Clinrex Munich
Dr. Dagmar Chase

GCP Basis:
ICH Guideline E6(R3) (ICH-GCP)
EU Clinical Trials Regulation (536/2014)
Einblick in FDA-Vorgaben

Referentin: Dr. Dagmar Chase

Introduction

- History of GCP
- International Council for Harmonisation – The ICH Process
- New Declaration of Helsinki (October 2024)

ICH Guideline E6(R3) (ICH-GCP)

- Principles of ICH-GCP
- Independent Review Board /Independent Ethics Committees (IRBs/IECs)
- 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
  - Trial Design
  - 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 Trial Regulation 536/2014

- An Overview
- Revised Transparency Rules

FDA requirements: Particularities to watch out for

- FDA “black lists”
- FDA Form 1572
- Financial Disclosure Form