Code of Federal Regulations

FDA Guidance

Selected Regulations & Guidance for Medical Device Studies

(April 1, 2023 - March 31, 2024)

CFR Title 21 Food & Drugs

Revised as of April 1, 2023

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)

2023

Book 2

CLINICAL RESEARCH RESOURCES