Code of Federal Regulations

FDA Guidance

2023

Book 4

# Selected Regulations & Guidance on Good Manufacturing Practice

## CFR Title 21 Food & Drugs

**Revised as of April 1, 2023**

- Part 11: Electronic Records; Electronic Signatures
- Part 210: Current Good Manufacturing Practice in Manufacturing, Processing, Packing or Holding of Drugs; General
- Part 211: Current Good Manufacturing Practice for Finished Pharmaceuticals
- Part 820: Quality System Regulation

## FDA Guidance for Industry

- Part 11, Electronic Records; Electronic Signatures — Scope and Application
- ICH Guideline on GMP for Active Pharmaceutical Ingredients (Q7)
- Questions and Answers on Current Good Manufacturing Practices (cGMP) for Drugs
- PAT — A Framework for Innovative Pharmaceutical Development, Manufacturing and Quality Assurance
- Drug Manufacturing Inspections: Compliance Manual for FDA Staff (#7356.002)
- Quality Systems Approach to Pharmaceutical CGMP Regulations

CLINICAL RESEARCH RESOURCES