

21 CFR Part 11 Basics

What Everyone Should Know of Electronic Records and Electronic Signatures

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Core Competency Training

Version: 2.0.0

Duration: 30 minutes

Number of Chapters: 3

Number of Course Pages: (including test pages & title pages): 55

Number of Test Questions: 14

Course Description

Three (3) chapters with qualifying tests after each chapter cover the course content. Chapter 1 teaches the requirements to understand the scope, the objectives, and the effect of 21 CFR Part 11. Chapter 2 focuses on the concepts of electronic records and electronic signatures. Chapter 3 concludes by detailing the personal responsibility in company compliance with 21 CFR Part 11.

Learning objectives

- Understand the most important facts in the development of 21 CFR Part 11
- Understand the scope of 21 CFR Part 11
- Understand the objectives and effect of 21 CFR Part 11
- Understand the concept and what constitutes electronic records & electronic signatures
- Understand the personal responsibility in company compliance with 21 CFR Part 11

Intended Audience

Every employee who uses or develops electronic records or electronic records and electronic signatures.

Prerequisites

Trainees are required to possess a basic working knowledge of the computer, and possess basic competency in Good Manufacturing Practices.

Related courses

21 CFR Part 11 for QA and IT – *coming soon*. This course provides sound foundation for the assessment, risk evaluation and gap analysis of 21 CFR Part 11 Compliance Life Cycle.