next inspection assignment? What framework they follow, and what affects their thinking during an inspection? This presentation will give you a glimpse into the inner workings of an investigator’s mind before, during and after an inspection.

Attendees will learn:

• What information does an investigator have before he or she shows up at your door?
• Do investigators prepare differently for different companies, plants or products?
• What is the first thing they notice when they enter a plant?
• How do investigators apply QSIIT and other inspectional techniques to the QSR?
• Why they include items in the EIR and Form 483 and how they take into account your comments

PLUS, this panel will take your questions (anonymously if you wish). So, here is your chance to ask questions and get answers straight from investigators in the field every day! Don’t miss this opportunity to get your answers!

5:15 p.m. – 6:30 p.m. | NETWORKING RECEPTION

8:00 a.m. – 8:30 a.m. | REGISTRATION & CONTINENTAL BREAKFAST

8:30 a.m. – 8:45 a.m.

Opening Comments by Chairperson Steve Niedelman, Lead Quality Systems and Compliance Consultant, King and Spalding, former FDA Deputy Associate Commissioner for Regulatory Operations

8:45 a.m. – 9:30 a.m.

FDA’s Office of Regulatory Affairs: Enforcement Update

This presentation will focus on ORA’s Office of Enforcement priorities for 2018, and changes to how the office approaches the process. This session will ensure attendees have the latest information on how they can more proactively prepare for FDA investigators.

Attendees will learn:

• The latest on the FDA’s re-organization of the inspectional corps
• The FDA’s position on recalls and the possible actions the Office of Enforcement can take in the wake of them
• Effectiveness of criminal sanctions in improving compliance among drug and device company senior management
• Whether 483s and warning letters will be produced more quickly and highlighted for the public as a deterrent to poor corporate behavior

Douglas Stearns, Director, Office of Enforcement and Import Operations, ORA (Invited)

9:30 a.m. – 10:15 a.m.

Building Your Best Internal Audit Team for Quality Results

An internal audit of your quality management system should be a collaboration, not a confrontation, with auditor and auditee working together to spot issues that weaken your system. You need to move your audit team beyond the “blame and shame” mindset that can keep them from openly and honestly sharing the information you need to work out solutions and make your QMS stronger.

Your internal audits can be a positive and productive experience for all if you apply the lessons in this session:

• How to train your employees to handle audits in the most productive way;
• How to select the best auditor to work with your team;
• How to follow the internal audit with corrective action;
• How to report audit findings to management and get them to buy in to suggested solutions; and
• How to evaluate your internal auditing system’s effectiveness.

Susan Schniepp, Distinguished Fellow, Regulatory Compliance Associates, Inc.

10:15 a.m. – 10:30 a.m. | BREAK

10:30 a.m. – 12:00 p.m.

How to Deal with Difficult Inspections

Co-Chair Steve Niedelman and long-time industry expert, David Chesney, will provide real-world scenarios for dealing with tense inspections. Through open discussion and feedback, the audience will work together to come to the correct conclusion for each scenario.

Steve Niedelman, Lead Quality Systems and Compliance Consultant, King and Spalding LLP; former FDA Deputy Associate Commissioner for Regulatory Operations

David Chesney, Principal and General Manager, DL Chesney Consulting, LLC; former FDA District Director for the San Francisco office

12:00 p.m. | SUMMIT ADJOURNS

“Great and interesting sessions. Great panel discussions and attendee participation.”

— Johanna Stamates, Executive Director - Research Compliance and Quality Assurance, University of Miami

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YES! Sign me up for the 12th Annual FDA Inspections Summit

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*Register by September 29, 2017 to take advantage of our Early Bird discount.

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Written cancellations received at least 21 calendar days prior to the start date of the event will receive a refund — less a $200 administration fee. No cancellations will be accepted — nor refunds issued — within 21 calendar days from the start date of the event. A credit for the amount paid may be transferred to any future FDAnews event. Substitutions may be made at any time. No-shows will be charged the full amount. In the event that FDAnews cancels the event, FDAnews is not responsible for any airfare, hotel, other costs or losses incurred by registrants. Some topics and speakers may be subject to change without notice.

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Room rate: $182 plus 13% tax
Reservation cut-off: Oct. 2, 2017

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Tuition includes the preconference workshop, all conference sessions, conference and workshop materials, two breakfasts, one luncheon, one reception, and refreshments. BONUS: Registration includes six month access to archived session recordings after the conference.

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PRE-CONFERENCE WORKSHOP ONLY
Tuition includes the preconference workshop, workshop materials, and refreshments.

LIVESTREAMING
We know that not everyone can travel to the 12th Annual FDA Inspections Summit, so we have decided to stream it live! It’s a great way to see sessions as they happen. Registration is quick and accessing the live sessions is as simple as clicking your mouse. BONUS: Includes six month access to archived session recordings after the conference.

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The FDA Inspections Summit — now in its 12th year — has fast become the “go-to” event for regulatory, compliance and quality assurance professionals and the one place to discover the tools and techniques to improve your inspectional readiness.

Join us for this rare opportunity to interact with top officials from CDER, CDRH, the Office of Regulatory Affairs and other outstanding industry leaders to discuss debate and uncover the latest priorities, expectations and best practices.

NO OTHER conference brings together so many of the industry’s inspectional professionals. This is your one chance to come to the nation’s capital and interact with the top minds in the FDA arena. As you network with these senior-level professionals, you’ll discuss the latest developments from the FDA and Congress and how you need to position your firm to assure successful inspections.