

Handbook of Computer and Computerized System Validation for the Pharmaceutical Industry

By Stephen Robert Goldman

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Much has been written about "why" to validate. The Handbook of Computer and Computerized System Validation for the Pharmaceutical Industry is an SOP-centric explanation of "how" to validate. Creating a state of sustainable compliance with FDA regulations including 21 CFR Part 11, Electronic Records; Electronic Signatures is daunting task. This handbook follows FDA guidelines and "Best Industry Practices" in defining the roles, responsibilities, and requirements of computer and computerized system validation for the pharmaceutical, biotechnology, and medical device industries. It details the requirements for Standard Operating Procedures and Protocols for User Requirements, Functional Requirements, Design Specifications, Installation Qualification, Operational Qualification, and Performance Qualification. 21 CFR Part 11 Assessment and validation gap analysis methods are prescribed to determine the state of compliance of systems with current regulation.

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