
Course Outline for ISO 19011:2002 QMS & EMS Auditor

Course objective

The auditor training program is based on ISO 19011:2002, which is a guideline document for auditing and implementing quality systems ISO 19011:2002, and getting the skills necessary to quickly and efficiently audit using the new QMS and EMS auditing guideline to ISO 19011:2002.

Course length

2 days are required to complete the ISO 19011 course

Who should attend?

Anyone who wants to quickly and efficiently understand and learn how to audit using the new QMS and EMS auditing guideline to ISO 19011:2002, upgrade your expertise from auditing with ISO 10011-1 to ISO 19011:2002

The structure of the training is as follows:

1. DEFINITIONS
2. TYPES OF AUDITS
3. AUDIT OBJECTIVES
4. ROLES AND RESPONSIBILITIES
5. AUDITOR ACTIVITIES
6. INITIATING THE AUDIT
7. PREPARING THE AUDIT
8. EXECUTING THE AUDIT
9. WHAT THE AUDITOR IS LOOKING FOR
10. AUDIT DOCUMENTS
11. AUDIT TECHNIQUES: TELL ME/SHOW ME
12. AUDIT TECHNIQUES: AUDIT PATH
13. AUDIT TECHNIQUES: GRADUAL ELEVATION
14. AUDIT TECHNIQUES: SAMPLING
15. AUDIT COMPLETION AND CORRECTIVE ACTION FOLLOW-UP

Course approval

This online training course is approved by the German Registrar RWTUV-USA. The certificate bears all the approvals. And, 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

- If you are not familiar with the ISO 9000:2000, it is recommended to take the ISO 9000:2000 training course first.

- 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.

Course Outline for ISO 14001:2004 Auditor

Course objective

The auditor training program is based on ISO 14001:2004, which is a guideline document for auditing and implementing quality systems ISO 14001:2004, upgrading expertise from auditing ISO 9000 to ISO 14001:2004 and from auditing to ISO 14001:1996 to ISO 14001:2004, and upgrading expertise from auditing with the guidance ISO 10011-1 to ISO 19011:2002.

Course length

2 days are required to complete the ISO 14001 auditor course

Who should attend?

Anyone who wants in-depth understanding of the ISO 14000 Audit Process. This is the ideal training course for responsible in charge of planning and scheduling an audit program or must perform audits to ISO 14000: Quality Assurance and Environmental Affairs Managers, Quality Assurance and Environmental Professionals

The structure of the training is as follows:

1. DEFINITIONS
2. TYPES OF AUDITS
3. AUDIT OBJECTIVES
4. ROLES AND RESPONSIBILITIES
5. AUDITOR ACTIVITIES
6. INITIATING THE AUDIT
7. PREPARING THE AUDIT
8. EXECUTING THE AUDIT
9. WHAT THE AUDITOR IS LOOKING FOR
10. AUDIT DOCUMENTS
11. AUDIT TECHNIQUES: TELL ME/SHOW ME
12. AUDIT TECHNIQUES: AUDIT PATH
13. AUDIT TECHNIQUES: GRADUAL ELEVATION
14. AUDIT TECHNIQUES: SAMPLING
16. AUDIT COMPLETION AND CORRECTIVE ACTION FOLLOW-UP
17. ENVIRONMENTAL CASE STUDIES

Course approval

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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.

Course Outline for ISO 13485:2003 Training

Course objective

This course gives an overview of all important aspects for managers of an organization in order to implement and maintain an ISO 9001:2000 compliant management system.

Course length

1 day is required to complete the ISO 13485 course

Who should attend?

This is the ideal course for anyone who do NOT have time to allocate a full day to take a LIVE course on ISO 13485:2003, and who wants to quickly and efficiently understand what ISO 13485:2003 and ISO 9001:2000 are about, You want to upgrade your knowledge and expertise from ISO 13485:1996 or ISO 9000:1994, en 46001 to ISO 13485:2003.

The structure of the training is as follows:

- The Standard
- The Process Approach
- Scope
- Quality Management System
- Management Responsibility
- Resource Management
- Product Realization
- Measurement, Analysis and Improvement

Course approval

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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.

Course Outline for ISO 13485:2003/ ISO 19011 Auditor

Course objective

This course has been specifically designed to meet the needs of the Medical Device Industry and is for individuals responsible for planning and scheduling an audit program for ISO 13485 and those who must perform audits to ISO 13485 for quality assurance. It provides in-depth understanding of the ISO 13485 Audit Process

Course length

2 days are required to complete the ISO 13485 auditor course

Who should attend?

This is the ideal course for anyone who wants to quickly and efficiently learn how to audit to ISO 13485:2003, upgrade his/her expertise from auditing ISO 13485:1996 to ISO 13485:2003, and upgrade his/her expertise from auditing with the guidance ISO 10011-1 to ISO 19011:2002,

The structure of the training is as follows:

1. DEFINITIONS
2. TYPES OF AUDITS
3. AUDIT OBJECTIVES
4. ROLES AND RESPONSIBILITIES
5. AUDITOR ACTIVITIES
6. INITIATING THE AUDIT
7. PREPARING THE AUDIT
8. EXECUTING THE AUDIT
9. WHAT THE AUDITOR IS LOOKING FOR
10. AUDIT DOCUMENTS
11. AUDIT TECHNIQUES: TELL ME/SHOW ME
12. AUDIT TECHNIQUES: AUDIT PATH
13. AUDIT TECHNIQUES: GRADUAL ELEVATION
14. AUDIT TECHNIQUES: SAMPLING
18. AUDIT COMPLETION AND CORRECTIVE ACTION FOLLOW-UP
19. MEDICAL DEVICE CASE STUDIES

Course approval

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Course requirements

- If you are not familiar with the ISO 9000:2000, it is recommended to take the ISO 13485:2003 training course first.
- 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.

Course Outline for ISO/TS 16949:2002 Training

Course objective

This course gives an in-depth understanding of the TS 16949:2002 Audit Process. It has been specifically designed to meet the needs of the Auto Industry. Those responsible for planning and scheduling an audit program for TS 16949:2002 and those who must perform audits to TS 16949:2002 for quality assurance.

Course length

1 day is required to complete the ISO/TS 16949:2002 course

Who should attend?

Anyone who do not have time to allocate a full day to take a LIVE course on ISO/TS 16949:2002, wants to quickly and efficiently understand what ISO/TS 16949:2002 and ISO 9001:2000 are about, and ISO 9001:2000 are about, and wants to upgrade his/her knowledge and expertise from QS 9000 or ISO 9000:1994 to ISO/TS 16949:2002.

The structure of the training is as follows:

- The Standard
- The Process Approach
- Scope
- Quality Management System
- Management Responsibility
- Resource Management
- Product Realization
- Measurement, Analysis and Improvement

Course approval

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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.

Course Outline for ISO/TS 16949:2002/ISO 19011 Auditor

Course objective

This course has been specifically designed to meet the needs of the Auto Industry and those responsible for planning and scheduling an audit program for TS 16949:2002, and those who must perform audits to TS 16949:2002 for quality assurance. This course gives an in-depth understanding of the TS 16949:2002 Audit Process has to take this course.

Course length

2 days are required to complete the ISO/TS 16949 auditor training course

Who should attend?

Anyone who do not have time to allocate two full days to take a LIVE course on ISO/TS 16949:2002, wants to quickly and efficiently learn how to audit to ISO/TS 16949, upgrade his/her expertise from auditing QS 9000 to ISO/TS 16949 and from auditing with the guidance ISO 10011-1 to ISO 19011:2002.

The structure of the training is as follows:

1. DEFINITIONS
2. TYPES OF AUDITS
3. AUDIT OBJECTIVES
4. ROLES AND RESPONSIBILITIES
5. AUDITOR ACTIVITIES
6. INITIATING THE AUDIT
7. PREPARING THE AUDIT
8. EXECUTING THE AUDIT
9. WHAT THE AUDITOR IS LOOKING FOR
10. AUDIT DOCUMENTS
11. AUDIT TECHNIQUES: TELL ME/SHOW ME
12. AUDIT TECHNIQUES: AUDIT PATH
13. AUDIT TECHNIQUES: GRADUAL ELEVATION
14. AUDIT TECHNIQUES: SAMPLING
15. AUDIT COMPLETION AND CORRECTIVE ACTION FOLLOW-UP
16. AUTOMOTIVE INDUSTRY CASE STUDIES

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

- If you are not familiar with the ISO 9000:2000, it is recommended to take the ISO/TS 16949:2002 training course first.
- 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.

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

1 day is required to complete the Quality System Requirements -21CFR820 course.

Who should attend?

Anyone who does not have time to allocate a full day to take a LIVE course on the cGMP Quality System Requirements (QSR), wants to quickly and efficiently understand what the FDA's GMP for medical devices is about, and implement the GMP without using a consulting firm

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
- 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

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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.

Course Outline for FDA-cGMP Food Industry Training

Course objective

This training course has been designed for individuals involved in the food industry. It offers an introduction to food security for state and local sanitarians, USDA FSIS field inspectors, and HHS FDA field inspectors.

Course length

1 day is required to complete this cGMP course

Who should attend?

Anyone who do not have time to allocate a full day to take a LIVE course 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

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]
- 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 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.

Course Outline for FDA-cGMP for Finished Pharmaceuticals Training

21CFR210-211

Course objective

This training course has been designed for individuals involved in pharmaceutical industry. It offers to understand what the FDA's GMP for finished pharmaceuticals is about.

Course length

1-2 days are required to complete the FDA's GMP for finished pharmaceuticals course.

Who should attend?

Anyone who do not have time to allocate a full day to take a LIVE course 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

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
- Subpart H--Holding and Distribution
- Subpart J--Records and Reports
- Subpart K--Returned and Salvaged Drug Products

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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.

Course Outline for FDA-GLP Good Laboratory Practices Training

21CFR58

Course objective

This training course has been designed for individuals involved in Laboratories and Testing Facilities. It provides training on the FDA's Good Laboratory Practice for nonclinical Laboratory Studies.

Course length

1 day is required to complete the GLP course.

Who should attend?

Anyone who do not have time to allocate a full day to take a LIVE course on FDA's GLPs, wants to quickly and efficiently understand what the regulation and requirements are, and implement the GLP without using a costly training or consulting firm.

The structure of the training is as follows:

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

PART 58--GOOD LABORATORY PRACTICE FOR NONCLINICAL LABORATORY STUDIES

- 58.1 Scope.
- 58.3 Definitions.
- 58.10 Applicability to studies performed under grants and contracts.
- 58.15 Inspection of a testing facility.
- 58.29 Personnel.
- 58.31 Testing facility management.
- 58.33 Study director.
- 58.35 Quality assurance unit.
- 58.41 General.
- 58.43 Animal care facilities.
- 58.45 Animal supply facilities.
- 58.47 Facilities for handling test and control articles.
- 58.49 Laboratory operation areas.
- 58.51 Specimen and data storage facilities.
- 58.61 Equipment design.
- 58.63 Maintenance and calibration of equipment.
- 58.81 Standard operating procedures.
- 58.83 Reagents and solutions.
- 58.90 Animal care.
- 58.105 Test and control article characterization.

- 58.107 Test and control article handling.
- 58.113 Mixtures of articles with carriers.
- 58.120 Protocol.
- 58.130 Conduct of a nonclinical laboratory study.
- 58.185 Reporting of nonclinical laboratory study results.
- 58.190 Storage and retrieval of records and data.
- 58.195 Retention of records.
- 58.200 Purpose.
- 58.202 Grounds for disqualification.
- 58.204 Notice of and opportunity for hearing on proposed disqualification.
- 58.206 Final order on disqualification.
- 58.210 Actions upon disqualification.
- 58.213 Public disclosure of information regarding disqualification.
- 58.215 Alternative or additional actions to disqualification.
- 58.217 Suspension or termination of a testing facility by a sponsor.
- 58.219 Reinstatement of a disqualified testing facility.

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Course requirements

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

Certificate requirements

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