Clinrex Munich
Dr. Dagmar Chase

GCP Refresher:

ICH Guideline E6(R3) (ICH-GCP)
CTR / CTIS / EU Biotech Act
4. AMG Änderungsgesetz und Medizinforschungsgesetz (MFG)
Aktuelle Fragen zu GCP

Referentin: Dr. Dagmar Chase

ICH Guideline E6(R3) (ICH-GCP Principles and Annex I)

- History of ICH E6
- New Structure, Scope and Summary of Changes
- Principles of ICH GCP
- Investigators, in particular
  - Responsibilities
  - Protocol Deviations
  - Participant Medical Care and Safety Reporting
  - Informed Consent of Trial Participants
  - Investigational Product Management
  - Records (Source and Case Report Forms)
- Sponsors, in particular
  - Agreements
  - Sponsor Oversight
  - Risk-based Quality Management / Risk-based Monitoring
  - Safety Assessment and Reporting
  - Investigational Product
  - Data and Records
  - Reports
- Data Governance – Investigator and Sponsor
- Essential Records (TMF / eTMF)

EU Clinical Trials Regulation 536/2014 (CTR) and CTIS

- New Concepts
- CTIS Roles and Permissions
- Safety Reporting
- Revised Transparency Rules

Überblick über die Änderungen der EU CTR durch den EU Biotech Act

4. AMG Änderungsgesetz und Medizinforschungsgesetz (MFG)

Aktuelle Fragen zu GCP

- Protocol Waivers
- Unblinding