A Summit on FDA Inspections Policies ... Practices ... and Plans for the Future
Presented by **FDAnews**

FDA Inspections Skyrocket ... All to Feel the Impact: Drugs, Devices, Biologics ... Global Push for Drug and Device Safety ... How Will Industry Cope? ... The Eighth Annual FDA Inspections Summit

Oct. 23–25, 2013 • Bethesda North Marriott Hotel & Conference Center • Bethesda, MD

EIGHTH ANNUAL FDA INSPECTIONS SUMMIT

10 DISTINGUISHED FDA REPRESENTATIVES

JOHN TAYLOR III
Counselor to the Commissioner and Acting Deputy Commissioner for Global Regulatory Operations and Policy, OC, FDA (invited)

DR. LESLIE BALL
Assistant Commissioner for International Programs, Deputy Director, Office of International Programs, Office of Global Regulatory Operations and Policy, ORA, FDA (invited)

ELIZABETH DICKINSON
Chief Counsel, OC, FDA (invited)

RICK FRIEDMAN
Associate Director, Office of Manufacturing & Product Quality, CDER, FDA (invited)

DAVID GLASGOW
Director, Division of Domestic Field Investigations, ORA, FDA (invited)

BRIAN HASSELBALCH
Acting Associate Director, Policy and Communication, OMPQ, CDER, FDA (invited)

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

GRACE MCNALLY
Senior Policy Advisor, OC, CDER, FDA (invited)

DIANE AMADOR TORO
District Director, ORA, FDA, Parsippany District

KIMBERLY TRAUTMAN
Associate Director, International Affairs, Medical Device International Quality Systems Expert, Office of the Center Director, CDRH, FDA (invited)

BARBARA K. IMMEL
Chair, President, Immel Resources LLC
A leading consultant in quality systems, regulatory compliance and training for more than 27 years, Barbara K. Immel is one of the most listened-to voices in FDA-regulated industry. She chaired last year's Summit.
"*Barbara was simply fantastic,*" said attendee Nicole Landreville, Xltek.

FDANEWS

Visit www.FDAInspectionsSummit.com or call (888) 838-5578

SPECIAL PRECONFERENCE WORKSHOPS

Wednesday, Oct. 23 • Registration 12:00 p.m. – 1:00 p.m. • Workshops 1:00 p.m. – 4:00 p.m.

Drugs and Biologics— Proven Procedures for Preparing for Drug and Biologic FDA Inspections: From Introductions to What Not to Say

In this session, Frederick Branding will take attendees through an interactive mock inspection. In this exercise attendees will learn about model procedures to handle nearly every aspect of a standard inspection, including introductions, phone trees, escorts, documentation, photographs and tapings. They'll find out about when to provide records access and when not to. And maybe one of the most important lessons during this half-day seminar? When to say no and how to say no to an FDA inspector.

You'll also take away:

- Developing inspection procedures
- Tips for handling a difficult inspector
- Following up after an FDA inspection
- Responding to inspectional observations
- The closeout meeting with management

Frederick Branding, Principal, Olsson Frank & Weeda

Medical Devices— QSIT Then and Now: Tips and Tools for FDA Compliance and Building Stronger Internal Quality Systems

Tim Wells, who led the CDRH team that wrote QSIT, 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; and what tools should industry use for internal audits.

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

Tim Wells, President, QualityHub; former Team Leader for the QSIT Project, CDRH, FDA

SUMMIT AGENDA

DAY ONE: THURSDAY, OCT. 24

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

8:45 a.m. – 9:00 a.m.
Opening Comments by Chairperson
Barbara Immel, President, Immel Resources LLC (Chairperson)

9:00 a.m. – 10:00 a.m.
FDA KEYNOTE — FDA's Strategy for Protecting the Global Supply Chain
Today, nearly 40 percent of finished drugs are imported, and nearly 80 percent of active ingredients come from overseas sources. The US imports from more than 150 different countries, many with less sophisticated and strict standards. In the past 10 years, the number of FDA-regulated shipments at more than 300 US ports has quadrupled, and there are now more than 24 million shipments annually. This has dramatically impacted international inspections, with a 168% increase in foreign inspections since 2008. In this talk, John Taylor III dissects the FDA's globalization strategy for implementing the new authorities under FDASIA and how it will impact companies' inspections and importing standards.
Attendees will learn:

- How the FDA plans to implement FDASIA on a global scale
- Challenges of globalization of FDASIA for imports into the US and how the FDA will respond to these issues
- Threats throughout the drug supply chain and global supply chain risks
- Why the FDA is transforming from a domestic safety agency to an agency fully prepared for a rapidly changing global environment
- How borders are no longer the primary line of defense for drug safety standards
- FDA efforts to combat counterfeit and substandard drugs

John Taylor III, Counselor to the Commissioner and Acting Deputy Commissioner for Global Regulatory Operations and Policy, OC, FDA (invited)

10:00 a.m. – 11:00 a.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 or device company staff during an inspection can run the gamut 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 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.
***Special Focus**: On July 12 the FDA issued a draft guidance entitled, "Circumstances that Constitute Delaying, Denying, Limiting, or Refusing a Drug Inspection." Attendees will be provided a copy of the guidance and panelists will go through the guidance and its examples and offer their insights into how industry can best comply.*

Moderator:
David Chesney, Vice President and Practice Lead, Strategic Compliance Services, PAREXEL Consulting; former FDA District Director for the San Francisco office

Panelists:
David Glasgow, Director, Division of Domestic Field Investigations, ORA, FDA (invited)
Elaine Messa, Executive Vice President of the Medical Device Practice, Becker & Associates Consulting; former Director of the Los Angeles District, 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**

3:30 p.m. – 4:15 p.m. Networking Break

4:15 p.m. – 5:30 p.m.
Plenary Panel Discussion

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

DRUG & 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.
FDA's Clinical Trial Inspections in China — Lessons Learned From the First 5 Years
FDA established its China office in 2008, with the goal of strengthening cooperation with Chinese regulatory officials, providing relevant Chinese entities information about FDA requirements, and increasing FDA inspections in China. Since then,

FDA has made great strides in deepening its relationship with Chinese counterparts and increasing its understanding of the Chinese regulatory system for medical products in China. In this presentation, Dr. Leslie Ball will dissect the findings of her recent trip to China and what lessons have been learned from the first five years of the China FDA office.

Attendees will learn:

- Which trial sites are directly regulated and inspected by the FDA
- Challenges in ensuring the integrity of clinical trials conducted in China
- Lessons learned from a three-part training program with CFDA
- Common mistakes and risk factors for noncompliance

Dr. Leslie Ball, Assistant Commissioner for International Programs, Deputy Director, Office of International Programs, Office of Global Regulatory Operations and Policy, ORA, FDA (invited)

12:15 p.m. – 1:00 p.m.

Kiss & Tell: How to Prove to the FDA Investigator that Your Outsourcing Oversight Works

With the enforcement of FDASIA in full swing and new warning letters citing firms and executives under the Park Doctrine for poor supplier oversight, learn what you need to prove to an FDA investigator that you are in control of your outsourced, regulated activities.

Attendees will learn:

- Key questions FDA investigators ask to uncover weak or missing supplier oversight
- Specific supplier oversight elements to clearly document in your annual quality system management review or annual product review
- Documents to obtain and retain from your suppliers every year
- Components of a supplier dossier that will show every FDA investigator that you are in control
- How to document accountabilities in your contracts to please the FDA and frustrate product liability lawyers

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

1:00 p.m. – 2:00 p.m. Lunch

2:00 p.m. – 2:45 p.m.

EU and US Joint Inspections: Data as the Cornerstone for the Future

It's never been more important for pharmaceutical companies to comply with both Annex 11 and Part 11. Today, computerized automation is a key element of any manufacturing and distribution area of pharmaceutical manufacturing; therefore, the requirements for data integrity are now considered a fundamental expectation for all types of systems, including laboratory and process control systems.

Attendees will learn:

- Differences between European and US regulations addressing the use of computerized systems in regulated activities
- Part 11 and Annex 11: a common approach to computerized systems validation compliance
- Understanding data integrity as the cornerstone for future inspections

Gilda D'Incerti, CEO, Pharma Quality Europe

2:45 p.m. – 3:30 p.m.

Warning Letter Recovery Strategies — What to Do When You've Been Hit with Repeat Violations

Recently, the FDA has been cracking down on repeat offenders and offering up tough talk within 483 and warning letters. Firms dinged for multiple and repeat violations at the same facilities are deemed high risk and will face years of FDA scrutiny. If you've been cited for multiple or repeated violations it's time to employ a warning letter recovery strategy. But where to begin? Drawing on decades of experience, this presentation will provide a roadmap to recovery.

Attendees will learn:

- How to convert your root cause analysis investigations into actionable operational compliance strategies
- Best practices for interacting with the FDA after the agency has placed you in a high-risk status
- Tips for managing staff that must work under consent decrees and third-party auditors

Marie McDonald, Senior Director, Quality & Compliance Consulting, Quintiles

3:30 p.m. – 4:15 p.m. Networking Break

MEDICAL DEVICE TRACK

11:20 a.m. – 11:30 a.m.

Moderator Comments

Moderator:

Dan O'Leary, President, Ombu Enterprises LLC

11:30 a.m. – 12:15 p.m.

Case Study: Domestic Importer Hit with Warning Letter Thanks to Overseas Supplier

A US-based company received a warning letter for problems identified in a facility inspection. The company is registered with the FDA and acts only as an importer. All the complaint investigation and MDR filings occur at its parent company outside the US The US. company received a very strong 483, and responded with corrective action. In addition, it applied for an MDR exemption and it was granted (meaning it does not have to file MDRs because it would be duplicative). In spite of this, it received a warning letter. Could the company have done anything differently to avoid the warning letter? What can it do going forward to prevent this from happening in the future? This interactive presentation will assess this nuts-and-bolts case study.

Attendees will learn:

- When to push back during the FDA inspection
- How to respond to the 483
- Should the company involve regulatory attorneys or consultants? If yes, at what stage?
- Once the warning letter was issued, what should the company have done within the first 24 hours?
- How should the company respond to the warning letter and how far up the chain of command should the response to the warning letter be sent?
- Should the company ask to have the warning letter rescinded?

Connie Hoy, Vice President, Global Regulatory Affairs, Palomar Medical Technologies

12:15 p.m. – 1:00 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, the European Union, Japan and the US, will create the framework for a single-audit program. How will these changes impact the way you do business? Where and when should you weigh in to make certain your concerns are heard? In this session, you'll hear the latest developments and get a better understanding of how to make this work for you.

Attendees will learn:

- Results from the March IMDRF meeting and the latest on the work items in the pipeline and newly proposed items
- Roadmap for global implementation of the UDI system
- MDSAP WG Update — with results from the September meeting
- Details on the slated January 2014 pilot program in which four regulatory authorities (Australia, Brazil, Canada and US) will conduct inspections that will be recognized by all four authorities

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

1:00 p.m. – 2:00 p.m. Lunch

2:00 p.m. – 2:45 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
- 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

2:45 p.m. – 3:30 p.m.
Assuring Your ISO 14971 Risk Management Strategy Adopts a Holistic Approach
US devicemakers have recently experienced shock, disappointment and downright anger because of failed EU audits. As of August 1, 2012, all US devicemakers that want to sell products in the EU must be in compliance with EN ISO 14971:2012 and in particular Annexes: ZA, ZB and ZC. These Annexes are commonly overlooked by devicemakers — but not by EU auditors. Failure to understand the nuances of the Annexes and how they need to be accounted for in your risk management and Quality Management Systems assessments can find you in noncompliance. This presentation, led by BSI's Technical Director, Dr. Ibim Tariah, will assure that the requirements found in the Annexes are incorporated into your risk management programs.
Attendees will learn:
- How to assure the EU's holistic approach to risk management and QMS assessment are covered in your risk management strategy
- What auditors are looking for and ways to assure that your documentation meets EN ISO 14971:2012 and hence the MDDs requirements
- Pointers to how firms can properly plan for and document their QMS assessments to ensure compliance with the MDDs

Dr. Ibim Tariah, Technical Director, BSI Healthcare Solutions

3:30 p.m. – 4:15 p.m. Networking 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

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

Panelists:
Tim Wells, President, QualityHub; former Team Leader for the QSIT Project, CDRH, FDA
Diane Amador Toro, District Director, ORA, FDA, Parsippany District
Larry Spears, Director, Deloitte & Touche LLP, former Deputy Director for Regulatory Affairs at CDRH, FDA

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

DAY TWO – FRIDAY, OCT. 25, 2013

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

8:45 a.m. – 9:00 a.m.
Opening Comments by Chairperson
Barbara Immel, President, Immel Resources LLC (Chairperson)

9:00 a.m. – 10:00 a.m.
FDA KEYNOTE — Top Inspection-Related Legal Issues to Watch
The FDA expects industry to comply with regulations. But sometimes the agency and industry just can't agree, and the courts have to take over to settle disputes. For example, there's a brewing controversy on whether the FDA has the legal right to take photographs within your facility. The FDA is confident it can. Industry and outside counsel say no. Might this come to a head in a legal battle? Only time will tell. This and many other disputes are handled by the FDA's chief counsel's office. This presentation, by the FDA's top legal officer, will highlight the agency's current legal thinking on the industry's most pressing topics.
Attendees will learn:
- What compels the FDA to initiate legal action and how it works with the DOJ or state authorities
- What current inspections related cases is the FDA currently pursuing and why
- How recent enforcement cases could have been avoided

Elizabeth Dickinson, Chief Counsel, OC, FDA (invited)

10:00 a.m. – 10:45 a.m.
Writing (And Ensuring) Good Failure Investigations and CAPA Reports
A good CAPA starts with a solid investigation and a well-written report. Barbara Immel, with 31 years of industry experience in quality assurance, regulatory compliance and training, will provide a roadmap on how to successfully write and ensure a good investigation to prevent future citations.
Attendees will learn:
- How to use the "CAPA starburst" approach to quality data trending
- Examples of recent FDA inspection findings
- 22 great investigation tools for a successful investigation
- Roadmap to inverted pyramid writing style
- How to determine root cause
- The three key sections of a good investigation

Barbara Immel, President, Immel Resources LLC (Chairperson)

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

11:00 a.m. – 12:00 p.m.
FDASIA Year 2: Where Are We and What's Ahead for Supply Chain Regulation? Panel Discussion
It's been a year since FDASIA required formal control over the pharma supply chain. But the agency still hasn't modified the regulations to reflect the change in the law. This panel discussion, moderated by an ex-FDAer and consisting of current FDA officials, will provide answers.
Attendees will learn:
- What should firms be doing now to comply with the new legal requirements?
- What are investigators being told to look at during inspections, and what sorts of gaps might lead to a 483 observation today that would not have previously?
- How far down the supply chain must companies now audit API companies, excipient suppliers, container manufacturers and precursor chemicals?

Moderator:
David Chesney, Vice President and Practice Lead, Strategic Compliance Services, PAREXEL Consulting; former FDA District Director for the San Francisco office

Panelists:
Rick Friedman, Associate Director, Office of Manufacturing & Product Quality, CDER, FDA (invited)
Brian Hasselbalch, Acting Associate Director, Policy and Communication, OMPQ CDER, FDA (invited)
Grace McNally, Senior Policy Advisor, OC, CDER, FDA (invited)

12:00 p.m. Conference Adjournment

SUMMIT HIGHLIGHTS & SPECIAL OFFERS

The FDA Inspections Summit — now in its eighth 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.

Can't make it to the Eighth Annual FDA Inspections Summit?

LIVE STREAM IT!

We know that not everyone can travel to the Eighth 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.

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- BONUS: A streaming video registration includes six-month access to archived session recordings after the conference.

TESTIMONIALS

"Excellent conference. Thank you for putting it together!"
— **Stephanie Hendrickson**, Life Sciences Quality and Compliance, Accenture

"The summit was very informative. There were powerful insights about FDA that I took away from the summit. It will be helpful in setting strategy for my organization."
— **Raghu Jainapur**, Director of Quality Assurance, Roche

"I liked the breadth and knowledge of the speakers."
— **Daniel Bolle**, Manager, Supplier Quality, Baxter Healthcare

"Very well rounded; included most recent FDA developments; interesting as always."
— **Johanna Stamates**, Executive Director, Regulatory Support and Quality Assurance, University of Miami

WHO SHOULD ATTEND

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

TEAM DISCOUNTS

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Call (888) 838-5578 for details.

ABOUT THE CONFERENCE CHAIR

Barbara K. Immel is president of Immel Resources LLC, a management consulting firm specializing in quality systems, regulatory compliance and training. For more than 30 years, Ms. Immel has been one of the most listened-to voices in FDA-regulated industry. She has taught at the Universities of California-Berkeley, Wisconsin, Georgia and Stanford; authored more than 50 articles in industry journals; and written the Quality Assurance chapter in Dekker's Encyclopedia of Pharmaceutical Technology. She is a former compliance columnist for BioPharm Magazine and is currently the editor of the Immel Report™ newsletter.

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Room Rate: $209 single or double (plus 13% tax)
Hotel reservation cutoff date: Oct. 1, 2013

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For exhibit and sponsorship opportunities at this event, please contact:
Jim Desborough, Business Development Director
Phone: +1 (703) 538-7647
Email: jdesborough@fdanews.com

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☑ ***Yes!*** I want to attend the **EIGHTH ANNUAL FDA INSPECTIONS SUMMIT**.
Sign me up for the option(s) I've selected below:

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	Early Bird Fee through Sept. 23, 2013	No. of Attendees	Regular Fee Sept. 23 – Oct. 25, 2013	No. of Attendees
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