
21 CFR 820: Essential Elements

Purpose

To review the 21 CFR 820 regulations from inside a medical device manufacturing facility. Learn the rules effecting medical device manufacturing while getting a glimpse of medical device production techniques.

Objectives

At the completion of the class, employees will be able to summarize the 15 subparts.

Prerequisite

None

Who should attend this course?

This class is appropriate for all employees of medical device 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: Quality System Requirements

Subpart C: Design Controls

Subpart D: Document Controls

Subpart E: Purchasing Controls

Subpart F: Identification and Traceability

Subpart G: Production and Process Controls

Subpart H: Acceptance Activities

Subpart I: Nonconforming Product

Subpart J: Corrective and Preventative Actions

Subpart K: Labeling and Packaging Control

Subpart L: Holding, Storage, Distribution, and Installations

Subpart M: Records

Subpart N: Servicing

Subpart O: Statistical Controls