



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
- Institutional Review Board / Independent Ethics Committees (IRB/IEC)
- Investigators, in particular
 - Responsibilities
 - Protocol Compliance / Protocol Deviations
 - Participant Medical Care and Safety Reporting
 - Informed Consent of Trial Participants
 - Investigational Product Management
 - Records (Source Records 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