

6th

CLINICAL TRIALS INSPECTION READINESS

SUMMIT

Instill an Inspection-Ready Culture to Improve Documentation Standards, Stakeholder Engagement and Trial Success

EXPLORE INSPECTION READINESS ISSUES IN CLINICAL TRIALS

- > Outline common findings during inspections
- > Interpret the requirements described by ICH GCP E6R2 and strategize how to move forward as an organization
- > Determine how quality management systems can improve inspection readiness and promote quality

USE RISK MANAGEMENT AND SELF CHECKS TO UNDERSTAND AREAS OF OPPORTUNITY

- > Utilize and leverage risk-based monitoring to improve inspection readiness
- > Understand how sites prepare for inspections and what they need from sponsors to succeed
- > Analyze metrics of past inspections to identify trends in findings, using them to better prepare

SPECIAL FOCUS

MAINTAIN INSPECTION READINESS

- > Guarantee the integrity, safety and security of data to safeguard the clinical trial and its participants
- > Maintain an inspection ready TMF
- > Manage oversight of outsourced trials to remain prepared for inspections and ensure quality

INSPIRE CULTURE OF INSPECTION READINESS TO IMPROVE CLINICAL QUALITY

- > Instill quality by design – a look at trial design and how it affects inspection readiness
- > Implement eTMF and training program to ensure exceptional documentation management
- > Explore the differences between medical device clinical trial inspections and traditional clinical trial inspections

“GREAT conference – easy to meet people and discuss issues informally.”

–Associate Director, Quality Compliance, SANTEC

“Great Topics! Good information sharing! Many networking opportunities!”

–Senior GCP Auditor, CELGENE



FEATURED SPEAKERS



CONFERENCE CHAIR
Ivan Walrath, Head of Audit and Inspection Quality, **PFIZER**



Stephanie deRijke, Director, Clinical Trials Audit and Compliance, **EMORY UNIVERSITY**



Angela Berns, Director and Head of Vendor Management, **UCB BIOSCIENCES INC.**



Andreas Kateifides, Manager, Process Management & Business Analytics, **VERTEX PHARMACEUTICALS**



Pamela Perry, Global Lead, Global Quality Management, **OTSUKA PHARMACEUTICAL COMPANIES**



Linda Coleman, Director, Human Research Protection Program, **YALE UNIVERSITY**



Tipsuda Kongtong, Clinical Quality Assurance, **EISAI**



Nancy Bitters, GCP Inspection Lead, **EMD SERONO**



Ellen Kelso, Senior Consultant and Subject Matter Expert, **THE AVOCA GROUP**



Stacey Basham, Assistant Director, R&D GCP QA, **ABBVIE**

SPONSORS



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DEAR COLLEAGUE,

As clinical trials are conducted, inspections by regulatory authorities are done to ensure quality and integrity of care, data and drug performance; but most of all they ensure GCP and good documentation practices. As sponsors for clinical trials, pharmaceutical companies are required to ensure GCP guidelines are upheld by implementing inspection readiness throughout their organization. This activity can include preparations from documentation standards to staff training, but with a culture in place, these different areas and the quality they deserve are ingrained in the fabric of the organization and quality in GCP is second nature to all staff working on the clinical trial. This new trend is more of a culture change than process, as all aspects of a trial need to be done in an inspection-ready manner.

Implementing an effective inspection readiness plan is contingent upon creating the right environment. The cultural change needs to extend to all service providers and vendors used during the clinical trial, which can range from a CRO to all of the different clinical sites where the trial is taking place. Proper training and management of all stakeholders is a necessary component of the preparation process. Millions of dollars are spent on the development of effective strategies to plan and execute inspections, yet many issues can still arise. Failing an inspection can lead to severe consequences — and potentially result in the shutdown of a clinical trial.

The **6th Clinical Trials Inspection Readiness Summit** is designed as an educational environment where pharmaceutical and research professionals can come together to understand the importance of an organizational culture of inspection readiness and learn how to implement that cultural change with team building, training and procedures. With two days of interactive sessions and case studies concerning effective documentation standards, the culture of preparedness, and improved stakeholder engagement, we will discuss and explore how attendees can shift their organization to a quality-first, quality-always culture. Join us this August in Philadelphia, and take home the knowledge that will help your organization be inspection ready.

I look forward to seeing you in Philadelphia this summer!

Sincerely,

Christopher Summa
Conference Production Director
ExL Events, a Division of Questex, LLC

 **The Rittenhouse Hotel**
210 West Rittenhouse Square
Philadelphia, PA 19103

To make reservations, please call 1-800-635-1042 or 215-546-9000 and request the negotiated rate for **ExL's August Meetings**. You may make reservations online by using the following weblink <http://bit.ly/2qrVSi4>. The group rate is available until **July 18, 2017**. Please book your room early, as rooms available at this rate are limited.

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Do you want to spread the word about your organization's solutions and services to potential clients attending this event? Take advantage of the opportunity to exhibit, underwrite an educational session, host a networking event or distribute promotional items to attendees. ExL Events will work closely with you to customize a package that will suit all of your needs.

WHO SHOULD ATTEND

This conference is designed for representatives from pharmaceutical, medical device and biotechnology companies with responsibilities in the following areas:

- Quality Assurance/Quality Control/Quality Compliance/Quality Management
- Clinical Operations/Research/Planning/Outsourcing/Development
- Good Clinical Practices
- Records/Data Management
- Trial Master File
- R&D Operations
- Trials Management/Research
- Risk-Based/Centralized Monitoring
- Safety and Risk Management Operations
- Site Performance Management
- Internal/External Auditing
- Clinical Project Management
- Regulatory Affairs
- Metrics and Benchmarks
- Process Optimization

This conference is also of interest to:

- CROs
- Inspection Readiness Software Providers
- Data/Records/Archive Management Vendors
- TMF Vendors
- Quality Management Service Providers
- Electronic Signature Companies



8:00 REGISTRATION AND CONTINENTAL BREAKFAST

9:00 CHAIRPERSON'S OPENING REMARKS

Ivan Walrath, *Head of Audit and Inspection Quality*, **PFIZER**

9:15 EXPLORE THE EFFECTS NEW DATA INTEGRITY GUIDELINES AND REQUIREMENTS HAVE ON INSPECTION READINESS

- 🕒 Provide a summary of changes in data integrity and how these new guidelines further audit the safety, security and efficacy of data in clinical trials
- 🕒 Determine how to implement the new requirements within an organization's clinical trial structure and staff
- 🕒 Challenge the new guidelines and requirements to understand how they assist in data integrity and clinical trials

10:00 DETERMINE HOW QUALITY MANAGEMENT SYSTEMS CAN IMPROVE INSPECTIONS READINESS AND PROMOTE QUALITY

- 🕒 Explore quality management systems and the benefits they provide to clinical trial inspection readiness
- 🕒 Leverage the QMS to improve quality and guarantee favorable inspection findings and clinical trial success
- 🕒 Understand the roadblocks and potential pitfalls of a QMS to ensure your organization is properly prepared for the implementation of the system and your staff are properly trained

Stephanie deRijke, *Director, Clinical Trials Audit and Compliance*, **EMORY UNIVERSITY**

Pamela Perry, *Global Lead, Global Quality Management*, **OTSUKA PHARMACEUTICAL COMPANIES**

10:45 NETWORKING BREAK

11:15 MOCK INSPECTION ACTIVITY: FDA

During this mock inspection activity, Eisai's Tipsuda Kongtong will lead attendees through a simulated FDA inspection. Experience this rare interactive approach to better understand the process, and take away the knowledge and tools you need to be inspection ready. Tipsuda will utilize her years of experience conducting independent audits and preparing for inspections to create a learning session that you will not want to miss.

- 🕒 Creating a learning experience that actively simulates an FDA inspection
- 🕒 From classroom to experiential learning: The benefits of hands-on preparedness
- 🕒 Management support: Getting senior management on board with allocated time and resources to mock inspections
- 🕒 Debriefing: Lessons learned and action items moving forward

Tipsuda Kongtong, *Manager, Clinical Quality Assurance*, **EISAI**

12:45 LUNCHEON

1:45 INTERPRET THE REQUIREMENTS DESCRIBED BY ICH GCP E6R2 AND STRATEGIZE HOW TO MOVE FORWARD AS AN ORGANIZATION

- 🕒 Define the new guidance to better understand its requirements for compliance within inspection readiness
- 🕒 Examine ICH GCP E6R2 and plan how to implement its changes into the organizational structure and prepare for a regulatory inspection
- 🕒 Integrate these requirements into any of the inspection preparedness planning processes and ensure compliance

Ellen Kelso, *Senior Consultant and Subject Matter Expert*, **THE AVOCA GROUP**

2:30 UTILIZE AND LEVERAGE RISK-BASED MONITORING TO IMPROVE INSPECTION READINESS

- 🕒 Recognize the benefits of using RBM to promote inspection readiness by conducting a risk assessment and implementing a risk management
- 🕒 Discuss why RBM predominantly fails at improving inspection readiness and how it can be improved to better serve a purpose in inspection readiness
- 🕒 Design or acquire the correct RBM system to fit the needs of an organization to ensure the system can perform at an optimal level

Ivan Walrath, *Head of Audit and Inspection Quality*, **PFIZER**

3:15 NETWORKING BREAK

3:45 USE REGULATORY SURVEILLANCE TO PROACTIVELY IDENTIFY AREAS OF INCREASED REGULATORY RISK

- 🕒 Cross-functional collaboration between Regulatory Affairs, Clinical QA and Clinical Business Operations
- 🕒 Review of updated regulations, warning letters, debarments, 483s, draft regulations and inspection trends
- 🕒 Engagement of SMEs and facilitation of in-depth reviews
- 🕒 Revision of the Quality Management System to address regulation changes and other external information
- 🕒 Notification of study team when potential issues are identified – Management of quality issues

Andreas Kateifides, *Compliance Oversight Systems*, **VERTEX PHARMACEUTICALS**

4:30 MAINTAIN AN INSPECTION READY TMF

- 🕒 Understand how TMF readiness plays a role in SOPs, trial teams and resources throughout a trial
- 🕒 Explore who drives TMF inspection readiness from a quality, trial-team or CRO perspective
- 🕒 Understand inspector direct access and how an eTMF system needs to be designed to access certain information
- 🕒 Incorporate an eTMF training process in your SOPs

Dawn Niccum, *Associate Director, Quality*, **ENDOCYTE**

5:15 CONFERENCE DAY ONE ENDS

8:15 CONTINENTAL BREAKFAST

9:00 CHAIRPERSON'S RECAP OF DAY ONE

Ivan Walrath, *Head of Audit and Inspection Quality*, **PFIZER**

9:15 PANEL: NAVIGATING A CHINA FDA INSPECTION – DISCOVER THE DIFFERENCES FROM EXPERTS WHO HAVE BEEN THERE

- 🕒 Inspection Announcements: Explore the differences from FDA AND EMA inspections
- 🕒 Inspection Conduct: Tips and strategies on managing the actual inspection
- 🕒 Self Assessments: Learn how they are done and their impact
- 🕒 Inspection Responses: Unique considerations to keep in mind

Moderator:

Nancy Bitters, *Inspection Management Lead, Biopharma | Global Research and Development Quality*, **EMD SERONO**

Panelists:

Stacey Basham, *Assistant Director, R&D GCP Quality Assurance*, **ABBVIE**

10:45 eTMF STUDY MIGRATIONS – PLANNING WITH INSPECTION READINESS IN MIND

- 🕒 Approaches to ensure eTMF inspection readiness for a migrated study
- 🕒 Discuss how the data and content “Chain of Custody” can demonstrate a complete and accurate migrated study for inspectors
- 🕒 Consider migration sources (CRO end-of-study handover, acquisition, legacy system) and the impact each may have on a migrated study
- 🕒 Look Ahead: How the TMF Reference Model Exchange protocol will help ensure a migrated eTMF is inspection ready

Lou Pasquale, *Customer Success*, **QUINTILESIMS**

11:30 NETWORKING BREAK

12:00 GCP HOT TOPICS – AN INTERACTIVE SESSION

In this interactive session, we will cover hot topics in the area of Good Clinical Practice, the most common inspectional and audit finding, and the types of systems that can be put in place to prevent them from occurring.

- 🕒 Hot Topic in the area of Good Clinical Practice
- 🕒 Common Agency Inspection Findings and How to Avoid Them
- 🕒 Agency Inspection and Audit Readiness

Linda M. Coleman, *Director, Human Research Protection Program*, **YALE UNIVERSITY**

Alyssa K. Gateman, *Associate Director, Yale Center for Clinical Investigations, Director Office of Quality Assurance and Training*, **YALE UNIVERSITY**

12:45 LUNCHEON

1:45 GUARANTEE THE INTEGRITY, SAFETY AND SECURITY OF DATA TO SAFEGUARD THE CLINICAL TRIAL AND ITS PARTICIPANTS

- 🕒 Minimize compromised data by instituting software and procedures that work cohesively and ensure data integrity
- 🕒 Audit data regularly to repair any anomalies or breaches that could harm the integrity of the trial or safety of the patients
- 🕒 Develop data integrity training to improve staff competency and ensure the culture of inspection readiness

2:30 CASE STUDY: CHALLENGES AND OPPORTUNITIES PRESENTED BY DATA STORAGE INNOVATIONS

- 🕒 Balance the protection of system content with the identity management of those granted access
- 🕒 Look into new technology adoption and how it affects data availability during inspections
- 🕒 Lessons learned and advice from key stakeholders with personal experiences

Betsy Fallen, *Special Topics Consultant*, **SAFE-BIOPHARMA ASSOCIATION**

3:15 MANAGE OVERSIGHT OF OUTSOURCED TRIALS TO REMAIN PREPARED AND READY FOR INSPECTIONS AND ENSURE QUALITY

- 🕒 Leverage partnerships with outsourced vendors and guarantee cross-functional consistency in inspection readiness
- 🕒 Analyze vendors and their processes and procedures, to ensure their standard of quality aligns with the culture of the clinical trial and organization
- 🕒 Schedule routine and non-routine inspections to ensure constant surveillance of the clinical trial and the staff conducting it

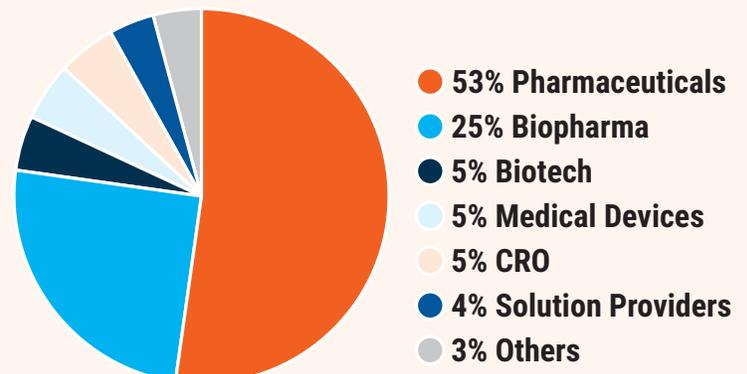
Angela Berns, *Director and Head of Vendor Management*, **UCB SA**

4:00 CHAIRPERSON'S CLOSING REMARKS

Ivan Walrath, *Head of Audit and Inspection Quality*, **PFIZER**

4:15 CONFERENCE CONCLUDES

PAST ATTENDEES BREAKDOWN



REGISTRATION
to register *CLICK HERE* or

Call: 201 871 0474
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SRP Standard Rate Pricing	OSP Onsite Pricing
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August 7-8, 2017 // The Rittenhouse Hotel // Philadelphia, PA

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