Internal Auditor Training

Course description

This Internal Auditor Training course is designed to prepare participants to assess, monitor, and improve the Quality Management System (QMS) in the medical device industry, in accordance with ISO 13485 and applicable regulatory requirements. Throughout the program, students will thoroughly explore regulatory requirements, fundamental audit principles, and the full audit cycle, from planning to closure. Content includes scheduling and executing internal audits, analyzing findings, and preparing accurate reports that support continuous improvement. Through real-life case studies, participants will develop the ability to identify nonconformities, assess compliance with critical processes, and formulate effective recommendations.

At the end of the course you will able to:

- Interpret and apply the requirements of ISO 13485 in a quality management system.
- Understand and apply the fundamental principles of internal auditing.
- Plan internal audits by defining objectives, scope, criteria, and necessary resources.
- Execute internal audits through document review, interviews, and process observation.
- Identify and document audit findings, including nonconformities, observations, and opportunities for improvement.
- Prepare clear, accurate audit reports based on objective evidence.
- Formulate recommendations for continuous improvement of the quality management system.
- Conduct audit closing meetings, communicating findings and conclusions effectively.
- Evaluate corrective and preventive actions derived from the audit results.

Main topics

1 ISO 13485 Requirements
- Quality management system: Documentation, control of documents and records.
- Management responsibility: Management commitment, customer focus, quality policy.
- Resource management: Resource provision, human resources, infrastructure, work environment.
- Product realization: Planning, design and development, purchasing, production, control of monitoring and measurement devices.
- Measurement, analysis, and improvement: Internal audit, control of nonconforming product, data analysis, continual improvement.

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Main topics

2 Audit Principles
- Integrity: The foundation of professionalism.
- Fair Presentation: The obligation to report accurately and precisely.
- Due Professional Care: The application of due diligence and judgment when auditing.
- Confidentiality: Security of information.
- Independence: Basis for the impartiality and objectivity of audit conclusions.
- Evidence-Based Approach: Rational method for reaching reliable audit conclusions.

3 Audit Cycle
- Planning: Definition of audit objectives, scope, and criteria.
- Execution: Document review, interviews, observation of activities.
- Reporting: Documentation of findings and conclusions.
- Follow-up: Evaluation of implemented corrective and preventive actions.

4 Audit Scheduling
- Frequency: Based on the risk, size, and complexity of the organization.
- Resources: Assignment of qualified auditors.
- Schedule: Date and duration of audits.
- Process audit: methodology that reviews each process and the applicable requirements
- Regulatory requirements: identify applicable regulatory requirements

5 Audit Execution
- Document Review: Assessment of compliance with requirements.
- Interviews: Interaction with staff to assess understanding and compliance.
- Process Observation: Validation of process compliance.

6 Audit Results
- Findings: Nonconformities, observations, and opportunities for improvement.
- Conclusions: Assessment of compliance with the quality management system.
- Recommendations: Suggestions for continuous improvement.

7 Audit Closing
- Closing Meeting: Presentation of findings and discussion with management.
- Final Report: Detailed document of the results and conclusions.

Course features

Instructor Led
Duration: 24 hours
Tools and templates
Applied learning
Course certificate

Contact

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