CERTIFICATION SYLLABUS

# ISO 9001: Quality Management Systems Lead Implementer

*Exam Code: CQLI™*




A complete preparation guide covering exam objectives, core competencies, domain weightage, and topics to prepare.

©2026 Certaining, Inc. All rights reserved.

## Table of Contents

1. **Exam Name & Code** ..... 1
2. **Table of Contents** ..... 2
3. **Objective of the Certification** ..... 3
4. **Core Competencies** ..... 4-5
5. **Who Should Take This Certification** ..... 6
6. **Exam Information** ..... 6
7. **Examination Domain & Weightage** ..... 7
8. **Topics to Prepare** ..... 8-9

- *QMS Fundamentals & ISO 9001:2015 Requirements (Advanced)*
- *Implementation Project Planning & Gap Analysis*
- *Process Design, Documentation & Operational Controls*
- *Leadership, Resources, Competence & Change Management*
- *Monitoring, Internal Audit & Management Review*
- *Corrective Action, Continual Improvement & Maturity*
- *Certification Readiness & Sustaining the QMS*

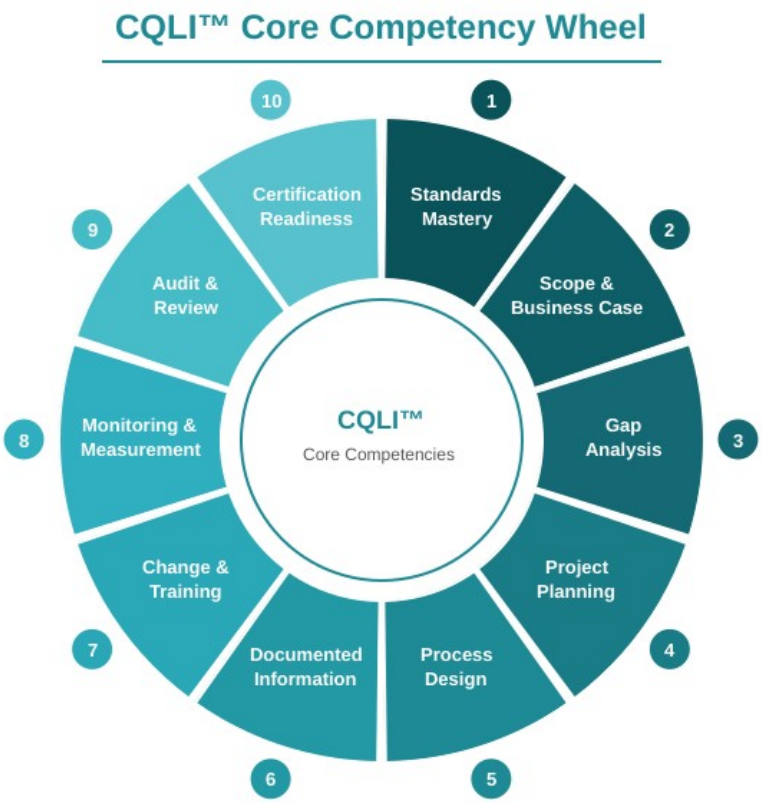
©2026 Certaining, Inc. All rights reserved.

## Objective of the Certification

- **Validate lead implementer competence:** the ability to plan, lead, and manage the implementation of a Quality Management System (QMS) based on ISO 9001:2015.
- **Deepen standards expertise:** apply the ISO 9001:2015 requirements and quality management principles with the judgment needed to lead an implementation project.
- **Establish scope and business case:** define the QMS scope, objectives, and benefits, and secure top management commitment.
- **Perform gap analysis:** compare current practices with ISO 9001 requirements and prioritize actions.
- **Plan the implementation project:** define phases, resources, responsibilities, milestones, and risks.
- **Design processes and documented information:** map processes, set controls and indicators, and create right-sized documented information.
- **Lead change and build competence:** manage resistance, communicate, train, and engage people at all levels.
- **Monitor and evaluate performance:** use indicators, internal audits, and management review to evaluate the QMS.
- **Drive corrective action and improvement:** address root causes and pursue continual improvement.
- **Prepare for certification and sustain the QMS:** get ready for stage 1, stage 2, surveillance, and recertification audits.

©2026 Certaining, Inc. All rights reserved.

# Core Competencies — CQLI™ (ISO 9001: Quality Management Systems Lead Implementer)




©2026 Certaining, Inc. All rights reserved.

- **Standards mastery:** interpret ISO 9001:2015 clauses 4 to 10 and the related guidance in depth.
- **Scope and business case:** define the QMS scope and objectives and justify the project to top management.
- **Gap analysis:** assess current processes against requirements and prioritize gaps.
- **Implementation planning:** build and manage the implementation plan, resources, and risks.
- **Process design:** map processes, define owners, controls, and performance indicators.
- **Documented information:** create and control right-sized documents and records.
- **Change and training:** lead change, communication, awareness, and competence development.
- **Monitoring and measurement:** select indicators and analyze data to evaluate the QMS.
- **Audit and review:** plan internal audits and management review and act on the results.
- **Certification readiness:** prepare for external audits and sustain the QMS after certification.

©2026 Certaining, Inc. All rights reserved.

## Who Should Take This Certification

- Quality managers and QMS managers responsible for implementing ISO 9001.
- Project managers and process improvement leaders leading QMS implementation projects.
- Management representatives and ISO 9001 coordinators.
- Consultants and implementers who support organizations through ISO 9001 certification.
- Internal auditors and quality professionals who want to move into implementation leadership.
- Professionals who have completed credentials such as CQIA™ or CQQM™ and want to advance.

## Exam Information

| | |
|---|---|
| **Exam Name** | ISO 9001: Quality Management Systems Lead Implementer |
| **Exam Code** | CQLI™ |
| **Exam Format** | Multiple Choice Questions (MCQ), including scenario-based questions |
| **Duration** | 120 minutes |
| **Number of Questions** | 80 |
| **Passing Score** | 70% |
| **Mode of Exam** | Test Center Based Testing / Online Testing |
| **Language** | English |
| **Validity** | Lifetime |
| **Open Book** | No |

©2026 Certaining, Inc. All rights reserved.

## Examination Domain & Weightage

| Domain | Weightage |
|---|---|
| **QMS Fundamentals & ISO 9001:2015 Requirements (Advanced)** | 20% |
| **Implementation Project Planning & Gap Analysis** | 15% |
| **Process Design, Documentation & Operational Controls** | 15% |
| **Leadership, Resources, Competence & Change Management** | 15% |
| **Monitoring, Internal Audit & Management Review** | 15% |
| **Corrective Action, Continual Improvement & Maturity** | 10% |
| **Certification Readiness & Sustaining the QMS** | 10% |
| **Total** | **100%** |

©2026 Certaining, Inc. All rights reserved.

# Topics to Prepare — CQLI™ (ISO 9001: Quality Management Systems Lead Implementer)

The topics below represent the core areas candidates should focus on for each domain, reflecting the implementation depth expected at the CQLI™ level.

## 1. QMS Fundamentals & ISO 9001:2015 Requirements (Advanced) (20%)

- **Quality principles:** the seven quality management principles and their use in implementation.
- **ISO standards:** ISO 9000, ISO 9001, ISO 9004, and guidance such as ISO 9002 and ISO 10005.
- **Structure:** the high-level structure (clauses 1 to 10) and how requirements connect.
- **Context and leadership (clauses 4 and 5):** issues, interested parties, scope, policy, roles, and customer focus.
- **Planning and support (clauses 6 and 7):** risks and opportunities, objectives, resources, competence, and documented information.
- **Operation (clause 8):** planning and control, requirements, design, external providers, production, release, and nonconforming outputs.
- **Evaluation and improvement (clauses 9 and 10):** monitoring, audit, review, corrective action, and improvement.

## 2. Implementation Project Planning & Gap Analysis (15%)

- **Project initiation:** top management commitment, business case, scope, and objectives.
- **Gap analysis:** comparing current practices with ISO 9001 requirements and prioritizing gaps.
- **Implementation plan:** phases, milestones, resources, responsibilities, and schedule.
- **Project team and stakeholders:** cross-functional representation and stakeholder analysis.
- **Project risks:** lack of support, resistance, resource limits, and how to treat them.
- **Scaling:** adapting implementation to organization size, complexity, and sector.

## 3. Process Design, Documentation & Operational Controls (15%)

- **Process mapping:** processes, inputs, outputs, interactions, owners, and indicators.
- **Documented information:** documents to be maintained and records to be retained, and the right level of detail.
- **Document control:** identification, approval, version control, distribution, and retention.
- **Operational controls:** criteria, work instructions, checks, and controls for key processes.
- **Quality plans:** planning for specific products, projects, or contracts.

©2026 Certaining, Inc. All rights reserved.

- **Usability:** designing simple, usable documents and visual aids.

## 4. Leadership, Resources, Competence & Change Management (15%)

- **Top management role:** providing direction, resources, and visible commitment.
- **Change management:** reasons for resistance and ways to engage people.
- **Competence and training:** determining needs, delivering training, and evaluating effectiveness.
- **Awareness and communication:** communication plans, messages, and channels.
- **Roles and responsibilities:** assigning ownership of processes and the QMS.
- **Organizational knowledge:** capturing and sharing knowledge needed for the QMS.

## 5. Monitoring, Internal Audit & Management Review (15%)

- **Performance indicators:** selecting and monitoring indicators and targets.
- **Analysis and evaluation:** using data to evaluate conformity, satisfaction, and effectiveness.
- **Internal audit program:** planning, scope, auditors, reporting, and follow-up.
- **Management review:** inputs, outputs, and top management participation.
- **Customer satisfaction:** monitoring perceptions through surveys, feedback, and complaints.

## 6. Corrective Action, Continual Improvement & Maturity (10%)

- **Corrective action:** react, determine causes, act, and review effectiveness (clause 10.2).
- **Root cause analysis:** 5 Whys and cause-and-effect diagrams.
- **Continual improvement:** improving suitability, adequacy, and effectiveness (clause 10.3).
- **Maturity assessment:** using self-assessment such as ISO 9004 to plan improvement.
- **Lessons learned:** capturing lessons from projects, audits, and incidents.

## 7. Certification Readiness & Sustaining the QMS (10%)

- **Certification body:** choosing an accredited certification body and understanding impartiality.
- **Certification audits:** stage 1, stage 2, surveillance, and recertification.
- **Readiness review:** checking internal audit and management review results before the audit.
- **Handling findings:** addressing nonconformities raised by the certification body.
- **Sustaining the QMS:** keeping the system alive after certification.

©2026 Certaining, Inc. All rights reserved.