Pharmaceuticals GMP Course Outlines

Course Outline for FDA-cGMP Pharmaceuticals Training
21CFR210-211

Course objective

This training course has been designed for individuals involved in manufacturing of Finished Pharmaceuticals products. It offers in-depth training on the FDA's GMP for finished pharmaceuticals requirements. With the current regulations in US and Europe, it is critical that the pharmaceutical industry be aware of the threat and of the guidance materials available from regulatory agencies to help address pharmaceutical security concerns. Pharmaceutical security and training experts from FDA and USDA wrote and approved the course.

Course length

2-3 days (a few hours everyday) are required to complete the FDA-cGMP for Finished Pharmaceuticals Training.

Who should attend

Anyone who do not have time to allocate a full day to take a LIVE class on FDA's GMP for finished pharmaceuticals, wants to quickly and efficiently understand what the pharmaceutical FDA's GMP requirements are, and implement the GMP without using a consulting firm

Course includes

The structure of the training is as follows:

- Sec. 210.3 Definitions
- Part 211 - Current good manufacturing practice for finished pharmaceuticals

- Subpart A--General Provisions

- Subpart B--Organization and Personnel

- Subpart C--Buildings and Facilities

- Subpart D--Equipment

- Subpart E--Control of Components and Drug Product Containers and Closures

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- Subpart F--Production and Process Controls

- Subpart G--Packaging and Labeling Control

- Subpart H--Holding and Distribution

- Subpart J--Records and Reports

- Subpart K--Returned and Salvaged Drug Products

Worldwide Course Recognition:

CALISO online training courses are recognized by all registrars and hiring companies as objective evidence of effective training on the particular standard and regulation. Since 1999, they have been the most popular and most widely used training courses in English, with over 30,000 trainees in the US and worldwide. The standards and regulations are provided online under licensing of the American National Standard Institute (ANSI), SAE International, or courtesy of the Federal Drug Administration (FDA).

Course requirements
The training is optimized for Microsoft Internet explore 5.0 or higher and Netscape 4.5 or higher

Certificate requirements
The course uses a continuous evaluation method with on-going quizzes to facilitate the information retention. If your final average is equal or greater to 70% you will be issued a **training certificate**. If your final average evaluation is less than 70%, you will have to take a final exam and score above 70% to be issued the training certificate.