Ensuring Trial Integrity by Effectively Assessing, Optimising, and Managing the Quality of Clinical Vendors and Sites

FEATURED SESSIONS

MHRA PERSPECTIVE

Evolving Technologies
Examining Electronic Systems in GCP and How to Remain Compliant in This Changing Environment
Gail Francis, Expert Inspector, Good Clinical Practice, MHRA

FDA Inspection Readiness
Understanding How the FDA Evaluates Practices and Procedures in Clinical Studies
Celeste M. Gonzalez, B.S., CVT, RQAP-GCP, CCRP, Principal Specialist, Clinical Quality Assurance, BOSTON SCIENTIFIC

GSK Case Study: Quality Management System
Examining Oversight Expectations of the Quality Management System and Outlining Changes in Response to ICH E6 R2
Heike Reinstaedtler, Director, Clinical Operations Quality, GSK VACCINES

Trial Master File (TMF)
Defining an Inspection-Ready Trial Master File and Knowing What to Expect During an Inspection
Michele Weitz, Director, GCP Compliance Operations, CLOVIS ONCOLOGY

Bayer Case Study: Clinical CAPAs
Establishing an Effective System to Initiate, Develop and Implement CAPAs to Monitor and Track Their Status
Pearl Boakye, Ph.D., Head Compliance Management, BAYER

Pfizer Case Study: QMS Vendor Assessment
Leveraging a Quality Management System (QMS) to Qualify and Assess New Vendors for Study Engagement
Martin Thorley, Director, Vendor Quality Lead, Pfizer
Lynette J. Bojko, Director, Sourcing and Vendor Management Lead, Operations Center of Excellence (COE), Global Product Development, Pfizer

CONFERENCE CHAIR
David Fryrear, Senior Director, Research and Development Quality Assurance, ABBVIE

Interactive Panel Discussions
- Data Quality Optimisation
- ICH E6 R2 Compliance
- Cross-Agency Inspection Collaboration

Half-Day Interactive Workshop
- Aligning to ICH E6 R2
Identifying Critical Variables, Assessing Risk and Defining Control Measures for Aligning With ICH E6 R2

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Dear Colleague,

Our inaugural European CQOF in 2017 attracted 100 clinical quality experts, with over 70% representing more than 45 different pharmaceutical, biotechnology, and medical device companies from all over the world. We are pleased to announce our 2nd European Clinical Quality Oversight Forum, taking place 26–27 February 2018, again in London. This interactive event focuses on ensuring trial integrity by effectively assessing, optimising, and managing the quality of clinical vendors and sites and attracts clinical quality, operations, management, and audit professionals to engage and candidly share their experiences, struggles, obstacles, and achievements when working with varying clinical partners including CROs and investigator sites. Learn from this experienced group and take away proven, results-driven, risk-based strategies for optimising your company’s clinical vendor and site oversight approach.

Sincerely,

Kristen Hunter
Event Director, ExL Events, a division of Questex, LLC
+1 212-400-6241 | khunter@exlevents.com

Who Should Attend

This event is designed for professionals from pharmaceutical, biotechnology and medical device companies; CROs; and other clinical service providers who have responsibilities in the following areas:

- Quality Management/Clinical Quality Management
  - Clinical Quality Assurance/QA/CQA
  - Clinical Quality Control/QC/CQC
- Clinical Operations/Management/Research/Development
- Compliance/Clinical Compliance/Regulatory Compliance
- Monitoring/Site Management/Study Management
- Clinical Outsourcing/Vendor Management/Third-Party Management
- Good Clinical Practice/GCP
- Auditing
- Clinical Risk/Risk Assessment
- Regulatory Affairs
- Medical Affairs

The event is also of interest to:

- Investigative Sites
- Academic Research Organisations
- Central, Imaging and ECG Labs
- IVRS Companies
- EDC Companies
- Other Clinical Service Providers

Do You Want to Reach the Audience at This Event?

Do you want to spread the word about your organisation's solutions for potential clients and prospects in attendance? Take advantage of the opportunity to exhibit, present an educational session, share your expertise on a panel discussion, host a networking event and/or distribute promotional materials at this conference. ExL works closely with our sponsors to create customised opportunities to fulfil your conference objectives.

To learn more about your options, please contact Justin Kreamer, at +1 917-932-0429 or jkreamer@exlevents.com.

Who You Will Meet

2017 Audience Demographics

Company

- 24% Clinical Service Providers
- 2% Other
- 74% Pharmaceutical, Biotechnology and Device Companies

Function

- 35% Clinical Operations Management
- 10% Outsourcing/Vendor Management
- 5% Other
- 50% Clinical Quality/Compliance

Over 70% Represented Director-Level and Above

www.exlevents.com/eurocqof
7:45 Registration Opens and Continental Breakfast for Workshop Participants

8:30 PRE-CONFERENCE WORKSHOP: ALIGNING TO ICH E6 R2

Identifying Critical Variables, Assessing Risk and Defining Control Measures for Aligning With ICH E6 R2

Keith Dorricott, Ambassador, METRICS CHAMPION CONSORTIUM (MCC)
Tammy Finnigan, Chief Operating Officer, TRIUMPH RESEARCH INTELLIGENCE

» Exploring the process of identifying critical variables and assessing risk
  - How to identify critical data and processes per the requirements in ICH E6 R2 — study risks versus system risks
  - Identifying risks to those critical data and processes
  - Assessing the risks

» Selecting and defining detection measures — Centralised Monitoring
  - How to review priority risks and determine appropriate detection mechanisms
  - Challenges and approaches to defining detection measures
  - Determining thresholds for the detection measures

10:00 30-Minute Networking and Refreshment Break

12:00 Lunch for Workshop Participants/Registration Opens for Main Conference

13:00 CHAIRPERSON’S OPENING REMARKS AND GLOBAL UPDATE

David Fryrear, Senior Director, Research and Development Quality Assurance, ABBVIE

» Discussing the developments in the global regulatory climate and the impact on clinical quality and operations

13:30 SERVICE PROVIDER PREQUALIFICATION

Centralising Clinical Service Provider Qualification Activities to Drive Consistency, Efficiency and Higher Quality

Dennis Salotti, M.S., MBA, CCRA, Vice President, Operations, THE AVOCA GROUP

» Employing strategies for effective risk and capability assessments when choosing a clinical vendor
» Determining which critical financial, business and quality factors to take into consideration
» Identifying effective assessment tools and processes for prequalification
» Streamlining prequalification operations across functions to optimise approach
» Examining the benefits of leveraging centralised resources for prequalification information and processing

14:15 PANEL: CROSS-AGENCY INSPECTION COLLABORATION

Understanding Experiences With Joint Inspections and the Comparison of Inspection Data Across Agencies

Panellists
Susan Callery-D’Amico, Vice President, R&D Quality Assurance, ABBVIE
Heike Reinstaedtler, Director, Clinical Operations Quality, GSK VACCINES

Additional Panellists TBD

» Discussing panellists’ experience with agency collaboration during inspections
  - Reviewing pre-inspection correspondence and onsite behaviour from the different agencies
» Evaluating the results of those inspections from the different agencies involved
  - Understanding if data was shared and interpreted the same
» Examining drivers behind cross-agency collaboration and if the intended goals were accomplished
» Predicting future cross-agency collaborations and the impact on inspection readiness

15:15 Networking and Refreshment Break
DAY ONE | MONDAY, 26 FEBRUARY

15:45 **MHRA PERSPECTIVE: EVOLVING TECHNOLOGIES**

Examining Electronic Systems in GCP and How to Remain Compliant in This Changing Environment

_Gail Francis, Expert Inspector, Good Clinical Practice, MHRA_

- Examining the evolution of electronic systems in GCP — the eSystem inspection model; challenges and changes
- Discussing common findings in relation to ePRO, IRT and eCRF
- Evaluating the requirements and expectations of inspectors related to electronic TMFs — how to get it right
- Understanding MHRA’s expectations for data integrity and common related findings during recent inspections

16:30 **FDA INSPECTION READINESS**

Understanding How the FDA Evaluates Practices and Procedures in Clinical Studies

_Celeste M. Gonzalez, B.S., CVT, RQAP-GCP, CCRP, Principal Specialist, Clinical Quality Assurance, BOSTON SCIENTIFIC_

- Evaluating how and why the FDA conducts BIMO inspections at the sponsor/CRO, investigative site levels
- Identifying the FDA’s major points of emphasis in the guidance documents relating to sponsor and clinical investigator inspections
- Discussing how the FDA:
  - Assesses the protection of the rights, safety and welfare of subjects in FDA-regulated clinical trials
  - Verifies the accuracy and reliability of trial data submitted in support of research or marketing applications
  - Determines compliance with GCP and applicable regulation

17:15 Close of Day One

DAY TWO | TUESDAY, 27 FEBRUARY

7:45 Registration and Continental Breakfast for Conference Participants

8:30 **CHAIRPERSON’S RECAP OF DAY ONE AND OPENING TO DAY TWO**

_David Fryrear, Senior Director, Research and Development Quality Assurance, ABBVIE_

8:45 **TRIAL MASTER FILE (TMF)**

Defining an Inspection-Ready Trial Master File and Knowing What to Expect During an Inspection

_Michele Weitz, Director, GCP Compliance Operations, CLOVIS ONCOLOGY_

- Evaluating what constitutes an inspection-ready TMF based on recent inspection experiences
- Executing QC programs to assess overall TMF health and uncover any possible issues
- Developing strategies for working with vendors to ensure the TMF reflects the integrity of the trial
- Discussing TMF inspection experiences with EMA and FDA, and managing expectations regarding access to and examination of the TMF

9:30 **GSK CASE STUDY: QUALITY MANAGEMENT SYSTEM**

Examining Oversight Expectations of the Quality Management System and Outlining Changes in Response to ICH E6 R2

_Heike Reinstaedtler, Director, Clinical Operations Quality, GSK VACCINES_

- Moving from an audit-focused to an integrated quality oversight approach that proactively supports GCP compliance and Quality Risk Management
- Further developing towards a fit-for-purpose R&D QMS that is common across all GxP disciplines in R&D — assessing opportunities and difficulties
- Establishing a quality culture in R&D that supports proactivity and continuous learning and improvement — quality as a business enabler

10:15 Networking and Refreshment Break
DAY TWO | TUESDAY, 27 FEBRUARY

10:45 BEYOND RISK-BASED MONITORING (RBM)
Leveraging Intelligent Analytics to Drive Regulatory Inspections and Support ICH E6 R2 Compliance
François Torche, CEO, CLUEPOINTS
» Understanding how ICH E6 R2 prioritizes RBM
» Evaluating the new paradigm and how it’s evolving RBM
» Incorporating Central Statistical Monitoring (CSM) into RBM to fulfill regulatory requirements and improve quality and cost efficiencies
» Evaluating a progressive approach to interrogating submission data to improve internal quality audits and drive site inspection readiness
» Defining the value of CSM and the ROI from an enhanced RBM approach

11:30 CLINICAL DATA INTEGRITY
Developing an Effective Strategy to Optimize Clinical Data Integrity
Milind Nadgouda, Director, RIVERARK LTD
» Identifying the regulations driving an increased focus on data integrity
» Understanding the concepts of data integrity and their applicability in clinical research
» Learning best practices from the GMP space and applying to clinical
» Developing a strategy to incorporate data integrity into clinical operations
  - Assessing the impact on systems and documentation
» Operationalizing the strategy with an implementation plan
» Reviewing and auditing to ensure effectiveness

12:15 Lunch

13:15 PFIZER CASE STUDY: QMS VENDOR ASSESSMENT
Leveraging a Quality Management System (QMS) to Qualify and Assess New Vendors for Study Engagement
Martin Thorley, Director, Vendor Quality Lead, PFIZER
Lynette J. Bojko, Director, Sourcing and Vendor Management Lead, Operations Center of Excellence (COE), Global Product Development, PFIZER
» Evaluating the need for the QMS framework to assess and manage vendors
» Navigating the framework principles, critical-to-success factors and barriers to implementation
» Determining critical quality factors and establishing risk levels for qualification and assessment of new vendors
» Examining the benefits of establishing a consistent process and data variables across the organisation

14:00 BAYER CASE STUDY: CLINICAL CAPAs
Establishing an Effective System to Initiate, Develop and Implement CAPAs, and Monitor and Track Their Status
Pearl Boakye, Ph.D., Head Compliance Management, BAYER
» Defining the criteria for when a CAPA is necessary within the sponsor and CRO
» Designing a system to manage CAPAs
» Evaluating sponsor oversight of CRO CAPAs
» Leveraging the CAPA system to monitor progress and ensure the effectiveness and timeliness of the necessary operations

14:45 Networking Break
DAY TWO | TUESDAY, 27 FEBRUARY

15:00 PANEL: ICH E6 R2 COMPLIANCE
Reflecting on the Actions and Process Adjustments Taken to Achieve ICH E6 R2 Compliance
Moderator: Janet Fernihough, Ph.D., MBA, Senior Consultant, NAVITAS LIFE SCIENCES
Panellists
Celeste M. Gonzalez, B.S., CVT, RQAP-GCP, CCRP, Principal Specialist, Clinical Quality Assurance, BOSTON SCIENTIFIC
Karen Hue, FRQA, Associate Director, Quality Assurance GCP, AIMMUNE THERAPEUTICS
Siobhan Hurley, Clinical QA Program Manager, R&D Quality Assurance, ABBVIE
Bodo Lutz, Global Clinical Quality Assurance, Compliance and Data Integrity Officer, NOVARTIS
> Examining how operations were assessed to determine where adjustments needed to be made to ensure compliance
> Conceptualising action plans and aligning responsibilities
> Evaluating the challenges and obstacles and how they were overcome
> Discussing lessons learned and what could have been done better

16:00 CHAIRPERSON'S CONCLUDING REMARKS
David Fryrear, Senior Director, Research and Development Quality Assurance, ABBVIE

16:15 Conference Concludes

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☐ Do you have questions or comments on the agenda?

☐ Is there a specific topic missing that you would like to see addressed?

☐ Would you like to get involved as a member of the speaking faculty?

Please contact Event Director Kristen Hunter at +1 212-400-6241 or khunter@exlevents.com. She'd be happy to discuss any of the above with you, or any other questions that you have about the conference!

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“Excellent range of hot topics and engaging speakers. Very interactive and enjoyable.”

—Director, Quality and Risk Management, ASTRazenECA

“The level of participants was excellent - so much experience in the room.”

—Associate Director, Clinical Operations Quality Oversight, BIOGEN

“Very good perspectives. Highlighted the challenges of operating in the Global world of research.”

—Senior Director, Clinical QA, GLAXOSMITHKLINE

“Great topics, speakers, and energy among attendees.”

—Senior Director, R&D Quality Assurance, ABBVIE

“All topics relevant and great to interact with other companies and hear points from others.”

—Quality Specialist, F. HOFFMAN-LA ROCHE LTD.