

**FDANEWS** PRESENTS THE

13TH ANNUAL

# FDA INSPECTIONS SUMMIT

OCT. 23-25, 2018  
BETHESDA NORTH MARRIOTT  
HOTEL & CONFERENCE CENTER  
BETHESDA, MD

#1 EVENT FOR QUALITY, COMPLIANCE AND INSPECTIONAL READINESS PROFESSIONALS

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## AGENDA

### Preconference Workshops

12:00 p.m. – 1:00 p.m.	Registration
1:00 p.m. – 5:00 p.m.	Flawless FDA Inspection Handling and Response
1:00 p.m. – 5:00 p.m.	Preparing Your Team for EU-MDR
1:00 p.m. – 5:00 p.m.	ICH E6 (R2) How to Build a Sponsor Risk Management Program

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## Drugs & Biologics Preconference Workshop

1:00 p.m. – 5:00 p.m.

Flawless FDA Inspection Handling and Response

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

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.

In this popular session featuring John Avellanet of Cerulean Associates — one of the industry's top inspectional readiness experts — 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.

Plus, John will explain how the FDA's New Inspection Protocol Project inspection technique has already tripped up companies with good compliance records. He'll go through the details related to how an organization

that had years of clean inspections can suddenly find itself blind-sided based on NIPP. No one charged with managing FDA inspections can afford to miss this session!

Attendees will learn:

- The critical inspection preparation techniques every member of your team must commit to memory — especially useful for those surprise FDA visits
- Tactics that 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
- Tips for what really needs to be in your inspections SOPs, how to cut corporate-speak and unnecessary verbiage in your SOPs that doesn't help, and how shorter SOPs are better
- 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

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

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## Medical Devices Preconference Workshop

1:00 p.m. – 5:00 p.m.

### Preparing Your Team for EU-MDR

The deadline for the EU-MDR is fast approaching; the Date of Application is May 26, 2020. Many device manufacturers focused on ISO 13485:2016 and preparing for an MDSAP audit. As a result, there had been limited capacity for EU-MDR planning and implementation. Now is the time.

The EU-MDR is a long and complex regulation with many interlocking parts. Articles refer to other articles and to annexes. Annexes use information from other annexes to develop plans and reports that, in some cases, are embedded in other plans or reports. This pre-conference workshop provides the overarching organization allowing you to identify and connect the pieces for your implementation.

The first component is the manufacturer's infrastructure. This includes extensive requirements for the Quality Management System, QMS. There are nearly 15 necessary elements, many of which are not fully covered by ISO 13485:2016. The infrastructure includes relationships with other economic operators as well as many new requirements for the Authorized Representative.

The second component is the device. The classification system changed, so your device may have a device class that is not the same as in the MDD. Annex I General Safety and Performance Requirements, is significantly expanded from the MDD Annex I and includes both new requirements and revised existing requirements. In addition, the Annex II and Annex III Technical Documentation is more complicated. While the EU anticipates

harmonized standards, there are none yet. There is a plan to create Common Specifications, but none have been issued.

The third component is the Notified Body, NB. Any potential NB must apply for EU-MDR because notifications for the MDD will expire. The EU-MDR has extensive requirements for the NB's audit of a device manufacturer. You need to understand these requirements to prepare for the initial and surveillance audits.

Participants will learn:

- The necessary elements in the QMS and some information about each one
- Why ISO 13485:2016 is not adequate for the EU-MDR
- The required elements in the QMS application to the Notified Body
- The qualifications and responsibilities for the Person Responsible for Regulatory Compliance
- The relationship with the other economic operators
- The role of the Annex I requirements
- The role of the Annex II and Annex III Technical Documentation
- The EU-MDR UDI system
- The required PMS reports based on device class and other characteristics
- How the NB assesses the manufacturer's quality system
- How the NB conducts product verification
- How the NB performs pre-clinical and clinical evaluation
- How the NB performs surveillance activities and post-certification monitoring

**Customized, Interactive and Full Of Valuable Take-Aways,  
This Pre-Conference Workshop is a Must Attend**

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

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## **Clinical Trials Preconference Workshop**

1:00 p.m. – 5:00 p.m.

ICH E6 (R2) How to Build a Sponsor Risk Management Program

ICH E6 has changed the landscape for clinical trial professionals. The guidelines now require trial sponsors to institute risk assessment at both the system and clinical trial levels. Have you established your program yet? Is your maintenance program complete? This workshop is built to help you understand the requirements and put you on the road to full compliance long before the issue comes up during an inspection.

Prepare to discover:

- What the new guidelines require
- How to establish your program step-by-step
- Critical elements of starting your program: A walk-through
- How to conduct risk assessment at both system and clinical trial levels
- Evaluating the risks: Your options
- Risk mitigation and reporting strategies
- Common pitfalls and how to sidestep them
- And *much* more!

Your leader, **Dr. Susan Leister**, Vice-President of Quality & Compliance, Technical Resources International, boasts 20-plus years of industry experience and holds CQA and CSSBB certifications from the American Society for Quality. She serves on the ASQ Section 509 Executive Committee and served as a 2012 and 2013 Maryland Performance Excellence Award Examiner and a 2013 ASQ International Team Excellence Award Judge. She has served as a part-time faculty member of the University of Phoenix Undergraduate and Graduate School of Business for the past five years.

**Customized, Interactive and Full Of Valuable Take-Aways,  
This Pre-Conference Workshop is a Must Attend**

**Susan Leister**, Vice-President of Quality & Compliance, Technical Resources International

**Day 1**

8:00 a.m. – 9:00 a.m.

Registration and Continental Breakfast

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9:00 a.m. – 9:10 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

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9:10 a.m. – 10:00 a.m.

Integrated Quality Assessment and the FDA's Move to Align Review and Inspections Staff

The FDA is continuing to move toward the use of "Integrated Quality Assessment" teams. This new, team-based approach is meant to foster greater communication and alignment between field and review staff so that the agency can make closer consideration of all elements that create risk, including the drug substance, the drug product, manufacturing processes, and the state of the facilities. For drug manufacturers, it's called a "concept of operations," for medical device manufacturers, it's called "Total Product Lifecycle Quality." Either way, the agency is changing how it manages product quality, and you need to change with it.

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10:00 a.m. – 10:45 a.m.

## Good Supply Practices (GSPs) for the Lifesciences

The FDA and industry professionals have collaboratively worked through Xavier University to develop Good Supply Practices for the 21st Century that increase the success of your product through an intentionally developed supply chain. The team identified one major paradigm shift and three new concepts that result in a step jump improvement in how you develop and manage your supply chain. Don't miss this opportunity to set your organization up for patient, product and business success!

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

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10:45 a.m. – 11:00 a.m.

## Refreshment Break

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11:00 a.m. – 3:15 p.m.

## Three Concurrent Breakout Tracks

- **Track 1 — Drugs & Biologics**
  - **Track 2 — Medical Devices**
  - **Track 3 — Clinical Trials**
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# Drugs & Biologics Track

11:00 a.m. – 11:10 a.m.

## Moderator Comments

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

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11:10 a.m. – 12:00 p.m.

## The US/EU Mutual Recognition of Drug GMP Inspections

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.

**Ellen Morrison**, Associate Commissioner, OMPTO, ORA, FDA (Invited)

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12:00 p.m. – 12:45 p.m.

#### The FDA's New Approach to Drug Inspections

Last fall, the CDER Office of Compliance began their Concept of Operations program — an initiative undertaken with the Office of Regulatory Affairs to increase efficiency and transparency in GMP drug inspections and regulatory decision-making. The Con-Ops program builds upon FDA's recent Program Alignment by commodity. CDER also has set a goal of communicating the final inspection classification within 90 days of the end of certain GMP inspection. One year in, come hear how the program is working and how the FDA and the inspected facilities are reacting to the changes.

**Cynthia Schnedar**, Executive Vice President, Regulatory Compliance, Greenleaf Health

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12:45 p.m. – 1:45 p.m.

Lunch

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1:45 p.m. – 3:15 p.m.

#### Panel Discussion: Global Data Integrity

Data integrity has always been important during inspections, but as international agencies have worked to recognize each other's inspections, global standards of data integrity have become more important. Multiple FDA warning letters and EU GMP non-compliance reports have highlighted major data integrity failures and falsification in companies globally. In addition, data integrity issues have become more complex for today's manufacturers, as they learn to manage greater use of information technology, increased availability of international data, evolving regulations around the electronic technologies and models built on global drug development and manufacturing. This expert panel will provide context for the latest developments, describe how drug manufacturers have responded and provide clues for where international regulators will be looking for at your facility.

Moderator: **Sue Schniepp**, Distinguished Fellow, Regulatory Compliance Associates, Inc.

**Kalah Auchincloss, J.D.**, Senior Vice President, Regulatory Compliance and Deputy General Counsel, Greenleaf Health

**Ronald Tetzlaff, PhD**, Corporate Vice President, PAREXEL Consulting

**John Avellanet**, Managing Director and Principal, Cerulean Associates LLC

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3:15 p.m. – 3:30 p.m.

Refreshment Break

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## Medical Device Track

11:00 a.m. – 11:10 a.m.

Moderator Comments

**Robert Ruff**, Executive Director of Medical Device Education and Training, International MDSAP Team Lead, NSF Health Sciences; former Medical Device Specialist and Senior Investigator at ORA and International Team Lead at CDRH, FDA

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11:10 a.m. – 12:00 p.m.

Getting to Root Cause During Your CAPA Investigation

Under the FDA's risk-based requirements, every company doing business in the medical products industry, including suppliers, must have a corrective and preventive action (CAPA) program. The most essential component of a CAPA program is a documented system for discovering the root cause of system failures, nonconformances, product complaints and inspection findings.

Attendees will receive step-by-step guidance on conducting an effective root cause analysis, from recognizing problems that need to be investigated to documenting the investigation so regulators can see you are on top of the situation.

**Karl Vahey**, Vice President Manufacturing Quality, Cardinal Health

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12:00 p.m. – 12:45 p.m.

The MDSAP Process

The Medical Device Single Audit Program allows an MDSAP recognized Auditing Organization to conduct a single regulatory audit of a medical device manufacturer that satisfies the relevant requirements of the regulatory authorities participating in the program.

**Brian Ludovico**, Executive Director, MDSAP Regulatory Certification, NSF Health Sciences

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12:45 p.m. – 1:45 p.m.

Lunch

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1:45 p.m. – 3:15 p.m.

Panel Discussion: MDSAP Audit Experience

If you've made a commitment to be certified through the Medical Device Single Audit Program, you certainly want to be ready for the audit. But let's not forget that this can be a new experience for the auditors, too. Canada is the first market to require the MDSAP audit as part of its medical device licensing scheme, beginning Jan. 1, 2019, so you can bet others will soon follow. What can medical device manufacturers expect during the audit? How do you demonstrate that your staff is appropriately trained? How can you identify possible gaps in your readiness? This expert panel will describe what an MDSAP audit is like, and what lessons everyone can learn to be ready.

Moderator: **Robert Ruff**, Executive Director of Medical Device Education and Training, NSF Health Sciences; former Medical Device Specialist and Senior Investigator at ORA and International Team Lead at CDRH, FDA

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

**Alexander Crosby**, Americas Program Manager, Medical Business Assurance, Intertek

**Maura Corcoran**, Senior Director, Quality Operations, Ethicon Wound Closure Repair (JnJ)

**Karl Vahey**, Vice President Manufacturing Quality, Cardinal Health

**Brian Ludovico**, Executive Director, MDSAP Regulatory Certification, NSF Health Sciences

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3:15 p.m. – 3:30 p.m.

Refreshment Break

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## Clinical Trials Track

11:00 a.m. – 11:10 a.m.

Moderator Comments

**David Borasky**, Vice President IRB Compliance, WIRB-Copernicus Group

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11:10 a.m. – 12:00 p.m.

## BIMO Update

Hear the latest news and initiatives coming out of the Office of Bioresearch Monitoring Operations

**David Glasgow**, Deputy Director, Office of Bioresearch Monitoring Operations, OMPTO, ORA, FDA

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12:00 p.m. – 12:45 p.m.

## Using Metrics to Achieve Inspectional Readiness

Performance metrics and risk indicators should be an integral part of your inspection readiness program. Come to this session to explore:

- Typical mistakes organizations make when selecting metrics
- Measurement considerations when implementing risk-based quality management programs
- Data organizations review in centralized monitoring programs
- Trial Master File metrics that help organizations build and maintain inspection ready TMFs

**Linda Sullivan**, Executive Director, Metrics Champion Consortium

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12:45 p.m. – 1:45 p.m.

## Lunch

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1:45 p.m. – 3:15 p.m.

## Panel Discussion: The 10 Best — and 10 Worst — Things to Do When FDA Staff Are on Site

The behavior of your 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 Borasky**, Vice President IRB Compliance, WIRB-Copernicus Group

**David Glasgow**, Deputy Director, Office of Bioresearch Monitoring Operations, OMPTO, ORA, FDA

**Phillip Leese**, President, Medical Consultants PA

**Cassandra Kennedy**, VP, Global Head, Regulatory Compliance and Quality Assurance, Covance

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3:15 p.m. – 3:30 p.m.

Refreshment Break

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## **Plenary Session Panel Discussion**

3:30 p.m. – 5:00 p.m.

The FDA's Vision and Strategy for Field Programs

The FDA's field operations are going through a major overhaul. With the reorganization and program alignment, how will this affect your dealings with FDA staff? Hear from representatives from the Office of Medical Device and Radiological Health Operations, the Office of Pharmaceutical Quality Operations and the Office of Bioresearch Monitoring Operations to get the latest developments.

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

**Alonza Cruse**, Director, Office of Pharmaceutical Quality Operations, ORA, FDA (Invited)

**David Glasgow**, Deputy Director, Office of Bioresearch Monitoring Operations, OMPTO, ORA, FDA

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**5:00 p.m. – 6:30 p.m.**

Networking Reception

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## **Day 2**

8:00 a.m. – 9:00 a.m.

Registration and Continental Breakfast

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9:00 a.m. – 9:10 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

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9:10 a.m. – 10:00 a.m.

### Ethical and Scientific Issues in Developing Deep Learning Systems in Medicine: More Like Drugs Than You Might Think

This session will compare the development of deep learning systems in medicine to the development new drugs. Building on prior work on the structure of clinical translation for new drugs (Kimmelman and London 2015) Professor London will argue that in both cases uncertainty about the structure of key causal systems necessitates prospective, empirical testing in well-controlled trials to assess claims of clinical utility. He will compare the demands to assess drugs in light of real world evidence to the importance of assessing the net effect on care from integrating deep learning systems into clinical practice.

**Alex John London**, Clara L. West Professor of Ethics and Philosophy and Director of the Center for Ethics and Policy, Carnegie Mellon University

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10:00 a.m. – 10:45 a.m.

### Total Cost of Quality and Industry 4.0: The Bi-Modal Challenge Facing Quality Leaders Today

As an FDA-regulated drug-manufacturing or device-maker, CRO or CDMO, your commitment to top quality goes without saying. You're 100% up to date on the latest tools and techniques. But lowering costs without disrupting product quality, safety, efficacy, compliance and continuity, presents a major hurdle that may seem impossible to overcome; a problem that is compounded by the rise of 3D printing, automation, cloud computing and personalized medicine within manufacturing. In this session, Steve McCarthy, Sparta's VP for Digital Innovation, demonstrates how digital technology is transforming quality management in companies like yours. You'll discover:

- Benefits and challenges of using cloud platforms and other digital technology in a Quality and/or GxP-regulated environment
- Consequences of an inferior quality management system
- Foundations of a superior quality management system
- How to use digital technology — including cloud platforms — to augment your quality strategy
- The GxP-regulated environment: Challenges and benefits of cloud platforms and other digital innovations
- Cost-saving and value-add opportunities to help *your* company thrive

**Steve McCarthy**, Vice President of Digital Innovation, Sparta Systems; former VP of Quality Systems Shared Services, Johnson & Johnson

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10:45 a.m. – 11:00 a.m.

Refreshment Break

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11:00 a.m. – 12:00 p.m.

### Panel Discussion: How to Manage a Combination Products Inspection

Co-Chair Steve Niedelman will provide real-world scenarios for dealing with inspections for combination products. The FDA expects manufacturers to be able to demonstrate how they meet applicable cGMP and QSR requirements, and that they are properly documented. How does a manufacturer deal with inspections when product is developed and manufactured at multiple sites? How does EU MDR change the landscape? All this and more will be discussed in a panel that will summarize the experiences of combination product manufacturers and help provide a roadmap for what others can expect.

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12:00 p.m.

Summit Adjournment