

A photograph of a business meeting in a modern office. Five people are gathered around a table, looking at a laptop. The room has large windows with blinds and a whiteboard in the background.

## Cognicert ISO 7101 Healthcare Quality Lead Auditor Course

### **Training Overview:**

The ISO 7101 Lead Auditor Course is designed to provide participants with the knowledge and skills required to lead audits of Healthcare Quality Management systems (HQMS) based on ISO 7101:2023. This comprehensive training program covers the principles, processes, and practices of auditing HQMS, focusing on key areas such as audit planning, conducting audits, reporting, and follow-up activities.

ISO 7101 Healthcare Quality Management System Lead Auditor Course provides participants with the knowledge and skills necessary to lead audits of quality management systems within healthcare organizations. This comprehensive training program covers the principles, processes, and practices of auditing healthcare quality management systems, focusing on key standards and regulations applicable to the healthcare industry.

### **Target Audience:**

- Healthcare Quality assurance managers and officers.
- Internal auditors responsible for auditing HQMS within organizations.
- Professionals seeking to become certified lead auditors for ISO 7101 audits.
- Personnel involved in implementing and maintaining HQMS within organizations.

### **Reference Standards:**

- ISO 7101:2023 – Healthcare Quality Management systems – Requirements.
- They will understand how to apply ISO 19011:2018 and ISO 17011:2017 principles to ensure effective auditing, conformity assessment, and continual improvement within the Artificial Intelligence industry.

### **Objectives:**

By the end of the course, participants will be able to:

- Understand the principles and requirements of ISO 7101:2023.
- Interpret and apply the requirements of ISO 7101 during audit activities.
- Plan and prepare for HQMS audits effectively, including developing audit programs and checklists.
- Conduct HQMS audits in accordance with ISO 7101 requirements, including gathering evidence, interviewing personnel, and documenting findings.
- Apply audit techniques and methodologies to identify nonconformities and areas for improvement.
- Prepare audit reports and communicate findings to relevant stakeholders.
- Understand the process for audit follow-up and verification of corrective actions.

**Learning Outcome:** Upon completion of the course, participants will be able to lead and conduct audits of HQMS effectively, in line with the requirements of ISO 7101:2023. They will possess the necessary knowledge and skills to plan, execute, report on, and follow up audits, contributing to the continual improvement of organizational processes and systems.

### **Course Content:**

- Introduction to ISO 7101:2023
- Overview of the standard
- Key concepts and principles of Healthcare Quality Management
- Principles of Auditing According to ISO 19011
- Fundamental concepts of auditing
- Roles and responsibilities of auditors
- Ethical considerations in auditing
- Audit Planning and Preparation according to ISO 17021:2015
- Developing audit objectives and scope
- Establishing audit criteria and methods
- Creating audit programs and checklists
- Conducting Audits
- Techniques for gathering evidence
- Interviewing skills and communication techniques
- On-site audit activities and observations
- Audit Reporting

- Documentation of audit findings
- Preparation of audit reports
- Presentation of findings to management and stakeholders
- Audit Follow-up and Corrective Actions
- Verification of corrective actions
- Monitoring and measuring audit performance
- Continuous improvement of the audit process
- Case Studies and Practical Exercises
- Application of audit principles and techniques through hands-on exercises and real-world scenarios.

Duration: 5 days

Training Methodologies

- Case Study
- Individual Exercises
- Role Play
- Group Exercises
- Group Presentation
- Examination

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