

Current List of Computer Based Classes

Compatible with most Learning Management Systems

21 CFR 211 Review - This 20-minute program summarizes the eleven subparts of 21 CFR 211. Through the use of interesting graphics and actual in-plant video, each subpart of the regulation is explained in easy to understand language. This class can also serve as a strong overview for contractor CGMP training.

21 CFR 820 Review - This 60-minute program summarizes the subparts of 21 CFR 820. Through the eyes of an actual medical device manufacturing facility, each subpart of the regulation is explained in easy to understand language. This class can also serve as a strong overview for contractor QSR training.

Building and Facilities - In support of CGMP compliance, the conditions under which a product is made are closely scrutinized during audits and inspections. This 78-minute program examines the elements from building design, layout and dedicated space, to material and product flow, work space responsibilities, repair, maintenance and other controls needed to assure a compliant facility. This program is a thorough review of 21 CFR Subpart C.

Contamination Control - This 25-minute program addresses the sources of contamination and methods of preventing contamination of products. This is a great session for new employees, or as part of a contamination control breach preventive action.

Equipment and GMPs - This 50-minute program explores the requirements of 21 CFR 211 Subpart D, specifically the design and construction requirements for equipment, including lubrication and coolants. The class addresses cleaning and maintenance requirements including automatic and electronic equipment, and also covers the requirements for equipment identification, personnel training and required documentation.

CGMPs for Non-GMP Personnel - In a television talk show format, an interview is conducted exploring questions and concerns of the industry. Austin Lee, interviewer, explores with Allan Dewes, how the regulations specifically impact those who traditionally feel they have "nothing to do" with CGMPs.

Surviving an FDA Inspection - This 88-minute program addresses the preparation and execution of the company's plan to successfully manage a regulatory inspection. Employee responsibilities, forming the company's inspection team, interacting with the FDA and management's response during the inspection are highlighted. Content is demonstrated through scenes between the inspector and company officials, and is suitable for all levels of the organization.

Materials and GMPs - This 40-minute program traces the CGMP requirements from supplier qualification through manufacturing and packaging. This is a solid review of 21 CFR 211 Subpart E.

Organization and Personnel - This 20-minute program summarizes the essential elements of 21 CFR 211 Subpart B. This is a great subpart orientation for new employees who need to understand their overall role and responsibility while working in the plant.

Production and Process Controls - This 20-minute program is an in-depth review of the requirements of Subpart F. This program uses a variety of video segments from actual plant operations as the essential elements of this subpart are reviewed.

Pure, Safe and Effective - This 25-minute program reviews the details in 21 CFR 211 necessary to assure everyone appreciates the importance of GMP compliance. If you need a quick overview for new employees or an annual refresher, then this is the solution.

Root Cause Analysis for Better Deviation Investigations - One of the top reasons companies receive 483 observations is related to the deviation investigation process. In this program, employees learn about the tools to effectively determine the real root cause of the problem. If your deviation investigation reports frequently conclude, "operator error ..." or "no assignable root cause...", then you need to take this course!

Understanding Validation - In 73 minutes, learn the intricate details of process validation. This course journeys through the history of validation and the sequence of activities that need to be completed for a robust validation program. This course is a great tool for kicking off a new validation project.

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