

## FDA Good Clinical Practice 2024 Reference Guide

(April 1, 2024 - March 31, 2025)

- **Code of Federal Regulations (CFR)**

- Title 21: Food & Drugs**

- Revised as of April 1, 2024

- 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
    - Sections 314.80, 314.81: Post-Marketing Reporting
    - Section 314.126: Adequate and Well-Controlled Studies

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

- **FDA Information Sheet Guidances**

- Includes:

- Frequently Asked Questions on Clinical Research
    - A Guide to Informed Consent
    - Recruiting Study Subjects
    - Frequently Asked Question about FDA Form 1572
    - Pre-Study Screening Tests
    - Foreign Clinical Studies for US Submission
    - FDA Inspections of IRBs and Investigators

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

- E6(R2): Good Clinical Practice: Integrated Addendum to E6(R1)
  - E2A: Clinical Safety Data Management: Definitions and Standards for Expedited Reporting
  - E8(R1): General Considerations for Clinical Trials

- **FDA Guidance Documents**

- A Risk-Based Approach to Monitoring
    - Questions & Answers on Monitoring
    - Informed Consent (August 2023)
    - Adverse Event Reporting to IRBs
    - Safety Reporting Requirements for INDs and BA/BE Studies
    - FDA Inspections: Compliance Program Guidance #7348.810

# Fda Good Practice Guide

**S Marginson**



## **Fda Good Practice Guide:**

## Unveiling the Magic of Words: A Review of "**Fda Good Practice Guide**"

In some sort of defined by information and interconnectivity, the enchanting power of words has acquired unparalleled significance. Their capability to kindle emotions, provoke contemplation, and ignite transformative change is actually awe-inspiring. Enter the realm of "**Fda Good Practice Guide**," a mesmerizing literary masterpiece penned with a distinguished author, guiding readers on a profound journey to unravel the secrets and potential hidden within every word. In this critique, we shall delve into the book's central themes, examine its distinctive writing style, and assess its profound effect on the souls of its readers.

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