FDANEWS PRESENTS THE

11TH ANNUAL

FDA INSPECTIONS SUMMIT

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#1 EVENT FOR QUALITY, COMPLIANCE AND INSPECTIONAL READINESS PROFESSIONALS

INVITED FDA SPEAKERS:

ROBIN NEWMAN
Director
Office of Compliance
CDHR, FDA

MARY ANN SLACK
Deputy Director
Office of Strategic Programs
CDER, FDA

SUMMIT CO-CHAIRS:

JOHN AVELLANET
Managing Director
and Principal
Cerulean Associates, LLC

JULIE LARSEN
Senior Partner
Director Inspection
Readiness Services
BioTeknica

STEVE NIEDELMAN
Lead Quality Systems and Compliance Consultant
King and Spalding, LLC, former Deputy Associate
Commisioner for Regulatory Opearions

NOVEMBER 2-4, 2016 | DOUBLETREE BETHESDA BETHESDA, MD (WASHINGTON, DC)

2016 SUMMIT HIGHLIGHTS

4 panels featuring current and former FDA officials, including:

- **New for 2016** - FDA Inspections – A New, Modern Record Review Technique
- **New for 2016** - After the Election: A Look Ahead to What a New Administration Could Bring and the Impact on the FDA
- Effective Management of Front and Back Inspection Rooms – Secrets You've Never Heard and Answers to Questions You've Always Wanted to Ask
- A Day in the Life of an FDA Field Investigator – How Inspectors Prepare and Approach Assigned Inspections

How the FDA's Realignment Program Impacts You

The Latest on the FDA's Re-organization of the Inspectional Corps and How Could it Impact Your Daily Operations and Your Upcoming Inspection

Measuring the Real Business Impact of Quality Metrics

Plus twin tracks for drug/biologics and device manufacturers and 2 pre-conference workshops, focusing on drugs and devices.

FEATURED EXPERT SPEAKERS:

MARC-HENRI WINTER, Staff Fellow, Division of International Compliance Operations, OC, CDRH, FDA (invited)

ARMANDO ZAMORA, Deputy Director, Office of Enforcement and Import Operations, Office of Global Regulatory Operations and Policy, ORA, FDA (invited)

DAVID CHESNEY, Principal and General Manager, DL Chesney Consulting, LLC

BRYAN J. COLEMAN, Senior Director Pharmaceutical & device Consulting Services, EAS Consulting Group

TERESA GORECKI, VP Global Business Quality, Janssen Pharmaceuticals

STEVEN GROSSMAN, President of HPS Group, LLC, former Deputy Assistant Secretary for Health, HHS, former Health Staff Director, Senate HELP Committee

KAY HOLCOMBE, Senior Vice President, Science Policy, Bio

DAN O'LEARY, President, Ombu Enterprises

JOHN TAYLOR, Principal, Compliance and Regulatory Affairs, Greenleaf Health LLC

KARL VAHEY, Senior Director , Manufacturing Quality, Europe and Asia, Medtronic

JOHN (JACK) GARVEY, Chief Executive Officer, Compliance Architects, LLC

ARMIN TORRES, Principal/Senior Software Consultant, BioTeknica

GILDA D'INCERTI, CEO, Pharma Quality Europe

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Pre-conference Workshops Agenda

WEDNESDAY, NOVEMBER 2

DRUGS & BIOLOGICS TRACK

12:00 p.m. – 1:00 p.m. | **REGISTRATION**

1:00 p.m. – 5:00 p.m.

Flawless FDA Inspection Handling and Response

FDA warning letters begin with a summary of the failed inspection, and then quickly dismiss a firm's effort to respond. In a very public way, FDA categorizes one company after another as "inadequate," "insufficient," "lacking" and worse.

Handling an inspection successfully requires a strategy designed to get the FDA investigator in and out as quickly as possible. The longer an FDA investigator is on site, the worse your chances are of avoiding a FDA 483.

And when the 483 arrives, do you know how to respond in less than 15 days to avoid a warning letter?

A defensible response can be hard to assemble – and get through internal review – with enough time to beat the enforcement clock at FDA.

This workshop gives you proven, practical techniques for fast, flexible and flawless inspection handling and responses that exceed FDA expectations and support your side. You'll learn how to prepare for an inspection, how to encourage the investigator to see you in a "state-of-control," and how – if the worst happens – to go from 483 observation to FDA's coveted untitled letter – and avoid the warning letter publicity.

Attendees Will Learn:

- Critical inspection preparation techniques to take – even if you get surprised by FDA
- Hidden tactics FDA investigators use to test your controls
- How to speed the inspection to minimize the risk of 483 findings
- Key elements of a realistic regulatory inspection handling SOPs
- How to write an inspection response designed to reduce warning letter likelihood
- Red flags FDA looks for in your inspection response

Attendees Will Receive:

- A sample SOP – ready for your immediate implementation
- Three inspection handling and response checklists – ready for you to use right away
- An observation-closure matrix – ready to speed you out of FDA trouble

John Avellanet, Managing Director and Principal, Cerulean Associates LLC

MEDICAL DEVICES TRACK

12:00 p.m. – 1:00 p.m. | **REGISTRATION**

1:00 p.m. – 5:00 p.m.

ISO 13485:2016 – Understand the Concepts of Risk and Their Applications

The new QMS standard, published in March, alerts manufacturers to the presence of risk in almost all operations—from design control to supplier management to software validation and more. While it does not specifically address the concept of risk management (you'll find that in ISO 14971:2007), ISO 13485:2016 makes it clear that manufacturers must be aware of the opportunity for risk in all they do.

This workshop examines the concept of risk as presented in the new standard and explains how to apply it in the quality management systems. Through examples that illustrate ISO 13485:2016's requirements, interactive exercises that help solidify understanding, and a unique set of checklists that cover all the QMS bases, attendees will learn:

- How the QMS standard integrates with the risk management standard in ISO 14971:2007
- How the implementation timeline may differ from country to country
- How inclusion in MDSAP could impact inspections of U.S. manufacturers
- How the European version differs from the international version

Quality systems expert Dan O'Leary explains ISO 13485:2016's concept of risk in clear terms that will prepare you for the changes ahead.

Dan O'Leary, President, Ombu Enterprises

What Past Attendees Have Said About the FDA Inspections Summit:

"This Summit is in the top 3 meetings I have attended. Looking forward to next year."

"I loved the ease to interact with FDA investigators and others involved in the conference."

"I really enjoyed having the opportunity to ask FDA investigators questions in a long open session."

Day 1 Agenda

THURSDAY, NOVEMBER 3

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

8:30 a.m. – 8:45 a.m.

Opening Comments by Chairperson John Avellanet, Managing Director & Principal, Cerulean Associates LLC

8:45 a.m. – 9:30 a.m.

FDA Realignment Program Is In Effect: How That Impacts You

Under its recent organizational changes, FDA is developing specific action plans to align its centers and the Office of Regulatory Affairs with new strategic goals and increased demands. The plans include critical actions to fulfill the agency's mandate in training; compliance and enforcement; imports; and information technology, all of which will affect all areas of medical products inspection and poses these vexing questions:

- What impact will the transition to a commodity-based and vertically integrated regulatory program have on inspections?
- What will be the major changes in MDSAP?
- How will new training and certification requirement impact medical product inspections?

9:30 a.m. – 11:00 a.m.

FDA Inspections – A New, Modern Record Review Technique: A Panel Discussion

It is becoming more common for investigators to review your documents and data maintained in your QMS in real time. An investigator may request electronic copies of your records on a memory stick. Or request the ability to browse through your complaint management system to review documentation. Are you prepared?

This panel will discuss:

- FDAs new ability to analyze your data – by sorting it and spotting trends which they can then link to potential issues in other quality management systems.
- The lack of SME preparation – as you don't know what they will look at you can't rehearse each document and be ready when questioned.
- Increased document challenges – some documents don't stand on their own without significant explanation.

(cont.)

- The importance of writing plain, simple English – all documents need to convey what you need without interpretation. Writing clearly and consistently has never been more important.

11:00 a.m. – 11:20 a.m. | BREAK

11:20 a.m. – 3:30 p.m.

Two Concurrent Breakout Tracks

Track 1 — Drugs & Biologics

Track 2 — Medical Devices

3:30 p.m. – 3:50 p.m. | BREAK

3:50 p.m. – 5:15 p.m. | PLENARY PANEL DISCUSSION

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

DRUGS & BIOLOGICS TRACK

11:20 a.m. – 11:30 a.m. | MODERATOR COMMENTS

11:30 a.m. – 12:15 p.m.

Understanding OPQ's New Inspection and Reporting Plan and Organizational Structure

This session will discuss how CDER's new "super" Office of Pharmaceutical Quality plans to divvy up inspections among its three offices, and how it will incorporate pre-approval inspections into the OPQ team review to standardize quality assessments.

Attendees will learn about OPQ's new inspection protocol that will focus on expert investigator-developed questions and assessment practices and how mobile technology will be incorporated to support investigators during inspections

12:15 p.m. – 1:00 p.m.

Quality-Driven Data Integrity Approach In the EU and US Inspections

Data integrity requirements have been strongly enforced in recent years by almost every regulated agency in the pharmaceutical environment: the expectations have been clarified in a number of guidances issued by MHRA, WHO and most recently by the FDA. Therefore, the requirements for data integrity are now considered a fundamental expectation and strictly connected to the relevant predicate rules.

This presentation will provide real life case studies and examples you can use to base your control measures upon the potential impact of data on product quality and patient safety.

1:00 p.m. – 2:00 p.m. | LUNCH

2:00 p.m. – 3:30 p.m.

How to Deal with Difficult Inspections

Co-Chair Steve Niedelman 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.

3:30 p.m. – 3:50 p.m. | BREAK

MEDICAL DEVICES TRACK

11:20 a.m. – 11:30 a.m. | MODERATOR COMMENTS

11:30 a.m. – 12:15 p.m.

Update from the Office of Compliance at CDRH: Priorities for 2017

This is not your father's CDRH. There's more emphasis on global activities and a greater expectation of transparency and privacy. You'll hear the director of compliance discuss and answer questions about these important issues:

- The new inspection approach/strategy for medical devices in 2017 and its practical impact on your business
- The new CDRH, ORA and the Office of Crisis Management (OCM) streamlined process for medical devices and what it all means for electronic product related consumer complaints and Allegations of Regulatory Misconduct (ARMs)
- The new CDRH and ORA process to measure, document, and report on public health outcome metrics and how it will affect inspection compliance

12:15 p.m. – 1:00 p.m.

Medical Device Single Audit Program Pilot (MDSAP) In Full Swing

Manufacturers entering the Medical Device Single Audit Program undergo an assessment performed by a single third-party inspector that proves compliance in the U.S., Canada, Australia, Brazil, the EU and Japan.

So far, one audit has been conducted and others are in the pipeline, and responses from participants have been positive.

One big advantage to the MDSAP is that because audits aren't performed by the U.S. government, their results aren't public record — and there's no Form 483 that can be requested via the Freedom of Information Act.

Attendees will hear first-hand progress on the program from the FDA's Marc-Henri Winter, who will share lessons learned from the pilot program. Devicemakers will learn what to expect from an audit and how multiple sites should be audited.

1:00 p.m. – 2:00 p.m. | LUNCH

2:00 p.m. – 3:30 p.m.

Effective Management of Front And Back Inspection Rooms — Secrets You've Never Heard and Answers To Questions You've Always Wanted To Ask: A Panel Discussion

As the FDA's field staff continues to grow, that long overdue inspection is more likely than ever to occur. Plus add the FDA's newest push to develop teams of highly qualified investigators with a deep knowledge of your device. Together, you're in for some really tough inspections. Worried? Don't be. This panel will provide you pages of great tips and tricks to designing, staffing and managing your inspectional war rooms. Our experts will also answer those questions that have been nagging at you for years. Don't miss this exciting panel!

Attendees will learn:

- Polite in the front, craziness in the back? It doesn't have to be. Understanding the synergy of the front and back rooms
- Handling data requests, particularly for electronic records — best practices from inspectional veterans

(cont.)

- Being a SME in your job doesn't make you an inspection SME. Tips for staffing your war rooms with the appropriate people to interact with the FDA

3:30 p.m. – 3:50 p.m. | BREAK

Plenary Session Panel Discussion

3:50 p.m. – 5:15 p.m.

A Day in the Life of FDA's Field Investigators — Current Field Investigators Explain What They Look For and Why: A Panel Discussion

Ever wonder what an investigator is thinking when she receives the next inspection assignment? Investigators typically create inspection plans based on a company's previous Form 483s, warning letters, responses to warning letters, consumer complaints and recalls. But they also study a company's website, including literature, products manufactured and recent press releases.

This presentation will give you a glimpse into the inner workings of an investigator's mindset before, during and after your inspections.

Attendees will learn:

- What does an investigator's prep package contain?
- What research – both internal and external – do they use to prepare themselves for your company, plant and products?
- What do they look for once inside your plant?
- How they apply QSIT 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

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

8:00 a.m. – 8:30 a.m. | BREAKFAST

8:30 a.m. – 8:45 a.m.

Opening Comments by Chairperson

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 2017, and how the office approaches the enforcement process. This session will educate attendees on how they can more proactively prepare for FDA investigators before they arrive.

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

9:30 a.m. – 10:15 a.m.

The Regulatory Intelligence Platform

Being prepared for inspections means that you understand both the internal and external data that affect your products. Now more than ever there is an expectation that companies are analyzing and acting on this data

In this session, you'll learn:

- What is regulatory intelligence and how does it affect your business
- How to leverage regulatory intelligence as integral part of inspection readiness
- What data is available through open systems and what you should be looking at
- What should be included in your regulatory intelligence platform

10:15 a.m. – 10:30 a.m. | BREAK

10:30 a.m. – 12:00 p.m.

After the Election: A Look Ahead To What a New Administration Could Bring and the Impact on the FDA

In this election year, if almost anyone tells you that they know who the next president is going to be or exactly what's going to happen at FDA in 2017 and beyond is probably just whistling in the wind. But these panelists bring incredible inside knowledge and decades of experience in the nitty-gritty of Washington politics to provide an educated analysis of FDA operations. Here's what you'll hear discussed at this lively, interactive session about the future of FDA:

- Will there be increased efforts at global regulatory harmonization or more country-by-country compliance
- Will there be increased agency enforcement or more reliance on voluntary industry compliance
- Will there be increased legislation or rollbacks in regulation

12:00 p.m. | CONFERENCE 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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*Register by September 30, 2016 to take advantage of our Early Bird discount.

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CANCELLATION AND SUBSTITUTION

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.

HOTEL INFORMATION

Doubletree Bethesda
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Room rate: $179 plus 13% tax
Reservation cut-off: Oct. 11, 2016

TEAM DISCOUNTS

Significant tuition discounts are available for teams of two or more from the same company. You must register at the same time and provide a single payment to take advantage of the discount. Call +1 (703) 538-7600 for details

COMPLETE SUMMIT

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.

CONFERENCE ONLY

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

PRE-CONFERENCE WORKSHOP ONLY

Tuition includes the preconference workshop, workshop materials, and refreshments.

LIVESTREAMING

We know that not everyone can travel to the 11th 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.

LIVESTREAMING BENEFITS INCLUDE

- The live stream is available from your computer or mobile device.
- Watch the live streaming video of the presenter and view the presentation materials in real-time.
- Easily download presentation materials and any other supporting documents provided.
- Ask questions of the speakers during the live conference from your home, office or on the go with your mobile device.

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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.

WHO SHOULD ATTEND?

- Executive Management
- Regulatory Affairs
- Quality Assurance/Quality Control
- Legal and Compliance Officers
- Consultants/Service Providers