Track 8 | R&D Quality and Compliance

This track provides a comprehensive view of the quality landscape across the preclinical, clinical, and pharmacovigilance domains within the biopharmaceutical industry. Sessions are focused on discussing innovative and risk-proportionate approaches to managing quality that are appropriate to an evolving development paradigm and in a global context. Sessions will address key topics in GLP (Good Laboratory Practice), GCP, and PV quality, providing knowledge and resources needed to implement pragmatic, proactive, and effective quality management.

DIA recommends this track and associated sessions to professionals within biopharma, CROs, and regulatory agencies interested or working in research and development, clinical research, clinical, preclinical, or PV quality, clinical monitoring, regulatory affairs, regulatory operations, compliance, pharmacovigilance, quality control/quality assurance, and clinical quality management systems.

Included Topic Areas

ICH E series guidelines, clinical quality management systems, quality risk management, quality culture, clinical quality-by-design, proactive quality, quality indicators, risk indicators, clinical quality metrics, data quality, data integrity governance/frameworks, GCP, GLP, audits, risk-based auditing, inspection management, CAPAs (Corrective and Preventive Actions), compliance, compliance oversight, global oversight. Topics related to bioethical issues are also welcome and may be considered for a special track in the meeting.

Priority Topics

1. **Quality by Design and Quality Risk Management: How to Balance Risk and Resources**
   a. Updates to ICH E8(R1)
   b. The role of good data governance in promoting clinical trial quality
   c. Quality Analytics: Strategies for using advanced analytics for quality assurance to improve efficiency, effectiveness, and continuous improvement including use of novel approaches (e.g., machine learning, artificial intelligence, real-world evidence [RWE])
   d. The role of quality by design (QbD) and the use of risk-based approaches in quality risk management: Strategies for incorporating QbD principles (e.g., plan, do, check, act workflow)
   e. Approaches for focusing resources on the critical to quality factors (as described in ICH E8 R1) to ensure the safety of trial participants and that trial data produced is of sufficient quality to give reliable results
2. **Ensuring Data Quality and Data Integrity**
   a. Anomalous data identified: how to further evaluate, understand potential impact, and determine when and what further actions are needed
   b. Role of electronic systems design, audit trails, system access, user management, and IT (Information Technology) security in data quality and monitoring for GCP compliance
   c. Understanding investigations, root cause, and implementing an effective CAPA (Corrective and Preventive Actions) system
   d. Assessing the reliability of real-world data and real-world data sources (RWD)/RWE)
   e. Application of data science
3. **Pharmacovigilance Quality: Optimizing data quality to achieve PV compliance targets and accurately assess benefit risk profiles**
4. **Risk-Based Approach to Clinical Trial Oversight: Risk management and collaborative transparency between regulators and sponsors**
   a. Updates to ICHE6(R3)
   b. CRO and service provider oversight measures that are fit for purpose and tailored to the complexity of and risks associated with the trial
   c. Risk-based approaches and issue management to support innovation: impact on improving clinical trial execution, data quality, and safety of trial participants
   d. Role of centralized monitoring and centralized quality-assurance activities such as analytics to improve quality and compliance
5. **Quality Innovation: Considerations for ensuring clinical trial quality when using innovative trial designs (e.g., decentralized trials, adaptive designs, pragmatic trials)**
6. **Maintaining GCP and data quality in a changing clinical trial landscape that is implementing more pragmatic and proportionate approaches for clinical trials.**
   a. Use of on-site, remote, and off-site quality control and quality assurance strategies for monitoring and auditing
   b. Using good risk assessment/management practices to guide decisions on clinical trial conduct
   c. Challenges and solutions in obtaining consent in remote, electronic +/or decentralized ways
   d. Expanding risk-based monitoring methods (e.g., right fit SDV/SDR, remote monitoring, centralized monitoring)
   e. Regulatory challenges: Innovating to meet GCP compliance requirements versus need for regulatory flexibility
7. **Quality Culture: Empowering Quality professionals in enabling innovation**
   a. Driving quality and compliance through strategic approaches and critical thinking across the organization to meet the changing landscape
   b. Competencies needed by quality professionals of the future
8. **Evolving approaches to inspections and associated inspection outcomes**
   a. Collaboration and cooperation across stakeholders to verify quality and compliance through innovative approaches whether remote, on-site or hybrid
   b. Collaboration between regulators