Agenda

Pre Conference

12:00 p.m. – 1:00 p.m.

Registration

Drugs & Biologics Preconference Workshop

1:00 p.m. – 5:00 p.m.

Flawless FDA Inspection Handling and Response

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.

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 is bad, even worse is crafting a response, plowing it through your internal departments and getting it back to the FDA in just 15 days.

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 discover:

- The results of a case study of how a firm that passed 9 previous inspections suddenly failed under the FDA's new 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

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 Preconference Workshop

1:00 p.m. – 5:00 p.m.

Process Validation for Medical Devices: Preparing for a QSR Inspection

Nearly half of every warning letter issued to medical device companies in 2018 cited process validation as a problem. That's a big problem.

Process validation can be a daunting prospect. What should you do? When should you do it? What records should you keep?

With no clear guidance from the FDA, finding the answers can be difficult.

Join industry expert Dan O'Leary, President of Ombu Enterprises, LLC, as he discusses the fundamental requirements of medical device process validation. Dan will walk you through his analysis of warning letters and help you apply lessons learned.

Dan O'Leary, President, Ombu Enterprises, LLC

Clinical Trials Preconference Workshop

1:00 p.m. – 5:00 p.m.

ICH E6(R2): How to be Inspection Ready with Your Sponsor Risk Management Program

The clinical trials world is going back to school. Recent ICH E6(R2) guidelines require trial sponsors to institute risk assessment at both the system and clinical trial levels; and require drug and biologics makers to qualify vendors.

You can get all the training you need to meet these challenges with four hours of hands-on professional development aimed at helping *you* understand and comply with new ICH E6(R2) requirements. Teaming up with

Technical Resources International Inc., we've created a workshop that meets the needs of everyone along the clinical trials spectrum, from trial sponsors to trial operators and overseers.

Risk assessment helps drug and biologics makers master the intricacies of the new guidelines with *interactive* training. You'll discuss:

- 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

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

Day 1

8:00 a.m. – 9:00 a.m.

Registration and Continental Breakfast

9:00 a.m. – 10:00 a.m.

Opening Comments by the Summit Committee

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

Cynthia Schnedar, Executive Vice President, Regulatory Compliance, Greenleaf Health; former Director, Office of Compliance, CDER

Brian Ludovico, Executive Director, NSF Medical Device Regulatory Certification

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

Susan Schniepp, Fellow, Regulatory Compliance Associates, Inc.

10:00 a.m. – 10:45 a.m.

Auditing Manufacturers: Linking Data Integrity with Quality Culture

Auditing a company to determine if its culture supports quality and data integrity is becoming an increasingly crucial part of inspections.

The FDA, the Medicines and Healthcare products Regulatory Agency (MHRA), the World Health Organization (WHO) and the Pharmaceutical Inspection Co-operation Scheme (PIC/S) have all incorporated the topic of a quality culture in their guidances on data integrity.

The trouble with a quality culture is determining how to measure it and how to train for it. Come hear a world-class expert discuss ways you can create a world-class quality culture.

Susan Schniepp, Fellow, Regulatory Compliance Associates, Inc.

10:45 a.m. – 11:00 a.m.

Refreshment Break

11:00 a.m. – 12:45 p.m.

Three Concurrent Breakout Tracks

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

Drugs & Biologics Track

11:00 a.m. – 11:10 a.m.

Moderator Comments

Cynthia Schnedar, Executive Vice President, Regulatory Compliance, Greenleaf Health; former Director, Office of Compliance, CDER

11:10 a.m. – 12:00 p.m.

Concept of Operations: How Integration of the FDA Facility Evaluation and Inspection Program Impacts Your Organization

CDER's Office of Compliance, through its Concept of Operations program, has set a goal of communicating final inspection classifications within 90 days of the end of all GMP surveillance inspections. 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; former Director, Office of Compliance, CDER

12:00 p.m. – 12:45 p.m.

Today's Track & Trace: What Merck and the FDA Have Learned

By 2023, the FDA will expect companies to use state-of-the-art digital technology — including AI, blockchain and machine learning — to track the origin and movement of drugs around the world.

Merck is currently teaming up in a new pilot program with IBM, KMPG, and Walmart to build on a Walmart platform for tracking produce and meat. Tracking that used to take more than a week can be done in a few seconds. Merck is confident that it can bring the same success to pharma.

12:45 p.m. – 1:45 p.m.

Lunch

1:45 p.m. – 2:45 p.m.

Panel Discussion: The US/EU Mutual Recognition Agreement (MRA) for Drug GMP Inspections

As of July, the FDA and EU regulators completed five years of work to formally allow mutual recognition of GMP inspections between all 28 EU member states and the US. While this means fewer inspections, it also means that each inspection carries more weight. Come hear experts talk about the practical implications of this agreement so you're not caught off guard.

Moderator: **Cynthia Schnedar**, Executive Vice President, Regulatory Compliance, Greenleaf Health; former Director, Office of Compliance, CDER

Mark Abdoo, Associate Commissioner for Global Policy and Strategy, OC, FDA

Chris Markus, Partner, and Deputy Chair, FDA & Life Sciences Practice, King & Spalding

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2:45 p.m. – 3:00 p.m.

Refreshment Break

Medical Device Track

11:00 a.m. – 11:10 a.m.

Moderator Comments

Brian Ludovico, Executive Director, NSF Medical Device Regulatory Certification

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11:10 a.m. – 12:00 p.m.

FDA's Shift from QSR to ISO 13485:2016: A Significant Change for Inspections

The FDA is months away from switching from the Quality Systems Regulation (QSR) to ISO 13485:2016 for medical device inspections. This means new regulations, new training, changes to the device inspection model, changes to IT systems and on and on.

Come to this session for helpful insights from a former field investigator to get you ready for a massive change.

Kristen Grumet, Senior Vice President, Regulatory Compliance, Greenleaf Health; former FDA Field Investigator specializing in medical devices

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12:00 p.m. – 12:45 p.m.

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

Devicemakers that export into Canada, Japan, Australia and Brazil face important changes to the audit and inspection process as the new Medical Device Single Audit Program (MSDAP) goes into effect. Canada imposed MDSAP as a requirement on Jan. 1. The changes differ in important ways from what you're used to.

Join us as an MDSAP veteran takes you through the changes and how you'll have to alter your thinking.

This session will entail:

- Using the companion document to most successfully prepare for the MDSAP audit
- Ensuring that your quality system completely covers specific country requirements
- Registration review details: Specifics to expect in this portion of the audit
- Differences in emphasis: Unfamiliar questions the MDSAP auditor is likely to ask
- Audit procedures: How the MDSAP audit is conducted and how it differs from FDA inspections and ISO audits
- Grading system for nonconforming: What it means

MDSAP is here — don't get caught short.

Connie Hoy, Consultant, Hoy & Associates Regulatory Consulting

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12:45 p.m. – 1:45 p.m.

Lunch

1:45 p.m. – 2:45 p.m.

Panel Discussion: EU-MDR: Final Push for Compliance by the May 26, 2020 Deadline

Devicemakers face a market upheaval in the EU. A new set of rules — the Medical Device Regulation (MDR) — will soon supplant the longstanding Medical Device Directive. You have until May 2020 to comply.

The new MDR dovetails with ISO 13485:2016 and MDSAP to push for greater standardization and stronger post-market surveillance. It also requires a person responsible for regulatory compliance to be available within an organization whose specific expertise is in medical devices.

Moderator: **Brian Ludovico**, Executive Director, NSF Medical Device Regulatory Certification

Phil Pontikos, Device National Expert Investigator with ORA, FDA (Invited)

Karl Vahey, Vice President Manufacturing Quality, Cardinal Health

Dan O'Leary, President, Ombu Enterprises, LLC

2:45 p.m. – 3:00 p.m.

Refreshment Break

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.

Meeting CRO-Vendor Oversight Requirements

No matter the size of your organization, strategic vendor oversight is a vital part of good clinical trial management. Regulators will be looking for red flags related to vendor management and may even request a vendor representative to be present at an inspection.

You'll leave this session understanding how to avoid the common pitfalls of effective sponsor/vendor engagements. Discover how to vet vendors well in advance and avoid wasting time and money on vendors not qualified to perform key processes and services.

Liz Wool, President, Wool Consulting Group, Inc.

12:00 p.m. – 12:45 p.m.

Validating Your Systems and Equipment for Compliance

Have you performed a Part 11 audit of your or your vendor's technology and is there proper evidence that it will withstand regulatory scrutiny? Part 11 has been around a long time yet many companies still fail to comply. Recent regulatory inspection documents prove that qualification and validation and electronic record keeping systems are a common target for investigators.

This session will tell you which equipment and systems need to be qualified or validated and how to record and document raw data and other records according to Part 11 and Annex 11. You'll be able to define and demonstrate Part 11 compliance to auditors and investigators. And be provided tips to be able to develop and maintain inspection-ready documentation.

12:45 p.m. – 1:45 p.m.

Lunch

1:45 p.m. – 2:45 p.m.

Quality by Design – Build Quality into Clinical Trials to Proactively Identify and Mitigate Risks

Ensure quality by design in your clinical trials to pass your next inspection. By taking a risk-based approached you'll more easily define the risks involved and proper methods for mitigating them. Join us to understand the meaning and purpose of quality by design. This session will outline proactive measures to perform in real time to avoid any retrospective reactions following an inspection.

And, examine case studies to showcase fundamental failures that would have been prevented by using a quality by design approach.

Reetu Dandora, Executive Director, Merck Research Laboratories Quality Assurance

Sharon Reinhard, Executive Director, Merck

2:45 p.m. – 3:00 p.m.

Refreshment Break

Plenary Session Panel Discussion

3:00 p.m. – 4:30 p.m.

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

Behavior during an inspection can run 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.

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

Cynthia Schnedar, Executive Vice President, Regulatory Compliance, Greenleaf Health; former Director, Office of Compliance, CDER

Susan Schniepp, Fellow, Regulatory Compliance Associates, Inc.

John McKay, SVP Global QA and Chief Compliance Officer, Hisun-SIPCO (Zhejiang Hisun Pharmaceutical Co. Ltd.)

4:30 p.m. – 5:30 p.m.

Mock Inspection: Practice Makes Perfect

Not everyone has been through an FDA inspection of their facilities and processes. The best way to be prepared is to practice and what better way than to participate in a mock inspection? Seasoned experts will walk through the inspection process and challenge you with tricky scenarios. This 60-minute interactive exercise will have you ready for anything the next time FDA shows up at your door.

5:30 p.m. – 6:30 p.m.

Networking Reception

Day 2

8:00 a.m. – 9:00 a.m.

Registration and Continental Breakfast

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.

FDA 483 and Warning Letter Trends

Doing an annual lookback at the 483s and warning letters the FDA has issued can provide great insights to prepare you for your next inspection and will give you a glimpse of some of the areas the FDA is focusing on. There are top citations that come up year after year, such as insufficient CAPA investigations and not following your SOPs, but new patterns crop up all the time. Come hear a new analysis of the trends and what you can do to pass your next inspection with flying colors.

Chalana Damron, Counsel, Crowell & Moring

10:00 a.m. – 10:45 a.m.

Organizing Data and Document Archives: Finding a Needle in a Haystack for FDA Inspections

Your documents may not be as organized as you think they are. Can you easily put your hands on the documents FDA investigators request? Or are you searching for that needle in a haystack?

Paper documents unscanned. Naming conventions that don't make sense. Emails as GXP documentation. Poor communication with the vendors that generate your data. Non-functional (or non-existent) SOPs. Documents missing altogether. Yes, data retrieval is in a sorry state at far too many drug, device, biologics and clinical trials companies.

But your next inspection day need not become scavenger hunt day. Create effective new SOPs for electronic document management or improve existing ones. This session will show you the tools you need to make it easy.

John Avellanet, Managing Director and Principal, Cerulean Associates LLC

10:45 a.m. – 11:00 a.m.

Refreshment Break

11:00 a.m. – 12:00 p.m.

FDA's Vision and Strategy for Field Programs

FDA's field operations are going through a major overhaul. With the reorganization and program alignment, how will this affect your inspection? Hear from representatives from the Office of Medical Device and Radiological Health Operations, Office of Pharmaceutical Quality Operations and 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

Jan Welch, Director, Office of Medical Device and Radiological Health Operations, ORA, FDA (Invited)

Alonza Cruse, Director, Office of Pharmaceutical Quality Operations, ORA, FDA

Chrissy Cochran, PhD, Director, Office of Bioresearch Monitoring Operations, OMPTO, ORA, FDA (Invited)

12:00 p.m.

Summit Adjourns