COBBLESTONE

COURSE ID 3096

21 CFR Part 211

Subpart I: Laboratory Controls

DIRECTED BY

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90 MINUTE

ACCREDITED COURSE

Course Topics Include:

- 21 CFR Part 211 Subpart I
- Laboratory Controls

about the course

Most industries in the US are regulated by local, state, and federal regulators and pharmaceutical manufacturing companies are some of the most highly regulated, particularly at the federal level. Pharmaceutical Quality affects every American hence the FDA regulates the quality of pharmaceuticals very carefully. The main regulatory standard for ensuring pharmaceutical quality are the Current Good Manufacturing Practice (cGMPs) regulations.

This 90-minute Accredited Course will discuss the FDA regulations 21 CFR 211 Subpart I addressing their words and meaning as they apply to the USA Pharmaceutical Industry. The course will show how these paragraphs are to be interpreted and how one should comply.

This training is one part of the 10-course series required for the Cobblestone GMP Professional Certification Program. Attend this as a step in the certification process or as a stand-alone course for personal career advancement and training.

who should attend

This course has been developed to meet the training needs of professionals in the Pharmaceutical, Medical Device and Cosmetic Industries. It will be especially valuable to those engaged in compliance with FDA regulations, Compliance, QA/QC, Formulation, Production, Manufacturing and Regulatory areas.

Engineers, chemists, QA/QC and manufacturing personnel will benefit greatly by attending this course by understanding the extent of the FDA regulations and how they affect daily job responsibilities.

learning objectives

Upon completion of this course, you will be able to:

- Outline the regulations in order to properly comply
- Explain the importance of GMP laboratories
- Identify how the regulations affect you and your job function
- Identify the critical role laboratories have with GMP operations
- Illustrate the consequences of not complying
- Show logically the best GMP approach
- Explain that all analytical methods need to be verified or validated
- Analyze the differences between OOS (out of specification) and deviations
- Illustrate that how you perform and what you make affects the health of many

course outline

Review of Learning Objectives
Subpart I Laboratory Controls

- Compliance requirements
- Procedures
- Testing and release
- Compendial vs. non-compendial

Question and Answer Session

Assessment Opportunity

course instructor

Mr. Angelucci is a pharmaceutical professional with over 30 years' experience in Quality Assurance, Quality Control, Regulatory Affairs, Validation, consent decree remediation as well as cGMP Compliance in the Medical Device and Pharmaceutical industries

He has worked for several well-known companies including Johnson & Johnson, Bristol-Meyer Squibb, Pfizer, Schering Plough and Merck. His experience has been either as a direct employee or as a contracting consultant while employed at Foster Wheeler and Aker Kvaerner. As a consultant Mr. Angelucci has worked at various project locations domestically and in Europe and Asia. With these firms he has been involved with auditing, GMP training, Bio-tech consulting as well as FDA audit and PAI readiness training and participation.

Mr. Angelucci is a degreed engineer with two master's degrees in engineering, holds industry certifications with ASQ as a CQE, CQA and CPGP. Previously, he was the ASQ Philadelphia chapter Education Chair. In addition, he holds a PMP certification through the Project Management Institute. He has published numerous articles on the subjects of Validation and compliance and has been a speaker to industry groups such as ISPE, IVT, DIA, PDA, ASQ and Cobblestone.

Accreditations

International Accreditors for Continuing Education and Training (IACET)
Cobblestone has been approved as a CEU Accreditor by IACET and awards CEUs for participation in qualified courses. Cobblestone has demonstrated that it complies with the ANSI/IACET Standards and is authorized to offer IACET CEUs for its programs. CEUs will be awarded for participation in Cobblestone's courses at the rate of .1 CEU per contact hour upon successful completion of the entire course and 70% accuracy in the required Learners' Assessment. A minimum score of 80% is required for all courses within a Cobblestone Certification Program. This course offers a total of 1.5 contact hours, or .2 CEUs. For further information, visit www.iacet.org