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

**Referent: 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
  - Participant Medical Care and Safety Reporting
  - Communication with IRB/IEC
  - Compliance with Protocol
  - Informed Consent of Trial Participants
  - Records (Source and Case Report Forms)
- Sponsors, in particular
  - Agreements
  - Communication with IRBs/IECs
  - Sponsor Oversight
  - Risk-based Quality Management / Risk-based Monitoring
  - Safety Assessment and Reporting
  - Investigational Product
  - Data and Records
- Data Governance
- 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