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INVITED FDA SPEAKERS:

JANET WOODCOCK
Director
CDER, FDA

MELINDA PLAISIER
Associate Commissioner
ORA, FDA

PHIL PONTIKOS
CSO, National Device Expert, OMPTO, ORA, FDA, Columbus, OH

DR. NEIL STIBER
Operations Research Analyst, Office of Strategic Programs, CDER, FDA

"The panels were great. Very informative and great discussions."

— **Nancy Carranza, VP, Operations, GSMS, Inc**

"Great discussion and knowledgeable panel. I enjoyed having the FDA give examples in their own words…"

— **Dan Lewis, Site Quality Leader, P&G**

NOVEMBER 4-6, 2015 | HYATT REGENCY BETHESDA BETHESDA, MD (WASHINGTON, DC)

2015 SUMMIT HIGHLIGHTS

4 panels featuring current and former FDA officials, including:

- **Understanding FDA's Quality Metrics Initiative** — what's the latest on the quality initiative and how can you get prepared for what's coming?
- **A day in the life of an investigator** – how inspectors prepare to conduct inspections
- **Discussing inspection protocols** — how to treat investigators when they are in your facility
- **Understanding how to avoid 483s**

What to expect with FDA's Mutual Inspection Program With Europe

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

FDA's Office of Regulatory Affairs: Enforcement Update

FEATURED EXPERT SPEAKERS:

JOHN AVELLANET, Managing Director and Principal, Cerulean Associates LLC – Conference Co-Chair

JULIE LARSEN, Senior Partner, Director Inspection Readiness Services, BioTeknica – Conference Co-Chair

STEVE NIEDELMAN, Lead Quality Systems and Compliance Consultant, King and Spalding, former FDA Deputy Associate Commissioner for Regulatory Operations – Conference Co-Chair

DENYSE BAKER, Senior Advisor, Scientific and Regulatory Affairs, PDA; former Quality Assurance Specialist, Office of New Drug Quality Assessment, CDER, FDA

DAVID ELDER, Vice President of Strategic Compliance Services, PAREXEL Consulting; former Director of the Office of Enforcement, ORA, FDA

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

MÁIRÉAD GOETZ, Head of Compliance, Group Compliance and Audit, Group Quality Assurance, Novartis Pharmaceuticals

ELAINE MESSA, President, Medical Devices, NSF Health Sciences; former director of the Los Angeles District, FDA

VICKY STOAKES, President, IntegRx, Inc.; former FDA Chemist, ACNA and Investigator, Atlanta District Office Drug Cadre

Pre-conference Workshops Agenda

WEDNESDAY, NOVEMBER 4

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.

Data Analysis Techniques for Device Manufacturers – Improve Performance to Avoid Warning Letters

Failure to implement corrective and preventive action remains one of the top QSR deficiencies on Form 483s and warning letters. The data analysis portion is the most frequently cited.

But using trend analysis alone to detect recurring quality problems may not be enough to analyze your data to meet FDA expectations. In fact, the quality system regulation was rewritten to require companies to use additional appropriate statistical tools beyond trend analysis to identify recurring problems. But figuring out which statistical technique is appropriate remains a murky area.

This workshop provides companies with a number of tools to show you how to apply appropriate statistical methodology to analyze your data and create more meaningful information.

The workshop explains data analysis in clear terms that don't require a background in math or statistics. It provides examples to illustrate concepts, exercises to help solidify understanding, and checklists to ensure your procedures implement the regulatory requirements.

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 5

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's Mutual Inspection Program With Europe

The FDA and EMA are establishing a mutual inspection program to allow inspections performed by the FDA to be acknowledged by EU regulators and vice versa. Mutual reliance would eliminate overlapping inspections so the agencies can focus on facilities that haven't been inspected recently.

The two agencies are in the early stages of sharing data under a pilot program. The long-term goal is similar to the medical device single-audit program currently being conducted by the FDA and other global regulators. And while Europe is the priority for now, the ultimate goal is to one day have worldwide convergence with regulatory agencies.

CDER Director Janet Woodcock will provide an update on the goals of the program and how the agency is working with international regulators

Janet Woodcock, Director, CDER, FDA (invited)

9:30 a.m. – 11:00 a.m.

FDA's Quality Metrics Program — The Latest Developments and How They Impact Risk-Based Inspections: Panel Discussion

The FDA will soon begin collecting quality data from drugmakers to develop scorecards for companies that ultimately will determine how often they will be inspected. CDER's new Office of Pharmaceutical Quality considered recommendations from a range of stakeholders and has released a draft guidance (7.27.15) outlining the manufacturing and postmarket quality metrics drugmakers need to collect.

This panel of industry experts will explore the current state of the FDA's quality metrics program, stakeholder efforts and other programs under development. They'll profile what activities have been performed to date, examining both the potential benefits and possible risks.

Moderator: John C. (Jack) Garvey, Principal, Chief Executive Officer, Compliance Architects LLC

Panelists:

- Dr. Neil Stiber, Operations Research Analyst, Office of Strategic Programs, CDER, FDA (invited)
- Máiréad Goetz, Head of Compliance , Group Compliance and Audit, Group Quality Assurance, Novartis Pharmaceuticals

(cont.)

- Denyse Baker, Senior Advisor, Scientific and Regulatory Affairs, PDA; former Quality Assurance Specialist, Office of New Drug Quality Assessment, CDER, FDA
- Dr. Patrick Brady, Deputy Vice President of Scientific and Regulatory Affairs, PhRMA (invited)
- Steven Lynn, Global Head Group Compliance and Audit, Novartis; former Director of CDER, FDA (invited)

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. – 5:30 p.m. |
PLENARY PANEL DISCUSSION

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

DRUGS & BIOLOGICS TRACK

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

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

11:30 a.m. – 12:15 p.m.

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

This panel 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.

Dr. Lawrence X. Yu, Acting Director, Office of Pharmaceutical Science, CDER, FDA; Adjunct Professor of Pharmaceutical Engineering, University of Michigan, and Associate Editor of AAPS Journal (invited)

12:15 p.m. – 1:00 p.m.

War Stories: Life on the Front Lines – The Saga Continues

Former FDA investigators and industry experts will use real-life situations encountered by pharmaceutical and medical device companies to help you understand current FDA expectations and improve your regulatory compliance strategies.

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

1:00 p.m. – 2:00 p.m. | **LUNCH**

2:00 p.m. – 3:30 p.m.

Former FDA Investigators Tell All: The 10 Best — and Worst — Things to Do When FDA Staff Are on Site: Panel Discussion

The behavior of drug company staff during an inspection runs from professional to downright comical. There are the stories of crack teams of QA/RA professionals who have every document and every answer an investigator needs, and then there are stories of firms that foolishly refuse to let the investigator into the plant. This panel takes the best and worst of the industry's performance and combines it into one great lesson for you and your staff. This year's panelists have seen it all and are here to give you the "skinny" on how to pass your upcoming inspection with flying colors.

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

Panelists:

- David Elder, Vice President of Strategic Compliance Services, PAREXEL Consulting; former Director of the Office of Enforcement, ORA, FDA
- Elaine Messa, President, Medical Devices, NSF Health Sciences; former director of the Los Angeles District, FDA
- Vicky Stoakes, President, IntegRx, Inc.; former FDA Chemist, ACNA and Investigator, Atlanta District Office Drug Cadre

3:30 p.m. – 3:50 p.m. | **BREAK**

MEDICAL DEVICES TRACK

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

Julie Larsen, Senior Partner, Director Inspection Readiness Services, BioTeknica

11:30 a.m. – 12:15 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.

Marc-Henri Winter, Staff Fellow, Division of International Compliance Operations, OC, CDRH, FDA

12:15 p.m. – 1:00 p.m.

Unraveling the Mystery of EU Unannounced Audits

Beginning in April 2014, the European Commission began requiring European Notified Bodies to enforce unannounced audits of medical device manufacturers of CE marked products.

The rules require notified bodies to inspect manufacturers of high-risk devices once every two years, but there have been hints that inspections may be more frequent if problems are detected. Medium- and low-risk devices will see auditors every three years.

Concerns have risen because manufacturers will have to pay fees for the audits, and if they refuse to pay, they risk being noncompliant.

In this 45-minute workshop, you'll learn exactly what to expect from your notified body so you can prepare your suppliers to perform to the best of their ability during the coming audits, including:

- Definition of a critical subcontractor or crucial supplier
- What should you expect on the day of the audit?
- Who will receive the audit report?
- Are IVDs included in the unannounced audit requirement?
- What are the fees for the unannounced audits?

Roberta Goode, MSBE, CQE, President and CEO, Goode Compliance International

1:00 p.m. – 2:00 p.m. | LUNCH

2:00 p.m. – 3:30 p.m.

Most 483 Observations Can Be Traced Back to Training — Deploying the Newest and Most Successful "Learning" Methods to Curb 483s: Panel Discussion

How can companies improve their training programs to ensure employees are truly trained and not just checking off boxes? Experts suggest that medical device firms need to convert their organizations from a "training-based" environment to a "learning-based" environment. Hear from medical device companies about what's working in their training programs and how they are succeeding in developing a learning mindset among their manufacturing and production employees.

Moderator: Julie Larsen, Senior Partner, Director Inspection Readiness Services, BioTeknica

Panelists:

- Phil Pontikos, CSO, National Device Expert, OMPTO, ORA, FDA, Columbus, OH (invited)
- Dr. Dave Gallup, Principal, Training and Communications Group and GMPTraining.com
- Connie Hoy, Senior VP of Regulatory Affairs, Cynosure
- Marie McDonald, Vice President, Consulting, Quintiles

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: 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

(cont.)

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

Panelists:

- Captain Cynthia Harris, Bioresearch Monitoring Specialist, ORA, FDA, Baltimore District Office
- Marc Neubauer, CSO, Medical Device Specialist, ORA, FDA, Baltimore District
- Phil Pontikos, CSO, National Device Expert, OMPTO, ORA, FDA, Columbus, OH (invited)

Day 2 Agenda

FRIDAY, NOVEMBER 6

8:00 a.m. – 8:30 a.m. | 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. – 9:15 a.m.

FDA's Office of Regulatory Affairs: Enforcement Update

This presentation will focus on ORA's Office of Enforcement priorities for 2016, 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

Melinda Plaisier, Associate Commissioner, ORA, FDA (invited)

9:15 a.m. – 10:15 a.m.

Combination Products: Integrating FDA's New Streamlined Approach

Following FDA's guidance on cGMPs for combination products, questions remain about how to apply and sustain cGMPs to meet FDA requirements. Numerous established device companies now have a combination product on their hands and are dealing with drug regulations for the first time. Large pharmaceutical companies well-versed in drug cGMPs, aren't sure how to integrate specific QSR requirements.

This session will take you through the tools you need to comply with both the drug and device requirements for combination products under FDA's new streamlined approach. Attendees will leave the session knowing the specific requirements and FDA expectations, but more importantly, how to apply them to develop cGMP approaches that work and methods to execute them within their operations.

Elaine Messa, President, Medical Devices, NSF Health Sciences; former Director of the Los Angeles District, FDA

10:30 a.m. – 12:00 p.m.

Data Integrity — Is Complacency Putting You at Risk?

The headlines remain unrelenting — significant data integrity observations continue to be identified during FDA inspections. Data integrity violations erode public confidence, impugn product quality and patient safety, and have a devastating impact on implicated organizations.

However, using FDA's findings as a standard, many businesses have not evaluated their internal data integrity systems to determine if similar underlying cGMP/QSR deficiencies exist and whether data manipulation has occurred. Is your company's prevailing mindset that data integrity problems only happen to "other people"? Is your firm in denial? This panel discussion will bring together top experts to dispel common misconceptions and help you determine the potential risk to your company and contractors.

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

Panelists:

- David Elder, Vice President of Strategic Compliance Services, PAREXEL Consulting; former Director of the Office of Enforcement, ORA, FDA
- John Avellanet, Managing Director & Principal, Cerulean Associates LLC
- Dr. Beverly Lorell, Senior Medical and Policy Advisor, FDA & Life Sciences Practice Group, King & Spalding
- Steve Niedelman, Lead Quality Systems and Compliance Consultant, King and Spalding, former FDA Deputy Associate Commissioner for Regulatory Operations

12:00 p.m. | CONFERENCE ADJOURNS

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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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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 10th 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.
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The FDA Inspections Summit — now in its tenth 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.

WHO SHOULD ATTEND?

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