AGENDA

Wednesday, Oct. 23, 2019 • PRE-CONFERENCE WORKSHOPS

Drugs & Biologics Preconference Workshop

12:00 p.m. – 1:00 p.m. **Registration** Glen Echo Foyer

1:00 p.m. – 5:00 p.m. Glen Echo

Flawless FDA Inspection Handling and Response

Rated #1 Pre-Conference Workshop in Inspection Summit History

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 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.

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 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

Clinical Trials Preconference Workshop

12:00 p.m. – 1:00 p.m. **Registration** **Glen Echo Foyer**

1:00 p.m. – 5:00 p.m. **Forest Glen**

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 training 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 meet the needs of everyone along the clinical trials spectrum, from trial sponsors to trial operators and overseers.

Trial sponsors now must institute risk assessment at both the system and clinical trial levels. This assists drug and biologics makers master the intricacies of the new guidelines with hands-on, *interactive* training. You'll 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

Susan Leister, VP, Quality & Compliance, Technical Resources International

Medical Devices Preconference Workshop

12:00 p.m. – 1:00 p.m. **Registration** **Glen Echo Foyer**

1:00 p.m. – 5:00 p.m. **Oakley**

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

DAY ONE – Thursday, Oct. 24, 2019

8:00 a.m. – 9:00 a.m. **Registration & Continental Breakfast**

9:00 a.m. – 9:10 a.m. **Salon G/H**

Opening Comments by Chairperson

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

9:10 a.m. – 10:00 a.m. **Salon G/H**

FDA and D.C. Politics: A Look at FDA Achievements and What Lies Ahead

Former FDA Associate Commissioner for Legislative Affairs, Marc Scheineson, will take a look back at the FDA's initiatives from the past three years and how their policies are reshaping the regulatory atmosphere. What were some of Gottlieb's accomplishments and what's in store for current Acting Commissioner Norman Sharpless or possible successor? With the election year approaching, Marc will also provide an analysis of what the FDA's regulatory landscape could look like in 2020.

Marc Scheineson, Partner, Alston & Bird LLP

10:00 a.m. – 10:45 a.m. **Salon G/H**

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. – 2:45 p.m.

Three Concurrent Breakout Tracks

- **Track 1 — Drugs & Biologics** **Salon G/H**
- **Track 2 — Clinical Trials** **Forest Glen**
- **Track 3 — Medical Devices** **Oakley**

12:45 p.m. – 1:45 p.m. **Birds-of-a-feather Lunch** -- Lunch tables will be labeled by job description providing an opportunity to meet and interact with others who do what you do

2:45 p.m. – 3:00 p.m. **Refreshment Break**

3:00 p.m. – 5:30 p.m. **Plenary Session** **Salon G/H**

5:30 p.m. – 6:30 p.m. **Networking Reception** **Salon G/H Foyer**

Drugs & Biologics Track

11:00 a.m. – 11:10 a.m. **Salon G/H**
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 Organizations
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.

John Taylor, President/Principal, Compliance and Regulatory Affairs, Greenleaf Health; former Acting Deputy Commissioner for Global Operations and Policy, FDA

12:00 p.m. – 12:45 p.m. **Salon G/H**
Audits, Inspections and Management of Suppliers in India and China
What are the chances that your suppliers in India or China will be inspected? Pretty good. Combined, these two countries, make them the largest pharmaceutical and medical device markets in Asia. India provides the U.S. with 25% of its generic drugs, and 80% of the global APIs are sourced from India and China. There is therefore a high probability that these suppliers will be inspected by the FDA. Come hear about how to prepare your suppliers for an upcoming inspection.

John McKay, CEO and Chief Compliance Officer, Q1 Associates LLC

12:45 p.m. – 1:45 p.m. **Lunch** **Salon F**

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 with all 28 EU member states and the U.S. 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, FDA**

CPT Helen Saccone, Senior Advisor, Office of Strategic Programs, CDER, FDA

Chris Markus, Partner, King & Spalding

2:45 p.m. – 3:00 p.m. **Refreshment Break**

Clinical Trials Track

11:00 a.m. – 11:10 a.m. **Forest Glen**

Moderator Comments

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

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 inspections.

You'll this 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. **Forest Glen**

Designing Data Integrity into Your Clinical Trials and Responding When an Issue Arises

Data Integrity is critically important in the context of clinical trials. GCP data integrity issues can at times be more crippling to a company than GMP data integrity issues. In the worst-case scenario, where GCP data integrity issues are severe, it can lead to FDA completely rejecting the data submitted in NDAs, SDAs and ANDA. This can set back the clinical development program for the study drug, costing the sponsor time, money and credibility, not to mention delaying patient access to new drugs. Sponsors who discover these data integrity issues mid-trial may be perplexed as to when and how to engage with FDA. You must know when it's required to report significant data integrity issues discovered pre-submission and the advantages of early disclosure to FDA even when no early disclosure obligation exists.

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

12:45 p.m. – 1:45 p.m. **Lunch** **Salon F**

1:45 p.m. – 2:45 p.m. **Forest Glen**

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.

Sharon Reinhard, M.S., Executive Director, Merck Research Labs Quality Assurance, Merck & Co., Inc.

2:45 p.m. – 3:00 p.m. **Refreshment Break**

Medical Devices Track

11:00 a.m. – 11:05 a.m. **Oakley**

Moderator Comments

Brian Ludovico, Executive Director, NSF Medical Device Regulatory Certification

11:05 a.m. – 11:55 a.m.

Preparing for a 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 MDSAP veteran, Connie Hoy, takes you through the changes — what's the same, what's different, how you'll have to alter your thinking.

MSDAP is here — don't get caught short. Start figuring things out now with this webinar. Join us by registering today.

Connie Hoy, Consultant, Hoy & Associates Regulatory Consulting

11:55 a.m. – 12:55 p.m. **Forest Glen**

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 who specific expertise in medical devices.

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

Karl Vahey, Vice President Manufacturing Quality, Cardinal Health

Dan O'Leary, President, Ombu Enterprises, LLC

Ibim Tariah, Vice President, EU MDR and IVDR Consulting Services, Regulatory & Quality Solutions (R&Q)

12:55 p.m. – 1:45 p.m. **Lunch** **Salon F**

1:45 p.m. – 2:45 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.

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

2:45 p.m. – 3:00 p.m. **Refreshment Break**

Plenary Session

3:00 p.m. – 4:30 p.m. **Salon G/H**

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

Susan Schniepp, Fellow, Regulatory Compliance Associates, Inc.

John McKay, CEO and Chief Compliance Officer, Q1 Associates LLC

David Elder, Executive Vice President, Greenleaf Health; former Director, Director, Office of Regional Operations, FDA

4:30 p.m. – 5:30 p.m. **Salon G/H**

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 inspections 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.

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

David Elder, Executive Vice President, Greenleaf Health; former Director, Director, Office of Regional Operations, FDA

Steven Lynn, Principal GxP Consultant/Owner, Lynn Consulting; former Director, Office of Manufacturing and Product Quality, CDER, FDA

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

5:30 p.m. – 6:30 p.m. **Networking Reception** **Salon G/H Foyer**

DAY TWO – Friday, Oct. 25, 2019

8:00 a.m. – 9:00 a.m. **Registration and Continental Breakfast**

9:00 a.m. – 9:10 a.m. **Salon G/H**

Opening Comments by Chairperson

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

9:10 a.m. – 10:00 a.m. **Salon G/H**

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 diagnostics 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

10:00 a.m. – 10:45 a.m. **Salon G/H**

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 inspections 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 inspections with flying colors.

Chalana Damron, Counsel, Crowell & Moring

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

11:00 a.m. – 12:00 p.m. **Salon G/H**

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 inspections? Hear from representatives from 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**

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

12:00 p.m. **Summit Adjourns**