9th Annual Inspections Summit
Oct. 22-24, 2014
Bethesda, MD

Pre-Conference Agenda

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 Conference Agenda

8:00 a.m. – 8:45 a.m. **Registration and Continental Breakfast**

8:45 a.m. – 9:00 a.m. **Opening Comments by Chairperson**

9:00 a.m. – 10:00 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. Deputy Commissioner, Howard Sklamberg 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?

10:00 a.m. – 11:00 a.m. **FDA's Quality Metrics Initiative — What To Expect and How Will It Impact Risk-Based Inspections: Panel Discussion**

In 2015 the FDA plans to start collecting quality data it will use to determine inspectional frequency of drug and biologics makers. The data will be company metrics including number of lot release tests, out-of-specification results, and lots attempted, rejected, reworked, and reprocessed. 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. They've have brought in internationally recognized consulting firm McKinsey & Co. to crunch the numbers.

This panel of industry experts will explore the current state of the FDA's Quality Metrics initiative and the ISPE efforts and provide an in-depth examination of the programs. 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 have been chosen 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 FDA ensure companies are reporting consistent, meaningful information to make appropriate "apples-to-apples" comparisons of different companies and different companies' sites?
- What regulations or guidance documentation will be developed to ensure consistency across individual corporations?
- What should companies be doing now to ready themselves?

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**

Drugs & Biologics Track

11:20 a.m. – 11:30 a.m. **Moderator Comments**

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

---

12:15 p.m. – 1:00 p.m. **War Stories: Life on the Front Lines**

Those who fail to learn from the mistakes of others are destined to repeat them. As a former FDA investigator Vicky Stoakes has almost seen it all. Using real situations encountered by pharmaceutical companies she will help you understand FDA expectations and improve your regulatory compliance strategies.

You'll learn:

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

1:00 p.m. – 2:00 p.m. **Lunch**

2:00 p.m. – 3:30 p.m. **The 10 Best — and 10 Worst — Things to Do When FDA Staff Are on Site to Conduct an Inspection: 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.

3:30 p.m. – 4:15 p.m. **Refreshment Break**

Medical Device Track

11:20 a.m. – 11:30 a.m. **Moderator Comments**

11:30 a.m. – 12:15 p.m. **Update on The International Medical Device Regulators Forum's Single-Audit Program**

The FDA's representative to an important new international forum will give you a fresh insider's take on what it will demand of auditors of medical device manufacturers' quality management systems. The forum, which represents Australia, Brazil, Canada, China, European Union, Japan and the US, will create the framework for a single audit program. So far, so good. But the devil will be in the details. How will these changes impact the way you do business?

Attendees will learn:

- Results from the latest IMDRF work items in the pipeline and newly proposed items
- Initial results from the U.S., Canada, Australia and Brazil shared audits that began in July
- Will the EU and Japan join the Single Audit Program?

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

---

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.

3:30 p.m. – 4:15 p.m. **Refreshment Break**

Plenary Session Panel Discussion

4:15 p.m. – 5:30 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: Plenary 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

---

5:30 p.m. – 6:30 p.m. **Networking Reception**

Day 2 Conference Agenda

8:00 a.m. – 8:45 a.m. **Continental Breakfast**

8:45 a.m. – 9:00 a.m. **Opening Comments by Chairperson**

9:00 a.m. – 10:00 a.m. **What Are ORA's Goals for 2014-2015?**

FDA's Office of Regulatory Affairs is responsible for imports, inspections, and enforcement policy. So as 2014 nears a close and 2015 is on the horizon, what is it focusing on? Some would say, scrutinizing companies that have a track record of noncompliance with GMP and conducting additional inspections. Others have suggested even more overseas-based investigators given the growth of non-US based suppliers and finished products manufacturers.

Attendees will learn:

- What programs ORA is focusing on for the remainder of 2014 and 2015
- Insights on how ORA's risk-based approach helps "good" companies and puts "bad" firms on its radar

---

10:00 a.m. – 10:45 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

---

10:45 a.m. – 11:00 a.m. **Refreshment Break**

11:00 a.m. – 11:55 a.m. **FDA's Globalization Strategy for Protecting the Integrity of the Global Supply Chain**

There has been a steady uptick in the number of FDA 483s that cite inadequate supplier controls — from 84 in 2011, to 110 in 2012 and 126 last year. The problem is now one of the most common 483 findings for drug and device makers. The agency continues to add to its inspection staff in India and China and support its investigators stationed in the EU and Latin America. With the FDA continuing to focus on the issue, drug and device makers need to sharpen their processes and procedures to assure that their entire supply chain is compliant. In addition, the FDA now has 60 agreements with foreign counterparts to share certain information in inspection reports and other non-public information that allows them to make better decisions about the safety of foreign produced products.

Attendees will learn:

- How the FDA communicates with foreign counterparts and how that could impact your next inspection

- What supplier quality controls and oversight the FDA expects from you if you import APIs, excipients or raw materials — especially from China or India
- How to leverage FDA's internationally based staff to help you with managing your suppliers

---

12:00 p.m. **Conference Adjournment**