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Medical, Pharmaceuticals, Human Food GMP Course Outlines

Course Outline for FDA-cGMP Medical Devices Training Quality System Requirements -21CFR820

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 do 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

Course includes

The structure of the training is as follows:

- PART 820--QUALITY SYSTEM REGULATION
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- 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



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- 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
- Subpart O Statistical Techniques

Course approval

This online training course is approved by the German Registrar RWTUV-USA. The certificate bears all the approvals. We have been selected by the prestigious ISO 9000 Registrar RWTUV of Germany to support the training of their clients worldwide (<http://www.rwtuvusa.com>)

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.



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Course Outline for FDA-cGMP Food Industry Training

Course objective

This training course has been designed for individuals involved in food industry. It offers an introduction to food security for state and local sanitarians, USDA FSIS field inspectors, and HHS FDA field inspectors. With the current threat of terrorism against the US, it is critical that the food industry from growers to retail be aware of the threat and of the guidance materials available from regulatory agencies to help address food security concerns.

Course length

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

Who should attend

Anyone who do not have time to allocate a full day to take a LIVE class on the cGMP and 21CFR110, wants to quickly and efficiently understand what the FDA's GMP for human food manufacturers is about, and implement the GMP without using a consulting firm

Course includes

The structure of the training is as follows:

- Subpart A--General Provisions
 - 110.3 - Definitions.
 - 110.5 - Current good manufacturing practice.
 - 110.10 - Personnel.
 - 110.19 - Exclusions.
- Subpart B--Buildings and Facilities
 - 110.20 - Plant and grounds.
 - 110.35 - Sanitary operations.
 - 110.37 - Sanitary facilities and controls.
- Subpart C--Equipment
 - 110.40 - Equipment and utensils
- Subpart D [Reserved]
- Subpart E--Production and Process Controls
 - 110.80 - Processes and controls.
 - 110.93 - Warehousing and distribution.
- Subpart F [Reserved]



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- Subpart G--Defect Action Levels
- 110.110 - Natural or unavoidable defects in food for human use that present no health hazard.
- PART 110--CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING HUMAN FOOD

Course approval

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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
- Subpart F--Production and Process Controls
- Subpart G--Packaging and Labeling Control



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- [Subpart H--Holding and Distribution](#)
- [Subpart J--Records and Reports](#)
- [Subpart K--Returned and Salvaged Drug Products](#)

Course approval

This online training course is approved by the German Registrar RWTUV-USA. The certificate bears all the approvals. We have been selected by the prestigious ISO 9000 Registrar RWTUV of Germany to support the training of their clients worldwide (<http://www.rwtuvusa.com>)

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.