

# FDA INSPECTIONS SUMMIT

#1 EVENT FOR QUALITY, COMPLIANCE AND INSPECTIONAL READINESS PROFESSIONALS

## SUMMIT CO-CHAIRS:



**STEVE NIEDELMAN**

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



**DAVID CHESNEY**

Principal and General Manager, DL Chesney Consulting, LLC



**JULIE LARSEN**

Senior Partner, Director Inspection Readiness Services, BioTeknica

## FDA SPEAKERS:



**ELLEN MORRISON**

Assistant Commissioner for Medical Products and Tobacco Operations, Office of Regulatory Affairs, FDA



**CAPT SEAN BOYD**

Acting Director, Office of Compliance, CDRH, FDA



**CAROL BENNETT, J.D.**

Deputy Director, Office of Regulatory Policy, CDER, FDA (Invited)



**NIRAJ MEHTA, Ph.D.**

Associate Director for Global Regulatory Policy, Office of Global Regulatory Operations and Policy, OC, FDA



**DOUGLAS STEARNS**

Director, Office of Enforcement and Import Operations, ORA (Invited)

NOVEMBER 1-3, 2017 |

DOUBLETREE BETHESDA  
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## 2017 SUMMIT HIGHLIGHTS

### NEW FOR 2017!

FDA's ORA Reorg and What it Means for Inspections

Preparing for the MDSAP Audit Process: A Case Study from the Manufacturer's Perspective

Building Your Best Internal Audit Team for Quality Results

Plus twin tracks for drug/biologics and device manufacturers and two pre-conference workshops, focusing on FDA Inspection Management and QSIT Secrets.

Expert panels featuring current and former FDA officials and industry professionals:

- FDA Field Investigators: What They Look For, What Problems are Emerging and AMA (Ask Me Anything)
- The US/EU Mutual Recognition of Drug GMP Inspections: Practical Consequences for Manufacturers
- European Medical Device Regulations — Preparing for the Storm

## FEATURED EXPERT SPEAKERS:

**JOHN AVELLANET**, Managing Director and Principal, Cerulean Associates LLC

**KATLIN BACKFIELD**, Attorney at Law, Consultant, Backfield PLLC

**PETER LEININGER**, Counsel, King & Spalding; former Associate Chief Counsel for Enforcement in FDA's Office of Chief Counsel

**CONNIE HOY**, Executive Vice President of RA/QA, Cynosure

**IBIM TARIAH**, Ph.D., Technical Director, BSI Americas Inc.

**DAN O'LEARY**, President, Ombu Enterprises LLC

**SUSAN SCHNIEPP**, Fellow, Regulatory Compliance Associates, Inc.

**CYNTHIA SCHNEDAR**, Executive Vice President, Regulatory Compliance, Greenleaf; former Director of the Office of Compliance, CDER, FDA

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

**KARL VAHEY**, Vice President Manufacturing Quality, Patient Monitoring and Recovery, MITG, Medtronic



## DRUGS &amp; BIOLOGICS TRACK

**Flawless FDA Inspection Handling and Response****Rated #1 Pre-Conference Workshop in Inspection Summit History — Updated for FDA's New Inspection Techniques!**

John Avellanet of Cerulean Associates — one of the industry's top inspectional readiness experts — is back to teach proven techniques to manage FDA investigators on-site, how to defend yourself where it's appropriate and craft 483 responses that fend off warning letters.

Plus, in a special portion of this must-attend pre-conference, he'll explain how the FDA's New Inspection Protocol Project inspection technique could trip up companies that have always had good compliance records. He'll profile a company that had years of clean inspections, only to be blindsided with a bad inspection based on NIPP. You can't afford to miss this session!

Compliance pros know that getting an FDA investigator in and out as quickly as possible is the best strategy. The longer an FDA investigator is on site, the more likely you'll be handed a multi-page 483.

And if you think racking up those observations are bad, even worse is crafting a response, plowing it through your internal departments and getting it back to the FDA in just 15 days. Oh, did we mention the response must be detailed, provide a well-documented root cause analysis and spell-out solutions to assure the problem never happens again?

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 manage a 483 observation and not get a warning letter.

Attendees will learn:

- The results of a case study of how a firm that passed 9 previous inspections suddenly failed under FDA's new NIPP inspection technique
- Critical inspection preparation techniques every member of your team must commit to memory — especially useful for those surprise FDA visits
- Hidden tactics FDA investigators use to test your controls and are taught to probe your answers for weakness
- How to speed the inspection to minimize the risk of 483 observations, while always remaining respectful
- What really needs to be in your regulatory inspection handling SOPs — tips for cutting corporate-speak and unnecessary verbiage that doesn't help
- How to write an inspection response designed to reduce the likelihood of a warning letter — and tips and tricks to get sign-offs quickly from even the toughest groups (like legal)
- What FDA staff look for in your replies and the top red flags they notice

**BONUS:** Attendees will receive:

- A sample regulatory inspection handling 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

**To QSIT or Not To QSIT – That is not the Question!****Customized, Interactive and Full Of Valuable Take-Aways, This Pre-Conference Workshop is a Must Attend**

Some industry experts and ex-FDAers are saying that QSIT is outdated, incomplete and FDA investigators are not always following the Guide to Inspections of Quality Systems, QSIT during inspections. It's true FDA inspections can vary and many times investigator's may not follow QSIT to the letter. So, what then is a device manufacturer to do to prepare?

Device manufacturers can spend time focusing on why it's not fair, or they can focus on being ready for anything. This interactive pre-conference workshop will do just that.

FDAnews is proud to have Medical Device Inspection expert Julie Larsen, Principal/Director, Inspection Readiness Services at BioTeknica, provide her insights for preparing for inspections, including risk based approaches and using the QSIT's details to assure your next inspection is squeaky clean.

Julie knows Inspections, the inspection guidances, the QSIT guidance, and how to prepare device companies of all sizes and all product classes. In just four hours, you'll learn the current issues in application of this important inspection technique and numerous take-away ideas you can put to immediate use.

This interactive workshop will dive deep into these key issues:

- Applying risk principals to inspection preparation
- Pros and cons of using the QSIT's specifics to assure your internal audits have covered and confirmed compliance with FDA's expectations
- Examples of companies that have used the QSIT in both positive and negative ways — many of these will surprise you!
- Tips and tricks for being uber-prepared — especially being prompt with answers to investigators' questions and being able to produce documents in a timely manner
- Experiential learning for SMES through simulated inspections

Unlike other preconferences you've attended in the past, Julie will break attendees into working groups to flush out inspectional problems attendees are having. She'll then offer her insights on the best-in-class tools available and best practices to solve your problems.

**BONUS:** In addition to Julie's expert tips, attendees will receive these MUST-HAVE reference documents worth the registration fee alone, including:

- A detailed Inspection preparation checklist that attendees can immediately apply to their current inspection prep SOP
- 10 key questions to use in assessing your company's state of readiness for an FDA QSIT inspection

**Julie Larsen, Principal/Director, Inspection Readiness Services, BioTeknica**

**Braulio Ortiz, Principal/Project Manager/Senior Quality Engineer, BioTeknica**

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

8:30 a.m. – 8:45 a.m.

**Opening Comments by Chairperson Steve Niedelman, Lead Quality Systems and Compliance Consultant, King and Spalding, former FDA Deputy Associate Commissioner for Regulatory Operations**

8:45 a.m. – 9:30 a.m.

**FDA's ORA Reorg and What it Means for Inspections**

The FDA reorganized its Office of Regulatory Affairs inspectorate to more closely align inspection efforts with the myriad types of products it regulates — essentially organizing staff by area of expertise instead of geographic region. Will inspections happen more frequently? Does this make inspection outcomes more predictable or less? Will inspections be conducted faster if they are done by experts, or will they take longer to go through more detail? Associate Commissioner Ellen Morrison will discuss the latest developments and talk about what to expect from the changes.

**Ellen Morrison, Assistant Commissioner for Medical Products and Tobacco Operations, Office of Regulatory Affairs, FDA**

9:30 a.m. – 10:15 a.m.

**The World of FDA Quality Metrics: Yesterday, Today and Tomorrow**

CDER and CBER have the Quality Metrics Submission guidance. CDRH has the Case for Quality initiative. All centers are driving towards a culture of quality within the life sciences industry. Marla Phillips has a unique perspective that comes from working on both sides of the line. With the FDA, she co-led the CDRH metrics initiative, and with PricewaterhouseCoopers, she co-led the pharmaceutical metrics initiative. Her presentation will examine the difference between the two initiatives, their progress, the differences and the similarities in their metrics. From her industry experience, she will examine the potential impacts, the unintended outcomes and how to protect everyone's time from doing busy work that does not achieve the end goal. She will also share her thoughts of where these initiatives are headed.

**Marla A. Phillips, Ph.D., Director, Xavier Health, Xavier University; former Head of Quality at Merck's North Carolina facility**

10:15 a.m. – 11:00 a.m.

**Postmarket Adverse Event Reporting and cGMP: What You Absolutely Need to Know**

The FDA issued two final rules that set forth the postmarket safety reporting and current good manufacturing practices (cGMP) requirements for combination product and constituent part sponsors. This session summarizes key concepts and provides insightful case studies about how the rules work in the real world.

(cont.)

**Katlin Backfield, Attorney at Law, Consultant, Backfield PLLC; former Associate Chief Counsel for Drugs, OCC, FDA**

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**

**David Chesney, Principal and General Manager, DL Chesney Consulting, LLC; former FDA District Director for the San Francisco office**

11:30 a.m. – 12:15 p.m.

**FDA Regulatory Policy Roadmap: FDA Shares its Priorities for 2018**

The FDA is constantly looking at new and more efficient ways to regulate drugs and medical devices. Under a new commissioner, the Office of Regulatory Policy (ORP) has identified a specific set of priorities that you need to know about. Some issues are very familiar, such as responding to an opioid epidemic that Commissioner Scott Gottlieb has called his “highest immediate priority.” Other initiatives are less publicized but just as important. How will the agency modernize its assessment of manufacturing facilities? How does it manage innovations in drug development? Now that Gottlieb has made getting more generic drugs approved a priority, what are the implications for regulatory development? Will initiatives to harmonize efforts with international regulatory organizations mean changes domestically? Carol Bennett, Deputy Director Office of Regulatory Policy at CDER will review the recent actions within CDER and the outline priorities looking into 2018.

**Carol Bennett, JD, Deputy Director, Office of Regulatory Policy, CDER, FDA (Invited)**

12:15 p.m. – 1:00 p.m.

**Cautionary Tales: Words to the Wise on Compliance**

Those who fail to learn from the mistakes of others are destined to repeat them. Using real situations encountered by pharmaceutical and biologics firms, discover strategies for staying up-to-date with FDA cGMP regulations. Examples of non-compliance are presented with suggestions for applying these lessons and improving 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.

**The US/EU Mutual Recognition of Drug GMP Inspections: Practical Consequences for Manufacturers**

In March, the US and European Union signed a mutual recognition agreement (MRA) to recognize each other’s drug GMP inspections. This is good news for the industry that should see fewer inspections. However, it doesn’t come without some concerns. First, each inspection now has greater consequences as any problem will now be a red flag for multiple agencies. Also, if regulatory agencies share information, what does that mean for information confidentiality? Plus, the EMA retained authority to conduct inspections in “extraordinary circumstances,” but what does that mean, exactly? The FDA has until November to assess regulatory authorities in eight EU countries to trigger the start of the implementation of the agreement. How close are they? The agreement doesn’t mean European GMP regulations are less important — in fact, they are as important as ever. Come hear experts describe the practical implications of this agreement for drug GMP inspections so you’re not caught off guard.

**Moderator: David Chesney, Principal and General Manager, DL Chesney Consulting, LLC; former FDA District Director for the San Francisco office**

**Niraj Mehta, Ph.D., Associate Director for Global Regulatory Policy, Office of Global Regulatory Operations and Policy, OC, FDA**

**Cynthia Schnedar, Executive Vice President, Regulatory Compliance, Greenleaf; former Director of the Office of Compliance, CDER, FDA**

**Katlin Backfield, Attorney at Law, Consultant, Backfield PLLC**

**Peter Leininger, Counsel, King & Spalding; former Associate Chief Counsel for Enforcement in FDA’s Office of Chief Counsel**

3:30 p.m. – 3:50 p.m. | **BREAK**

**MEDICAL DEVICES TRACK**

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

**Julie Larsen, Principal/Director, Inspection Readiness Services, BioTeknica**

11:30 a.m. – 12:15 p.m.

**CDRH’s New Inspection Strategy for 2018: How it Will Impact Your Company**

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

- The new inspection approach/strategy for medical devices in 2017-2018 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

**CAPT Sean Boyd, Acting Director, Office of Compliance, CDRH, FDA**

12:15 p.m. – 1:00 p.m.

**Preparing for the MDSAP Audit Process: A Case Study from the Manufacturer’s Perspective**

Manufacturers entering the Medical Device Single Audit Program undergo an assessment performed by a single third-party inspector that proves compliance in the US, Canada, Australia, Brazil, the EU and Japan. The audit process is not what you’re used to compared to an FDA or ISO audit. Cynosure has successfully certified two manufacturing sites in the last year. The Cynosure facility in MA (1,000 people) was audited as part of the MDSAP in October 2016 and their facility in NY (40 people) was audited to the MDSAP in March 2017. Both facilities passed the audit with only minor findings.

Executive Vice President of RA/QA Connie Hoy will take you through the preparation process from the manufacturing perspective. You will also hear what lessons they learned along the way, what they would have done differently and how it compares to a corporate audit versus a small manufacturing plant audit.

This presentation will cover:

- What they did to prepare for the audit
- The audit flow and how it differs from QSIT and ISO audits

(cont.)

- The differences and similarities between preparing the two plants
- What they would do differently to prepare now that they have undergone the process

**Connie Hoy, Executive Vice President of RA/QA, Cynosure**

1:00 p.m. – 2:00 p.m. | **LUNCH**

2:00 p.m. – 3:30 p.m.

### Panel Discussion: European Medical Device Regulations — Preparing for the Storm

Like a line of thunderstorms developed on a weather front, various regulatory agencies will move through your company to check up on the Quality Management System. Each visit will be different because they will look at different aspects. The FDA will check your adherence to US regulations. The MDSAP will help prepare you for Canada, Australia, Brazil and other jurisdictions in the program. The unknown factor is the status of the MDR Notified Bodies (NB). There aren't any yet, as the regulation moves through its transition process. We do know that qualifying NBs will conduct audits that are more rigorous than under the directives. The MDR Annex VII, Section 4.5. Conformity Assessment Activities, lists specific requirements for the NB to cover during an audit.

This expert panel will take you through the changes and what you need to know to be prepared to continue to market or bring your product to market in Europe.

**Moderator: Lenita Y. Sims Spears, Senior Quality Consultant/Senior Regulatory and Compliance Counsel, BioTeknica**

**Dan O'Leary, President, Ombu Enterprises LLC**

**Ibim Tariah, Technical Director, BSI Americas Inc.**

**Karl Vahey, Vice President Manufacturing Quality, Patient Monitoring and Recovery, Medtronic**

3:30 p.m. – 3:50 p.m. | **BREAK**

### Plenary Session Panel Discussion

3:50 p.m. – 5:15 p.m.

#### FDA Field Investigators Panel: What They Look For, What Problems are Emerging and AMA (Ask Me Anything)

Ever wonder what an investigator is thinking when they receive their next inspection assignment? What framework they follow, and what affects their thinking during an inspection? This presentation will give you a glimpse into the inner workings of an investigator's mind before, during and after an inspection.

Attendees will learn:

- What information does an investigator have before he or she shows up at your door?
- Do investigators prepare differently for different companies, plants or products?
- What is the first thing they notice when they enter a plant?
- How do investigators 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

**PLUS**, this panel will take your questions (anonymously if you wish). So, here is your chance to ask questions and get answers straight from investigators in the field every day! Don't miss this opportunity to get your answers!

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



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

8:30 a.m. – 8:45 a.m.

#### Opening Comments by Chairperson Steve Niedelman, Lead Quality Systems and Compliance Consultant, King and Spalding, former FDA Deputy Associate Commissioner for Regulatory Operations

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 2018, and changes to how the office approaches the process. This session will ensure attendees have the latest information on how they can more proactively prepare for FDA investigators.

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

**Douglas Stearns, Director, Office of Enforcement and Import Operations, ORA (Invited)**

9:30 a.m. – 10:15 a.m.

#### Building Your Best Internal Audit Team for Quality Results

An internal audit of your quality management system should be a collaboration, not a confrontation, with auditor and auditee working together to spot issues that weaken your system. You need to move your audit team beyond the "blame and shame" mindset that can keep them from openly and honestly sharing the information you need to work out solutions and make your QMS stronger.

Your internal audits can be a positive and productive experience for all if you apply the lessons in this session:

- How to train your employees to handle audits in the most productive way;
- How to select the best auditor to work with your team;
- How to follow the internal audit with corrective action;
- How to report audit findings to management and get them to buy in to suggested solutions; and
- How to evaluate your internal auditing system's effectiveness.

**Susan Schniepp, Distinguished Fellow, Regulatory Compliance Associates, Inc.**

10:15 a.m. – 10:30 a.m. | **BREAK**

10:30 a.m. – 12:00 p.m.

#### How to Deal with Difficult Inspections

Co-Chair Steve Niedelman and long-time industry expert, David Chesney, 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.

**Steve Niedelman, Lead Quality Systems and Compliance Consultant, King and Spalding LLP; former FDA Deputy Associate Commissioner for Regulatory Operations**

**David Chesney, Principal and General Manager, DL Chesney Consulting, LLC; former FDA District Director for the San Francisco office**

12:00 p.m. | **SUMMIT ADJOURNS**

*"Great and interesting sessions. Great panel discussions and attendee participation."*

— Johanna Stamates, Executive Director - Research Compliance and Quality Assurance, University of Miami

# FDA INSPECTIONS SUMMIT

**YES!** Sign me up for the 12<sup>th</sup> Annual FDA Inspections Summit

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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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 Room rate: \$182 plus 13% tax  
 Reservation cut-off: Oct. 2, 2017

**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 12<sup>th</sup> 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.

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- 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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# FDA INSPECTIONS SUMMIT

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12<sup>TH</sup> ANNUAL

# FDA INSPECTIONS SUMMIT

NOVEMBER 1-3, 2017 | DOUBLETREE BETHESDA, BETHESDA, MD (WASHINGTON, DC)

**The FDA Inspections Summit** — now in its 12<sup>th</sup> 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

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