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FDA Regulations and Associated Guidance Documents:

- Part 11 Electronic Records; Electronic Signatures
- Part 26 Mutual Recognition of Pharmaceutical Good Manufacturing Practice Reports,

Medical Device Quality System Audit Reports, and Certain Medical Device Product Evaluation Reports: United States and the European Community
- Part 200 Drugs General
- Part 207 Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution
- Part 210 Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs
- Part 211 Current Good Manufacturing Practice For Finished Pharmaceuticals
- Part 600 Biological Products: General
- Part 807 Establishment Registration and Device Listing for Manufacturers and Initial Importers of Devices
- Part 820 Quality System Regulation

Reference Tools:

Glossaries combined in one location
GMP Keyword Index for 21CFR211
Combined Index for all documents