Certified ISO 9001 Lead Implementer Training

Duration: **4 Day**

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Overview

What Can You Achieve with This Training?

- Develop the skills to **establish, implement, operate, and maintain a Quality Management System (QMS)** aligned with ISO 9001 requirements.
- Learn to plan and manage QMS implementation projects using **PECB's IMS2 Methodology** and recognised best practices.
- Apply **customer focus, the process approach, risk-based thinking, and the PDCA cycle** across organisational processes.
- Evaluate QMS effectiveness through **quality objectives, performance indicators, internal audits, and management reviews**.
- Support continual improvement using **nonconformity management, root cause analysis, and corrective actions**.
- Prepare organisations for **third-party ISO 9001 certification audits** and develop knowledge relevant to the **PECB Certified ISO 9001 Lead Implementer** credential.

The **Certified ISO 9001 Lead Implementer Training** develops the knowledge and practical competencies required to **establish, implement, operate, maintain, and continually improve a Quality Management System (QMS)** based on ISO 9001.

The course approaches ISO 9001 requirements from the perspective of professionals responsible for implementing a management system. Participants explore the fundamental principles of quality management and learn how these principles relate to organisational strategy, customer expectations, and operational activities.

Key topics include **customer focus, the process approach, risk-based thinking, the Plan-Do-Check-Act (PDCA) cycle, quality culture, and continual improvement**. The programme also examines the structure of **ISO 9001**, organisational context, interested parties, leadership responsibilities, and quality policy development.

Participants learn how to initiate, plan, and coordinate a QMS implementation project using **PECB's IMS2 Methodology** and recognised best practices. This includes establishing objectives, identifying resources, assigning responsibilities, planning communication, managing organisational change, and addressing implementation risks.

The operational modules cover **process management, product and service requirements, documented information, resource management, performance measurement, internal auditing, and management review**.

The final stages focus on **nonconformity management, corrective actions, continual improvement, and preparation for third-party certification audits**.

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The training supports organisations in managing product and service quality through a **structured, evidence-based, and customer-focused approach**.

After completing the course and passing the relevant certification examination, participants may apply for the internationally recognised **PECB Certified ISO 9001 Lead Implementer** credential, subject to meeting the applicable certification requirements.

Exams and Certification

The course includes the **PECB Certified ISO 9001 Lead Implementer** examination.

The exam assesses competency domains related to **ISO 9001 requirements and Quality Management Systems**.

Participants who successfully complete the training and pass the examination may apply for the internationally recognised **PECB Certified ISO 9001 Lead Implementer** credential, provided they meet the applicable certification requirements.

Prerequisites

Participants should have:

- Basic knowledge of **ISO management system standards**
- General familiarity with **ISO 9001** and its requirements
- An understanding of **management system implementation principles**

Familiarity with **ISO quality management principles** may also help participants follow the course more effectively.

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Who Should Attend

This training is intended for professionals responsible for **implementing, managing, maintaining conformity, or improving a Quality Management System** within an organisation.

It is particularly suitable for:

- Personnel responsible for **maintaining and improving product and service quality**
- Professionals responsible for **meeting customer requirements**
- Consultants, advisors, and specialists seeking detailed knowledge of **ISO 9001 QMS requirements**
- Individuals interested in implementing a QMS using **PECB's IMS2 Methodology**
- Personnel responsible for maintaining **QMS conformity with ISO 9001**
- Members of **QMS implementation and operations teams**
- Individuals seeking a career in **quality management**

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What You Will Learn

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

- Explain the fundamental **concepts, principles, and benefits of a Quality Management System** based on ISO 9001.
- Interpret **ISO 9001 requirements** from the perspective of a QMS implementer.
- Initiate and plan a **QMS implementation project** using **PECB's IMS2 Methodology** and recognised best practices.
- Analyse **organisational context, interested parties, customer expectations, and statutory requirements**.
- Determine the **QMS scope**, identify organisational processes, and define their interactions.
- Integrate **risk-based thinking** into quality management activities.
- Establish **measurable quality objectives and performance indicators** to monitor progress.
- Apply QMS requirements related to **operational control, product and service conformity, and externally provided processes**.
- Manage **resources, competence, training, and documented information**.
- Support **leadership involvement, employee engagement, and quality culture**.
- Evaluate **QMS performance, customer satisfaction, and process effectiveness**.
- Support the development of **internal audit programmes** and follow-up of audit findings.
- Plan **management reviews** and assess their outcomes.
- Apply **nonconformity management, root cause analysis, and corrective actions** to support continual improvement.
- Help an organisation **operate, maintain, and continually improve its ISO 9001-based QMS**.
- Prepare an organisation for a **third-party ISO 9001 certification audit** and develop action plans to address readiness gaps.

Outline

1. QMS Fundamentals and Implementation Initiation

- Understanding the **purpose and benefits of a Quality Management System**
- Exploring fundamental **quality management concepts**

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- Reviewing the **principles of quality management**
- Applying **customer focus**
- Understanding the **process approach**
- Introducing **risk-based thinking**
- Exploring the **Plan-Do-Check-Act (PDCA) cycle**
- Understanding **continual improvement**
- Developing a **quality culture**
- Aligning **quality objectives with organisational strategy**

2. Understanding ISO 9001

- Examining the **structure and purpose of ISO 9001**
- Evaluating the **context of the organisation**
- Identifying **interested parties**
- Defining the **QMS scope**
- Understanding **leadership and commitment**
- Developing the **quality policy**
- Establishing **roles, responsibilities, and authorities**
- Interpreting requirements for **planning, support, operation, performance evaluation, and improvement**

3. Initiating QMS Implementation

- Developing the **business case** for QMS implementation
- Defining **implementation objectives**
- Identifying relevant **stakeholders**
- Establishing **roles and responsibilities**
- Securing **leadership commitment**
- Forming the **implementation team**
- Determining required **resources**
- Establishing **implementation governance**
- Preparing an initial **implementation roadmap**

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4. Planning the QMS Implementation

- Developing the **implementation approach**
- Selecting the **implementation methodology**
- Creating a detailed **implementation plan**
- Defining **activities and milestones**
- Conducting **resource planning**
- Assigning **responsibilities and accountability**
- Preparing a **communication plan**
- Planning **change management**
- Managing **implementation risks**

5. Understanding the Organisation's Context

- Identifying relevant **internal and external issues**
- Evaluating **interested parties** and their expectations
- Analysing **customer requirements**
- Identifying **statutory and regulatory requirements**
- Determining the **QMS scope**
- Identifying **processes and their interactions**
- Reviewing **organisational objectives**

6. Risk-Based Thinking

- Identifying **risks and opportunities**
- Assessing **quality-related risks**
- Determining appropriate **controls**
- Integrating **risk management into organisational processes**
- Monitoring **risk controls**
- Connecting **risk management with continual improvement**

7. Quality Objectives and Planning

- Establishing **quality objectives**

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- Defining **measurable targets**
- Identifying **performance indicators**
- Developing **action plans**
- Assigning **responsibilities, resources, and timescales**, and monitoring progress

8. Implementing QMS Processes

- Applying **process management**
- Establishing **operational planning and control**
- Managing **customer requirements**
- Defining **product and service requirements**
- Managing **design and development**
- Controlling **externally provided processes**
- Managing **production and service provision**
- Addressing the **release of products and services**
- Controlling **nonconforming outputs**

9. Resources and Organisational Capability

- Assessing **people and competence** requirements
- Identifying **infrastructure** needs
- Maintaining the appropriate **environment for operation**
- Managing **monitoring and measuring resources**
- Addressing **organisational knowledge**
- Establishing **competence management** practices
- Planning **training and development**
- Promoting organisational **awareness**

10. Documented Information

- Creating and maintaining **documented information**
- Applying **document control**
- Managing **records**

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- Establishing **version control**
- Controlling **access and distribution**
- Ensuring **protection and retention**
- Managing **documented information within operational processes**

11. Leadership and Quality Culture

- Reviewing **leadership responsibilities**
- Strengthening **customer focus**
- Aligning the **quality policy** with organisational activities
- Promoting **accountability**
- Encouraging **employee engagement**
- Improving **communication**
- Embedding **quality into organisational culture**
- Managing **resistance to change**

12. Monitoring and Measuring the QMS

- Evaluating **QMS performance**
- Conducting **monitoring and measurement**
- Using **Key Performance Indicators (KPIs)**
- Assessing **customer satisfaction**
- Performing **data analysis**
- Monitoring **process performance**
- Evaluating **product and service conformity**
- Measuring overall **QMS effectiveness**

13. Internal Audit

- Understanding the **purpose of internal auditing**
- Developing an **internal audit programme**
- Planning **audits**
- Assessing **auditor competence**

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- Collecting and evaluating **audit evidence**
- Documenting **audit findings**
- Planning **corrective actions**
- Conducting **follow-up activities**

14. Management Review

- Understanding the **purpose of management review**
- Identifying **management review inputs**
- Analysing **performance trends**
- Reviewing **customer feedback**
- Evaluating **audit results**
- Assessing **risks and opportunities**
- Identifying **resource requirements**
- Recognising **improvement opportunities**
- Documenting **management review outputs**

15. Continual Improvement

- Identifying **improvement opportunities**
- Managing **nonconformities and corrective actions**
- Conducting **root cause analysis**
- Developing **corrective action plans**
- Evaluating **action effectiveness**
- Applying **continual improvement**
- Using **data to support improvement decisions**

16. Preparing for Certification

- Understanding **third-party certification**
- Reviewing the **stages of a certification audit**
- Planning **certification audit preparation**
- Assessing **QMS conformity with ISO 9001**

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- Identifying **implementation gaps**
- Completing **corrective actions before certification**
- Preparing **personnel for the audit**
- Organising **documented information**
- Preparing for **auditor interviews**
- Managing the **certification audit**
- Responding to **certification findings**

17. QMS Implementation Review

- Completing a final **implementation-readiness exercise** covering the full QMS lifecycle
- Identifying remaining gaps and developing a final **certification-readiness action plan**