CALISO Corporation

Course Outline for FDA-cGMP Medical Devices Training

Quality System Requirements -21CFR820 [2106]

Course objective

It has been specifically designed to meet the needs of people involved in current good manufacturing practices for medical devices. This course gives an in-depth understanding of the FDA and European cGMP requirements. It is helpful in understanding the legal requirements and regulatory expectations relating to CGMP, as well as the costs of non-compliance.

Course length

2-3 days (a few hours everyday) are required to complete the FDA-cGMP Medical Devices Training.

Who should attend?

Anyone who does not have time to allocate a full day to take a LIVE class on the cGMP Quality System Requirements (QSR), wants to quickly and efficiently understand what the FDA's GMP for medical devices is about, or wants to implement the GMP without using a consulting firm. The 2016 version include the unique device identifier (UDI) requirements.

Course includes

The structure of the training is as follows:

- PART 820--QUALITY SYSTEM REGULATION

- 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 Preventive Action
- Subpart K Labeling and Packaging Control
- Subpart L Handling, Storage, Distribution, and Installation
- Subpart M Records
- Subpart N Servicing

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- Subpart O Statistical Techniques

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 all recent browsers such as IE, Chrome and Safari.

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.

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