Related Guidance, Tools and Templates

Related Tools, Guidance and Templates

- 21 CFR Part 11
- Scope of Guidance for Industry: Computerized Systems Used in Clinical Trials)
- Validation Plan Example template
- Functional Requirements Example template
- Design/Configuration Document Example template
- Installation Qualification Example template
- Operational/Performance Qualification Example template
- Final Validation Report Example template
- Change Control Preapproval
- Change Control Closure
- Inspections of Sponsors, CROs and Monitors
- Guidance for Industry Computerized Systems Used in Clinical Investigations
- General Principles of Software Validation; Final Guidance for Industry and FDA Staff
- Learn more about DocuSign

If you have any questions or concerns about your system, it is highly recommended that you contact the Office of Compliance Services or 310-794-6763 for assistance.

Last updated: 3 Oct 2025

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