Code of Federal Regulations

ICH Guidelines

2019

Book 1A

Selected Regulations & Guidance for Drug Studies

(April 1, 2019 - March 31, 2020)

- **Code of Federal Regulations (CFR)**
  Title 21: Food & Drugs
  Revised as of April 1, 2019

  Part 11: Electronic Records; Electronic Signatures
  Part 50: Protection of Human Subjects
  Part 54: Financial Disclosure by Clinical Investigators
  Part 56: Institutional Review Boards
  Part 312: Investigational New Drug Application
  Part 314: Applications for FDA Approval to Market a New Drug

- **Index to 21 CFR parts 11, 50, 54, 56, 312, 314**

- **ICH Guidelines (Step 5, U.S.)**

  E6(R2): Integrated Addendum to E6(R1): Guideline For Good Clinical Practice (Step 5 US + ICH Step 4 Addenda)
  E2A: Clinical Safety Data Management: Definitions and Standards for Expedited Reporting
  E8: General Considerations for Clinical Trials

- **European Directives on GCP**
  - 2001/20/EC and 2005/28/EC

- **FDA Guidance Documents**
  - Adverse Event Reporting to IRBs—Improving Human Subject Protection
  - Safety Reporting Requirements for INDs and BA/BE Studies
  - A Risk-Based Approach to Monitoring

- **PhRMA Principles on Conduct of Clinical Trials**

- **FDA Inspections of Sponsors, CROs & Monitors: Compliance Guidance Manual #7348.810**

- **2019 International Websites on Drug Development**

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