
21 CFR 211: Pure, Safe and Effective

Purpose

To review 21 CFR 211 with the reminder that all these rules help us produce a product that is pure, safe and effective.

Objectives

At the completion of the class, employees will be able to summarize the eleven subparts.

Prerequisite

None

Who should attend this course?

This class is appropriate for all employees of drug or biologic manufacturing organizations.

Intent of the class

This course is intended for training purposes only and is not a substitute for technical recommendations, regulatory or legal advice. These materials are intended to raise compliance issues for further discussion at your company. It is recommended that you consult appropriate authorities for specific recommendations and advice.

Class Length: This time includes testing time.

51 Minutes in 11 segments

On-site Options

This class can be taught with a live instructor at your company. Call for details.

Topics Covered

Introduction

Subpart A: General Provisions

Subpart B: Organization and Personnel

Subpart C: Buildings and Facilities

Subpart D: Equipment

**Subpart E: Control of Components Drug
product Containers and Closures**

Subpart F: Production and Process Controls

Subpart G: Packaging and Labeling Controls

Subpart H: Holding and Distribution

Subpart I: Laboratory Controls

Subpart J: Records and Reports

**Subpart K: Returned and Salvaged Drug
Products**

