Code of Federal Regulations

FDA Guidance

Selected Regulations & Guidance for Medical Device Studies

(April 1, 2019 - March 31, 2020)

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 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)

2019

Book 2

CLINICAL RESEARCH RESOURCES