

Selected Regulations & Guidance for Medical Device Studies

(April 1, 2023 - March 31, 2024)

CFR Title 21 Food & Drugs

Revised as of April 1, 2023

- 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 801 Labeling
- Part 803 Medical Device Reporting
- Part 806 Medical Devices; Reports of Corrections and Removals
- Part 807 Establishment Registration and Device Listing for
Manufacturers and Initial Importers of Devices
- Part 812 Investigational Device Exemptions
- Part 814 Premarket Approval of Medical Devices
- Part 820 Quality System Regulation
- Part 822 Postmarket Surveillance
- Part 830 Unique Device Identification

FDA Guidance on Medical Device Reporting for Manufacturers

November 8, 2016 Version

Integrated Addendum to ICH Guideline E6 (R1) for Good Clinical Practice E6 (R2)

(Step 5 US + Step 4 Addenda)