

Part 11 and Drug Development: Regulation, Preamble, and FDA Guidance on Electronic Records and Electronic Signatures

(April 1, 2023 - March 31, 2024)

CFR Title 21 Food & Drugs Revised as of April 1, 2023

Part 11: Electronic Records; Electronic Signatures

Preamble to 21 CFR Part 11 62 FR 13429, March 20, 1997

FDA Guidance for Industry

- Electronic Records; Electronic Signatures – Scope and Application
- Providing Regulatory Submissions in Electronic Format – General Considerations
- Computerized Systems Used in Clinical Investigations
- Electronic Source Data in Clinical Investigations