Quality Management Systems (QMS) Auditing (ISO 9001/13485) Training Course

Professional Development Training Course Outline

Category	Biotechnology and Pharmaceutical Development	**Duration**	10 Days
Base Fee	$4,000 USD	**Delivery Mode**	Online / On-site Hybrid

Course Introduction

In today?ÇÖs fast-paced and competitive business environment, organizations are increasingly recognizing the importance of robust Quality Management Systems (QMS) to ensure continuous improvement, compliance, and customer satisfaction. Auditing a QMS, especially within the framework of globally recognized standards like ISO 9001 and ISO 13485, is crucial for assessing an organization?ÇÖs ability to meet these objectives. Quality Management Systems (QMS) Auditing (ISO 9001/13485) Training Course is designed to provide professionals with the essential skills and knowledge needed to evaluate, audit, and improve quality management systems effectively. By understanding and applying these auditing techniques, participants will be empowered to drive organizational success while ensuring compliance with international standards.

This specialized QMS Auditing Training course will equip participants with a deep understanding of auditing principles, methodologies, and tools used for assessing ISO 9001 and ISO 13485 systems. The course also emphasizes risk management, compliance, non-conformance management, and continuous improvement techniques. Participants will gain hands-on experience through case studies, real-world examples, and practical exercises that provide the confidence to conduct effective QMS audits. Whether for internal audits, third-party certifications, or supplier assessments, this course is tailored to help professionals navigate the complexities of auditing and improving their organization's QMS.

Programme Curriculum

Quality Management Systems (QMS) Auditing (ISO 9001/13485) Training Course.

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Course Duration

10 days

Course Objectives

By the end of this ISO 9001/13485 Auditing Training, participants will be able to:

1. Understand the core principles of ISO 9001 and ISO 13485 and their application in auditing.
2. Conduct internal audits of Quality Management Systems for compliance with international standards.
3. Master the methodologies for ISO QMS auditing in a practical, hands-on environment.
4. Develop auditing plans and checklists aligned with ISO 9001/13485 requirements.
5. Evaluate non-conformances and recommend corrective and preventive actions (CAPA).
6. Perform audits to assess the effectiveness of risk management practices within QMS.
7. Understand the audit process from planning, execution to reporting.
8. Apply knowledge of process-based auditing techniques to identify areas of improvement.
9. Interpret audit findings and prepare audit reports for management review.
10. Understand how to audit a supplier management process within a QMS.
11. Gain practical insights into ISO 13485 for medical device QMS auditing.
12. Enhance understanding of compliance audits and regulatory requirements.
13. Utilize modern tools and software for effective audit planning and execution.

Target Audience

1. Quality Managers.
2. Internal Auditors.
3. Compliance Officers.
4. Regulatory Affairs Professionals in industries like medical devices, automotive, etc.
5. Risk Management Professionals.
6. Consultants.
7. Production Managers.
8. Supply Chain Managers.

Course Modules

Module 1: Introduction to QMS and Auditing

- Overview of ISO 9001 and ISO 13485 standards.
- Importance of QMS in organizational success.
- Types of audits: Internal, External, and Supplier Audits.
- The role of an auditor in the QMS lifecycle.
- Case study: A successful QMS audit.

Module 2: Auditing Process and Methodologies

- Phases of an audit: Planning, Execution, Reporting.
- **Risk-based auditing** techniques.
- Auditing strategies: Process vs. Product-based.
- Developing an effective audit plan.
- Case study: Planning an internal audit in a manufacturing firm.

Module 3: Audit Documentation and Checklists

- Structuring audit documentation for ISO 9001/13485.
- Essential elements of an audit checklist.
- How to customize audit templates?
- Documenting audit findings.
- Case study: Creating a checklist for a medical device audit.

Module 4: Non-Conformance and Corrective Actions

- Identifying non-conformance during audits.
- Root cause analysis for non-conformance.
- Corrective and Preventive Actions (CAPA) in auditing.
- Communicating non-conformance issues to management.
- Case study: CAPA implementation in a pharmaceutical company.

Module 5: Auditing ISO 13485 for Medical Devices

- Key differences between ISO 9001 and ISO 13485.
- Special considerations for auditing medical device QMS.
- Regulatory requirements in medical device auditing.
- Risk management in ISO 13485 audits.
- Case study: Auditing a medical device manufacturing facility.

Module 6: Compliance Auditing and Regulations

- Understanding **regulatory frameworks** for ISO QMS.
- Preparing for regulatory audits.
- Dealing with regulatory authorities during an audit.
- Identifying compliance gaps.
- Case study: Conducting a compliance audit for an automotive supplier.

Module 7: Auditing Supplier Quality Management Systems

- Evaluating supplier audits as part of the QMS.
- Supplier risk assessment techniques.

- Tools for assessing supplier conformance to ISO standards.
- Building effective supplier relationships through audits.
- Case study: Auditing a key supplier in the electronics industry.

Module 8: Reporting Audit Findings

- Structuring audit reports for maximum impact.
- How to present audit results to top management?
- Handling difficult findings and corrective actions.
- Writing executive summaries for audit reports.
- Case study: Presenting audit findings to senior management.

Module 9: Auditing for Continual Improvement

- Linking audits to the continuous improvement process.
- Auditing for operational excellence.
- Role of audits in innovation and process improvements.
- Best practices in conducting audits for continuous improvement.
- Case study: Driving continual improvement through QMS audits.

Module 10: Audit Interviews and Evidence Collection

- Conducting effective interviews during audits.
- Collecting and analyzing audit evidence.
- Use of documentation, data, and records in audits.
- Ensuring objectivity and fairness in evidence collection.
- Case study: Interview techniques for successful audits.

Module 11: Audit Reporting and Corrective Action

- Writing non-conformance reports.
- Root cause analysis techniques.
- Developing corrective action plans.
- Monitoring the implementation of corrective actions.
- Case study: Implementing corrective action in a manufacturing firm.

Module 12: Auditing for Risk Management

- Identifying and assessing risks during an audit.
- Risk management frameworks within ISO QMS.
- Tools for effective risk assessment in audits.
- How to integrate risk management into audit processes?
- Case study: Auditing risk management in a healthcare organization.

Module 13: Auditor Competence and Ethics

- Key competencies for ISO auditors.
- Maintaining auditor objectivity and independence.
- Ethical considerations in auditing.
- Continuous professional development for auditors.
- Case study: Handling ethical dilemmas in an audit.

Module 14: Auditing for Performance and Efficiency

- Auditing to enhance organizational performance.
- Optimizing audit efficiency without compromising quality.
- Tools to assess process performance during audits.
- Auditing for customer satisfaction and loyalty.
- Case study: Streamlining audit processes in a retail company.

Module 15: Preparing for ISO Audits (Certification and Surveillance)

- Steps to prepare for ISO certification audits.
- Role of internal audits in surveillance audits.
- Handling non-conformances in surveillance audits.
- Continuous monitoring and improvement after certification.
- Case study: Preparing for ISO 9001/13485 surveillance audit.

Training Methodology

This course employs a participatory and hands-on approach to ensure practical learning, including:

- Interactive lectures and presentations.
- Group discussions and brainstorming sessions.
- Hands-on exercises using real-world datasets.
- Role-playing and scenario-based simulations.
- Analysis of case studies to bridge theory and practice.
- Peer-to-peer learning and networking.
- Expert-led Q&A sessions.
- Continuous feedback and personalized guidance.

Register as a group from 3 participants for a Discount

Send us an email: info@fineskilltrainingcenter.org or call +254769199797

Certification

Upon successful completion of this training, participants will be issued with a globally- recognized certificate.

Tailor-Made Course

We also offer tailor-made courses based on your needs.

Key Notes

a. The participant must be conversant with English.

b. Upon completion of training the participant will be issued with an Authorized Training Certificate

c. Course duration is flexible and the contents can be modified to fit any number of days.

d. The course fee includes facilitation training materials, 2 coffee breaks, buffet lunch and A Certificate upon successful completion of Training.

e. One-year post-training support Consultation and Coaching provided after the course.

f. Payment should be done at least a week before commence of the training, to Fineskill Training Center account, as indicated in the invoice so as to enable us prepare better for you.

Upcoming Scheduled Sessions

Start Date	End Date	Location	Price
23 Nov 2026	04 Dec 2026	Online	$2,000
23 Nov 2026	04 Dec 2026	Physical	$3,000
23 Nov 2026	04 Dec 2026	Physical	$6,000
23 Nov 2026	04 Dec 2026	Physical	$6,000
23 Nov 2026	04 Dec 2026	Physical	$12,000
23 Nov 2026	04 Dec 2026	Physical	$9,000
23 Nov 2026	04 Dec 2026	Physical	$12,000
23 Nov 2026	04 Dec 2026	Physical	$12,000

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