AGENDA

DAY 1

9:30 a.m. – 10:00 a.m. **Registration/Breakfast**

10:00 a.m. – 12:00 p.m. The Basis For Inspections

- Understand the current GMP compliance and enforcement environment
- European companies face a diverse group of investigators — learn how to be prepared for inspections from FDA, Switzerland, Brazil, Turkey, Russia and more
- FDA partners with numerous other national authorities to share resources and conduct joint inspections — how does this impact your next inspection?
- National regulatory authorities approach inspections differently and employ investigators with various career and educational backgrounds
- Understand the differences between being inspected by your host authority versus a foreign authority
- Top 10 compliance citations issued based on recent FDA and PIC/S data

12:00 p.m. – 1:00 p.m. **Lunch**

1:00 p.m. – 3:00 p.m. Preparation For Inspections

- Interactive Exercise: Learn from other participants and talk about real-world examples — attendees will share what's working for them and what's causing problems. This intel is crucial when it comes time for inspections.
- How having clear, concise project management procedures are key to producing successful audits
- Only prepared people can perform — keys to assure that your inspectional preparedness team is up to the challenge
- Interactive Exercise: Language and behavioral training. Investigators from various countries always behave differently from one another. How should you react?
- Language conflicts between your team and an investigator can derail even well-prepared companies — tips for assuring language difficulties are not part of the problem
- How to set up a world class back office, best practices for improving this vital but often overlooked facet of an inspection

- FDA and other national authorities expect compliance throughout a company, learn how to build a culture of quality and GMP compliance
- More than anyone, you know where the gaps are in your GMP environment — conduct internal audits that fix gaps before investigators find them
- Understanding the FDA's quality system inspection approach
- Tips and tricks to research the investigator who will be doing your next inspection and how to use their past inspectional findings as a preparation guide
- Best practices for setting up the perfect inspection team in your company

3:00 p.m. – 5:00 p.m. Quality System Under Observance

- The top 5 systems and procedures that receive the most attention during inspections
- Interactive Exercise: What are the most critical systems in inspections and how do you protect them against non-compliance? The areas that investigators focus on do not come out of the blue. Certain areas are hot spots for concern and frequently where attendees will be given inspectional citations. Imagine if attendees could have a built-in checklist of where the investigators are likely to look first? This exercise provides participants an opportunity to share insights into how regulatory bodies rate each quality system.
- Investigators are trained to identify non-conformances — are you trained to do the same?
- Interactive Exercise: Identify non-conformances in documents. In this exercise attendees will assume the role of an inspector and identify non-conformances based on documents. Attendees will be trained to find observations before the inspector finds them. The job of an inspector is challenging. Accept the challenge and act as an internal investigator.
- CAPA — Corrective Action /Preventive Action: Do you believe in it? The FDA does. It's one of the top citations for the past 10 years. Learn the role CAPA plays in inspectional preparedness.
- Best practices for assuring all the information you need from internal departments (i.e. R&D, CMC) and external suppliers are available before the inspection occurs.
- Deviation management: Is everything under control?
- Interactive Exercise: Reacting to and rating real inspectional finding by investigators. How should attendees react when an investigator notes an observation? This session will teach attendees what's important to object to and what they should accept. Using proven assessment criteria, this exercise gives participants an opportunity to apply techniques to bring back to their company.

- The keys to well-managed quality control units — how can QC support manufacturing to improve compliance and inspectional readiness
- Change management: Who wants to change? Innovative strategies for implementing change that supports continued quality improvment
- Where are the risks in risk management? The FDA and national regulatory authorities are placing increasing emphasis on risk management. Are you prepared?

5:00 p.m. **End of Day One**

DAY 2

9:00 a.m. – 12:00 p.m. Behavior In Inspections

- The five operational roles that each inspectional prep team must have and the importance of each role
- How your behavior during an inspection can influence the investigator and improve the outcome of an inspection
- Picking subject matter experts that are well trained to handle the questioning of investigators — mistakes in your selection could hurt your chances of a successful inspection
- Interactive Exercise: The inspection role tool kit. You'll learn the most important roles in an inspection. Every role is specific and needs specific skills. This exercise provides best practices for identifying and assigning the best people to be on your inspectional prep team. Let this exercise teach you how to work within the different roles and skill sets of your staff to assure you have a qualified team.
- Interactive Role-Play: A mock investigator grills participants, just like a real investigator would. Role playing is the perfect tool to get the most realistic inspection experience. The instructors challenge the participants just like a real investigator would. This proven technique can be transferred to your company and used with colleagues during in-house training.
- Top dos and don'ts in an inspection — learn from the mistakes of others

12:00 p.m. – 1:00 p.m. **Lunch Break**

1:00 p.m. – 2:30 p.m. After The Inspection

- Post inspection possible outcomes — what actions can FDA and national regulatory authorities take based on their finding
- Learn what typically happens within a company after an inspection — and it's usually not pretty
- Best practices for responding to inspection observations; explanation of the timelines and expected content that are needed in Form 483 and Warning Letter responses
- Proven strategies to improve communication within your organization during the crucial post-inspection remediation period

- Interactive Exercise: Rating real-world inspection observations using proven assessment criteria. This session will teach attendees how to use and apply proven post-inspection assessment techniques to rate observations and can effectively drive remediation efforts.
- Tips and tricks for writing remediation actions plans and progress reports for FDA and management.

2:30 p.m. – 3:00 p.m. Workshop Q&A/ Summary/Conclusion