Clinrex Munich
Dr. Dagmar Chase

GCP Basis:

ICH-GCP R2 und Ausblick auf R3
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
- The Principles of ICH-GCP and Declaration of Helsinki

ICH-GCP R2 and Outlook on R3

- Responsibilities of IRBs/IECs
- Responsibilities of Investigators, in particular
  - Proper Documentation in Source Documents and CRFs
  - Protocol Compliance
  - Informed Consent Procedure
  - AE / SAE Reporting
- Responsibilities of Sponsors, in particular
  - Risk-based Quality Management / Risk-based Monitoring
  - Sponsor Oversight
  - Handling of Computerized Systems
  - Investigational Medicinal Products
  - SUSAR Reporting
  - Follow-up of Non-Compliance
- Essential Documents, Filing and Archiving
- Outlook on ICH-GCP R3

EU Clinical Trial Regulation 536/2014

- An Overview
- Transitional Provisions
- New Transparency Rules

FDA requirements: Particularities to watch out for

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