6 Top FDA Officials To Headline This Year's Summit. Register Today!

FDANEWS PRESENTS THE

9TH ANNUAL

FDA INSPECTIONS SUMMIT

#1 EVENT FOR QUALITY, COMPLIANCE AND INSPECTIONAL READINESS PROFESSIONALS

FEATURED SPEAKERS:

KIMBERLY TRAUTMAN
Associate Director International Affairs, Office of the Center Director, CDRH, FDA

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

LORI LAWLESS
SCSO, Medical Device Specialist, ORA, FDA, Baltimore District

MARC NEUBAUER
CSO, Medical Device Specialist, ORA, FDA, Baltimore District

CAPT. CYNTHIA HARRIS
SRO, Medical Device/ Bioresearch Monitor, ORA, FDA, Baltimore District

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

OCT. 22–24, 2014

DOUBLETREE BETHESDA HOTEL, BETHESDA, MD

2014 SUMMIT HIGHLIGHTS

4 panels featuring current and former FDA officials, including:

- New for 2014 – **Understanding FDA's Quality Metrics Initiative** — what's the latest on the quality initiative and how can you get prepared for what's coming?
- New for 2014 – **The latest on the FDA's re-organization** of the inspectional corps and how could it impact your daily operations and your upcoming inspection
- **A day in the life of an investigator** – how inspectors prepare and approach assigned inspections
- **Discussing inspectional protocols** — how should you treat investigators when they are in your facility

EXPERT SPEAKERS:

STEVE NIEDELMAN, Lead Quality Systems and Compliance Consultant, King and Spalding

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

DAVID ELDER, Vice President of Strategic Compliance Services, PAREXEL Consulting

SANDRA OMROD, Global Quality Manager, Quality Standards & Compliance, AstraZeneca

DR. PATRICK BRADY, Deputy Vice President of Scientific and Regulatory Affairs, PhRMA

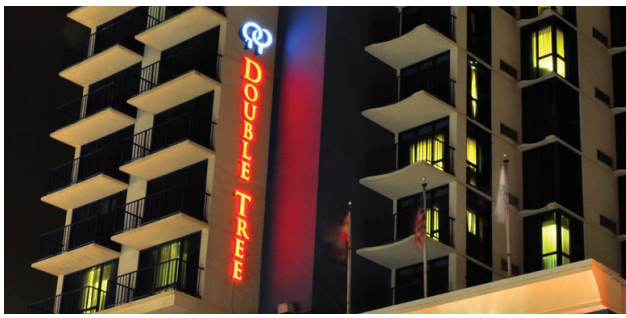
JOHN (JACK) GARVEY, Principal/CEO, Compliance Architects LLC

JOHN AVELLANET, Managing Director and Principal, Cerulean Associates LLC (Conference Chairperson, Drugs & Biologics Track Moderator)

JULIE LARSEN, Senior Partner, Director Inspection Readiness Services, BioTeknica (Medical Devices Track Moderator)

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

KEVIN ROBERSON, Director, CGMP Quality Assurance, ABC Laboratories



Pre-conference Workshops Agenda

WEDNESDAY, OCT. 22, 2014

12:00 p.m. – 1:00 p.m.

Registration

1:00 p.m. – 5:00 p.m.

Flawless FDA Inspection Handling and Response

"We found your response insufficient…."

"Your response is inadequate…."

FDA Warning Letters begin with a summary of the failed inspection, and then quickly dismiss a firm's earnest 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 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 response 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 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 SOP
- How to write an inspection response designed to reduce Warning Letter likelihood
- Red flags FDA looks for in your inspection response
- And much, much more….

Attendees Will Receive

- A set of detailed handouts
- 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
- And more …

John Avellanet, Managing Director and Principal, Cerulean Associates LLC

1:00 p.m. – 5:00 p.m.

No More 483s — QSIT Secrets to Assure Clean Inspections

Julie Larsen will provide best practices on how industry should use this inspection tool. In this workshop attendees will break into groups focusing on three key issues:

- positive and negative experiences with FDA's use of QSIT
- suggestions on how to improve QSIT
- what tools should industry use for internal audits

Each group will be asked to describe how they and their companies manage inspections in light of these three key issues. Team leaders will aggregate the results and report back to the assembled group. These on-the-ground suggestions are invaluable as they help companies learn from others who might be experiencing similar issues.

Attendees will learn:

- The highs and lows of QSIT from an industry perspective
- Is QSIT still applicable as a quality system audit tool?
- What are the best tools used today for successful audits
- The shortcomings of using QSIT for internal audits

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

Day 1 Agenda

THURSDAY, OCT. 23, 2014

8:00 a.m. – 8:30 a.m. | REGISTRATION AND 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 Inspectorate Reorganization — Changes Are Coming In 2015

No later than October 1, FDA Center and Directorate directors and ORA have been asked to submit plans to significantly change how the agency conducts inspections. FDA's inspectorate and its operational structure will shift from a geographically-based approach to a product-based one. The goals of the proposal call for specialized teams of investigators, HQ and support staff that will be deeply knowledgeable about specific drugs, biologics and devices. And they may, or may not be, based out of the closest regional FDA office. In addition, the program aims to cut down on red tape and streamline review and approval of enforcement actions.

This presentation will focus on how the re-organization will impact drug and device makers and will bring attendees up to date on the changes they can expect related to their upcoming inspections.

Attendees will learn:

- What's the latest on the specialization and training that investigators are receiving as described in the Program Alignment Program memo
- Will the process for issuing 483s and warning letters change and if so how
- Under the goals of the new initiative, the Centers are charged with development and communication of compliance policy and enforcement strategies, while ORA are charged with execution of the strategies. How will this work?

FDA Speaker To Be Announced

9:30 a.m. – 11:00 a.m.

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

In 2015 the FDA expects to start collecting quality data it will use to determine inspectional frequency and rigor of drug and biologics makers. The data being considered could include number of lot release tests, out-of-specification results, and lots

attempted, rejected, reworked, and reprocessed along with potentially other metrics as yet undetermined. In addition, by the end of this year the International Society for Pharmaceutical Engineering (ISPE) intends to have initial results of their own quality metrics reporting pilot program. They will be sharing their findings with FDA on how manufacturers are coping with the collection and reporting process. This panel of industry experts will explore the current state of the FDA's quality metrics program, ISPE efforts and other programs under development within the industry. They'll profile what activities have been performed to date, examining both the potential benefits and possible risks. Specific topics to be reviewed will be:

- What is the definition of a "metric" in FDA's view?
- What operational metrics are under consideration by FDA and industry and why?
- How does the FDA envision using reported metrics for inspection risk-management purposes?
- What data integrity standards will be applied to ensure meaningful information is reported?
- How can all stakeholders ensure companies are reporting consistent, meaningful information to make appropriate "apples-to-apples" comparisons of different companies and different companies' sites?
- What should companies be doing now to ready themselves?

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**
- **Dr. Patrick Brady, Deputy Vice President of Scientific and Regulatory Affairs, PhRMA**
- **Sandra Omrod, Global Quality Manager, Quality Standards & Compliance, AstraZeneca**
- **Kevin Roberson, Director, CGMP Quality Assurance, ABC Laboratories**
- **Máiréad Goetz, Head of Compliance , Group Compliance and Audit, Group Quality Assurance, Novartis Pharmaceuticals**
- **Denyse Baker, Senior Advisor, Scientific and Regulatory Affairs, PDA; former Quality Assurance Specialist, Office of New Drug Quality Assessment, CDER, FDA**
- **Steven Lynn, VP, Global Quality Compliance, Mylan; former Director of CDER, FDA**

11:00 a.m. – 11:20 a.m. | REFRESHMENT BREAK

11:20 a.m. – 3:30 p.m.

Two Concurrent Breakout Tracks

Track 1 — Drugs & Biologics

Track 2 — Medical Devices

4:15 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

Moderator:
John Avellanet, Managing Director & Principal, Cerulean Associates LLC

11:30 a.m. – 12:15 p.m.

Trends in CBER Inspectional Findings: A Review of Recent Warning Letters

CBER investigators conduct a wide range of inspections; from pre-approval to for-cause or complaint driven to surveillance of actively enrolling Phase I and II studies. In this presentation, you'll learn what CBER investigators focus on when conducting an inspection. Are there common trouble spots that biologics manufacturers can't seem to figure out? Plus, you'll learn how CBER plans inspections, how they are conducted and what observations are turning up with increased frequency.

Attendees will learn:

- How CBER selects sites for inspection — what criteria is used to choose a site for inspection and how frequently might a site be inspected
- Answers to common questions about FDA GCP inspections
- What the 483 observation data shows about weakness biologics makers are exhibiting and best practices for correcting these violations

FDA Speaker To Be Announced

12:15 p.m. – 1:00 p.m.

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

Those who fail to learn from the mistakes of others are destined to repeat them. Former FDA Investigator Vicky C. Stoakes will use real situations encountered by pharmaceutical and medical device companies to help you understand current FDA expectations and improve your regulatory compliance strategies.

You'll learn:

- How to avoid common problems and promote a culture of quality within your organization
- How to approach compliance issues from an FDA perspective

Vicky Stoakes, President, IntegRx; former FDA chemist and later investigator, Atlanta District 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 10 Worst — Things to Do When FDA Staff Are on Site: Panel Discussion

The behavior of drug company staff during an inspection runs from supremely 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:
David Elder, Vice President of Strategic Compliance Services, PAREXEL Consulting; former Director of the Office of Enforcement, ORA, FDA

Panelists:

- **Elaine Messa, President, Medical Devices, NSF Health Sciences; former Director of the Los Angeles District, FDA**
- **Vicky Stoakes, President, IntegRx; former FDA chemist and later investigator, Atlanta District Drug Cadre, FDA**
- **Joseph Famiglietti, Senior Consultant, EAS Consulting Group; former investigator and compliance officer, New York District, FDA**

3:30 p.m. – 3:50 p.m. | REFRESHMENT BREAK

MEDICAL DEVICE TRACK

11:20 a.m. – 11:30 a.m.

Moderator Comments

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

11:30 a.m. – 12:15 p.m.

Update on the Medical Device Single Audit Program Pilot

The International Medical Device Regulators Forum (IMDRF) recognizes that a global approach to auditing and monitoring the manufacturing of medical devices could improve their safety and oversight on an international scale. At its inaugural meeting in Singapore in 2012, the IMDRF identified a work group to develop specific documents for advancing a Medical Device Single Audit Program (MDSAP). Beginning in January 2014, FDA will be participating in a MDSAP Pilot alongside other international partners. FDA will accept the MDSAP audit reports as a substitute for routine Agency inspections. The MDSAP Pilot is intended to allow MDSAP recognized Auditing Organizations to conduct a single audit of a medical device manufacturer that will satisfy the relevant requirements of the medical device regulatory authorities participating in the pilot program.

International partners that are participating in the MDSAP Pilot include:

- Therapeutic Goods Administration of Australia
- Brazil's Agência Nacional de Vigilância Sanitária
- Health Canada
- Observers - Japan's Ministry of Health, Labour and Welfare, and the Japanese Pharmaceuticals and Medical Devices Agency, European Union, and World Health Organization Diagnostic Prequalification Program

How will these changes impact the way you do business? Attendees will learn:

- Latest results from the MDSAP Pilot
- Initial results from the U.S., Canada, Australia and Brazil shared audits that began in 2014
- Will the EU and Japan join the Single Audit Program officially?

Kimberly Trautman, Associate Director, International Affairs, Medical Device International Quality Systems Expert, Office of the Center Director, CDRH, FDA

12:15 p.m. – 1:00 p.m.

An FDA Investigator's Viewpoint: How To Assure Your Seven Subsystems are in Compliance and Linked Together

In 15 years, FDA medical device specialist Lori Lawless has seen every violation of the medical device QSR that you can think of. This top-rated speaker will create a lively and informative discussion about the Quality Systems Inspection Technique (QSIT) approach to inspections. Lawless will describe how she asks for information, analyzes that information and writes EIR and Form 483 reports using the QSIT and QSR framework.

Attendees will learn:

- What elements of QSIT the FDA focuses on and why
- Common mistakes firms commit and how they can be avoided
- What are red flags that investigators notice that typically go unnoticed by quality assurance and compliance managers
- How QSIT violations appear in EIRs, 483s and warning letters

Lori Lawless, SCSO, Medical Device Specialist, ORA, FDA, Baltimore District

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

The FDA has been placing ever-increasing pressure on firms to improve their training programs to assure employees are truly trained and not just reportedly trained. While this appears relatively simple, companies continually fall short. Recently, the FDA has specifically identified inadequate employee training within 483s and warning letters. Experts suggest that medical device firms need to convert their organizations from a "training-based" environment to a "learning-based" environment. But how? Join your colleagues for this engaging look at what's working in device company training programs and how they are succeeding in developing a learning mindset among their manufacturing and production employees.

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

Panelists:

- **Lori Lawless, SCSO, Medical Device Specialist, ORA, FDA, Baltimore District**
- **Dave Gallup, Principal, Training and Communications Group and GMPTraining.com**
- **Connie Hoy, VP Global Regulatory Affairs, Palomar Medical Technologies**
- **Len Valenti, Senior Consultant, EAS Consulting Group; former International Affairs Policy Analyst, Office of the Commissioner, FDA**
- **Marie McDonald, Vice President, Consulting, Quintiles**

3:30 p.m. – 3:50 p.m. | **REFRESHMENT BREAK**

Plenary Session Panel Discussion

3:50 p.m. – 5:15 p.m.

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

Ever wonder what an investigator is thinking when they receive their next inspection assignment? Investigators typically review their assignments, research the company or plant they are about to inspect and call on colleagues to help them with any questions. Then their training kicks in and they follow a framework for inspections. 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

Moderator:
Lori Lawless, SCSO, Medical Device Specialist, ORA, FDA, Baltimore District

Panelists:

- **CAPT 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**

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

Day 2 Agenda

FRIDAY, OCT. 24, 2014

8:00 a.m. – 8:30 a.m. | **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. – 9:15 a.m.

Program Alignment and FDA

The agency is making fundamental changes in operations to keep pace with the acceleration of scientific innovation, the global expansion off markets, and our new legislative authorities. Program Alignment is a process where ORA and the FDA Centers are aligning their work so that drug and device goals met.

Howard Sklamberg, J.D., Deputy Commissioner for Global Regulatory Operations and Policy, FDA

9:45 a.m. – 10:15 a.m.

Best Practices in FDA 483 and Warning Letter Management and Recovery

Preparing comprehensive, persuasive responses to FDA findings are critical to a company's success in regaining a positive compliance profile. Responses must incorporate well-designed and well-written corrective action plans that will convey a commitment for effective and sustained compliance. This session, led for the FDA's former director of the Los Angeles office, will help attendees develop best practices for what they must do after they receive a 483 and/or Warning Letter.

Attendees will learn:

- How to manage Form 483s and warning letters, including recovery from financial and competitor impact
- Best practices in preparing a response that meets FDA expectations
- Understanding your audience when writing your response
- Whether an effective response to a Form 483 can avert a warning letter

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

10:15 a.m. – 10:30 a.m | **REFRESHMENT BREAK**

10:30 a.m. – 12:00 p.m.

Data Integrity — Denial Ain't Just a River in Egypt: Panel Discussion

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, led by former FDA Chemist and Investigator Vicky C. Stoakes, will bring together top experts to dispel common misconceptions and help you determine the potential risk to your company and contractors.

Attendees will learn:

- The types of data integrity violations identified during recent FDA Inspections
- The regulatory, civil, and criminal penalties associated with data integrity violations
- FDA expectations for review of electronic laboratory data
- How to conduct internal and external audits from a data integrity perspective
- Actions to take if data integrity concerns are identified within your company or at a contractor

Moderator:
Vicky Stoakes, President, IntegRx; former FDA chemist and later investigator, Atlanta District Drug Cadre

Panelist:

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

12:00 p.m. | **CONFERENCE ADJOURNMENT**

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Room rate: $215 plus 13% tax
Reservation cut-off: Sept. 30, 2014

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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. Multi-attendee discounts are available and will be calculated at check out.

2-4 attendees – 10%
5-6 attendees – 15%
7-9 attendees – 20%
10+ attendees – 25%

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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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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 9th 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.

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.