

Module 1 - 5

- ISO 9001 Refresher & Why AI Matters Now
- Using AI to Build and Maintain a World-Class ISO 9001:2015 Quality Management System

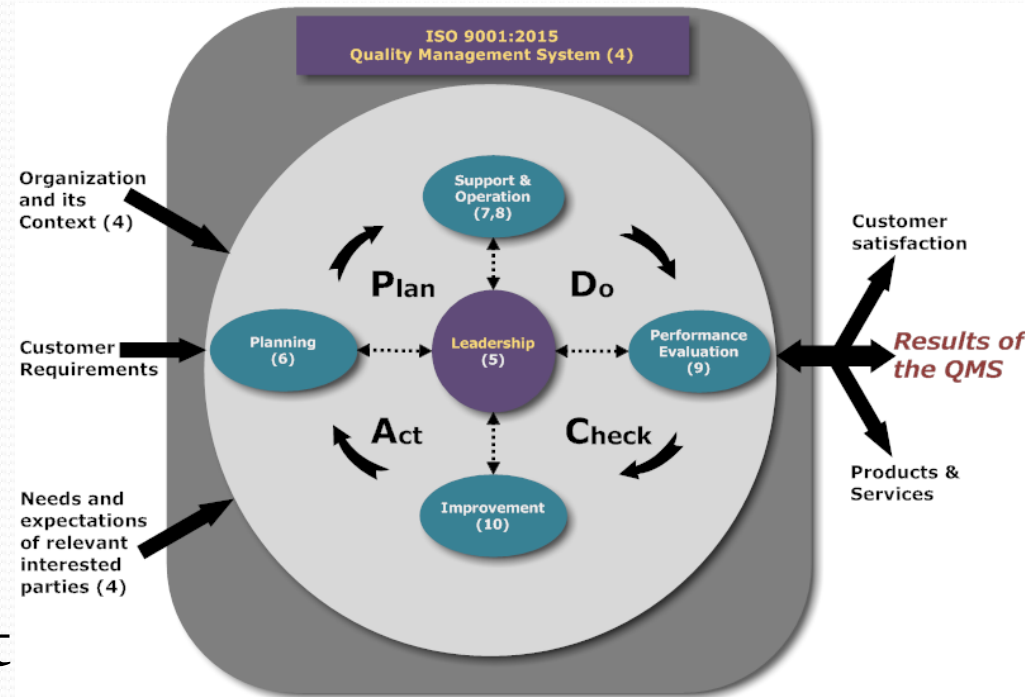
Module 1: Learning Objectives

By the end of this module you will be able to:

- Refresh the complete ISO 9001:2015 structure and key requirements
- Explain the PDCA cycle and its central role in every QMS
- Identify the biggest pain points of traditional QMS implementations
- Recognize the 2026 emphasis areas: climate change, quality culture, ethical behavior, and digital transformation
- Understand proven AI ROI in quality management
- Self-assess your current QMS maturity

The PDCA Cycle – The Heart of ISO 9001

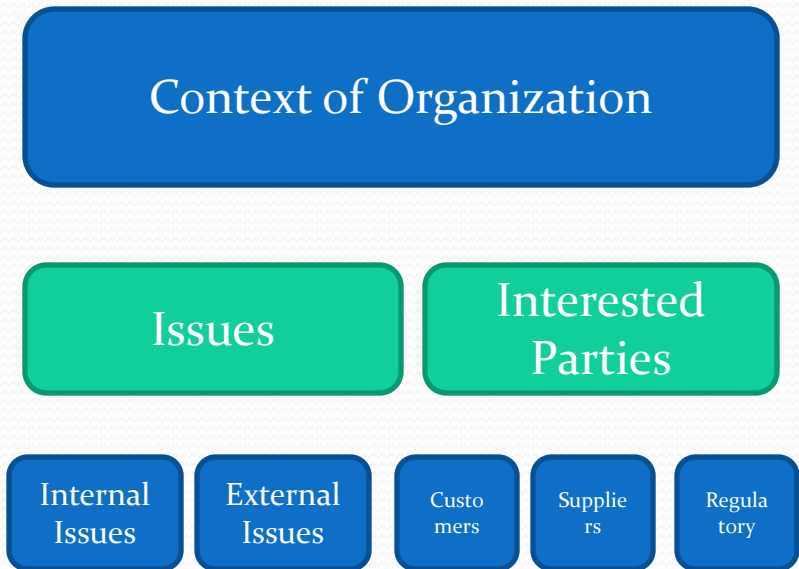
- Plan → Define objectives, risks & processes
- Do → Implement the plan
- Check → Monitor, measure & evaluate
- Act → Improve & Adjust



Clause 4 – Context of the Organization

Key Requirements

- Understand internal & external issues
- Identify needs & expectations of interested parties
- Define the scope of the QMS
- Establish, implement & maintain QMS processes
2026 Note: Climate change risks must now be explicitly considered.



Clause 5 – Leadership

Key Requirements

- Top management demonstrates leadership & commitment
- Establish & communicate quality policy
- Ensure customer focus
- Assign roles, responsibilities & authorities
- 2026 Note: Strong focus on quality culture and ethical behavior.

Clause 6 – Planning

Key Requirements

- Address risks and opportunities
- Set measurable quality objectives
- Plan changes to the QMS 2026
- Note: Risk-based thinking now includes climate-related and ethical risks.

Clause 7 – Support

Key Requirements

- Provide necessary resources
- Ensure competence & awareness
- Effective internal & external communication
- Control of documented information 2026
- Note: Digital tools and AI-ready competence are now expected.

Clause 8 – Operation

Key Requirements

- Operational planning & control
- Design & development of products/services
- Control of externally provided processes
- Production / service provision & release
- Control of nonconforming outputs

Clauses 9 & 10

Performance Evaluation & Improvement

Clause 9 – Performance Evaluation

- Monitor, measure, analyze & evaluate
- Internal audits

Management review Clause 10 – Improvement

- Nonconformity & corrective action
- Continual improvement
- Note: Strong emphasis on data-driven and proactive improvement.

Traditional QMS Pain Points

Why many QMS systems still struggle in 2026

- Documentation overload
- Reactive audits & fire-fighting
- Manual data collection & reporting
- Slow corrective actions
- Siloed departments & poor visibility
- Difficulty proving continual improvement

2026 ISO 9001 Updates & Emphasis

2026 Emphasis Areas

- Climate Change – Explicit consideration in Context and Planning
- Ethics & Quality Culture – Leadership must demonstrate and foster both
- Digital Transformation – Strong push for data analytics and AI integration Bottom line:
- ISO 9001 is evolving.
- AI is now the smartest way to meet these expectations

AI ROI Stats

Proven AI Impact in Quality Management

- Audit preparation time reduced 25–60 %
- Defect rates dropped up to 30 % (real case studies)
Additional wins
- Faster risk identification
- Predictive corrective actions 40–70 % less manual documentation
- How mature is your current QMS?

Module 2

AI 101 for Quality Professionals

Learning Objectives

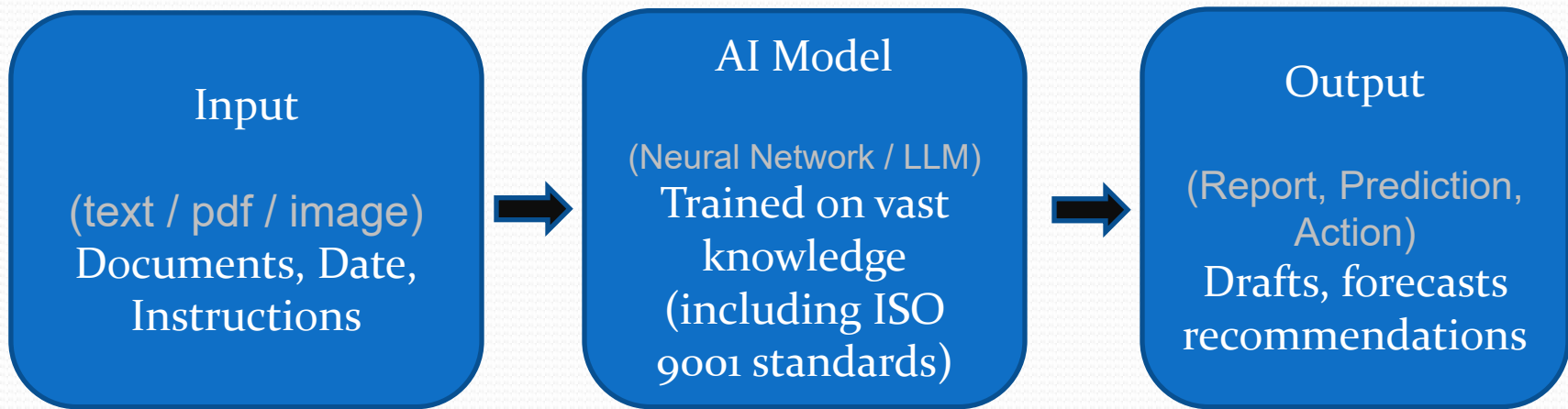
By the end of this module you will be able to:

- Explain what AI is and how it differs from traditional automation
- Identify the three types of AI most useful for QMS professionals
- Select appropriate 2026 AI tools for quality tasks
- Write effective prompts for ISO 9001-related work
- Recognize common pitfalls and how to avoid them

AI vs Automation

Aspect	Traditional Automation	Artificial Intelligence
Rule-based	Yes (if-then)	Learns and adapts
Handles variation	Poor	Excellent
Decision making	Pre-programmed	Probabilistic / contextual
QMS Example	Auto email on NCR	Draft full NCR + suggest root cause
Requires training	Minimal	Improves with use

How AI Works (Simple Model)



- Input: Documents, data, instructions
- Model: Trained on vast knowledge (including ISO 9001 standards)
- Output: Drafts, forecasts, recommendations

AI Types Relevant to QMS

Generative AI – Your Creative & Documentation Partner

- Creates new content (text, tables, procedures, reports)
- QMS Example: Drafting quality manuals, work instructions, management review agendas
- Speed: Minutes instead of hours
- Human role: Review & approve

Predictive AI

Your Risk & Performance Forecaster

- Analyzes data to predict future outcomes
- QMS Examples:
 - Non-conformance risk forecasting
 - Supplier delivery performance prediction
 - Equipment failure probability (Clause 7.1.3)
- Supports proactive Clause 6.1 risk actions

Agentic AI

- Your Autonomous Quality Assistant
- Can perform multi-step tasks with minimal supervision
- QMS Examples:
 - Run full internal audit workflow
 - Monitor KPIs and trigger actions
 - Update risk register when new data arrives
- Emerging tools (e.g., Microsoft Copilot Agents, ServiceNow)

Summary of AI Types

Which AI Type Should You Use?

- Recommendation:

Start with Generative → Add Predictive → Adopt Agentic

For a more detailed definition of Generative VS Agentic AI – go to:

<https://gracehost.net/seo-website-marketing-blog/define-generative-vs-agentic-ai>

Tool Landscape

Accessible AI Tools for Quality Teams

- Microsoft Copilot (<https://copilot.microsoft.com/>)
- Power Automate AI Builder (<https://learn.microsoft.com/en-us/power-automate/use-ai-builder>)
- Grok (<https://grok.com/>)
- Claude (<https://claude.com/>)
- ServiceNow Now Assist (<https://www.servicenow.com/>)
- SAP AI (<https://www.sap.com/products/artificial-intelligence.html>)

Live Prompt Demos

Demo 1 – Risk Register (Clause 6.1)

- Grok: “You are an ISO 9001:2015 expert. Generate a risk register for Clause 6.1 for a mid-sized electronics manufacturer, including climate-related risks as required in 2026.”
- Response

Risk Register for ISO 9001:2015 Clause 6.1 – Mid-Sized Electronics Manufacturer (including climate-related risks per 2024 Amendment / 2026 expectations)

This register addresses risks and opportunities that could affect the QMS's ability to achieve intended results (consistent product quality, on-time delivery, customer satisfaction, and regulatory compliance). Risks are evaluated on a 5x5 scale (Likelihood × Impact = Risk Score; 1-5 Low, 6-12 Medium, 15-25 High).

ID	Risk/Opportunity	Category	Likelihood(1-5)	Impact (1-5)	Risk Score	Planned Actions/Controls	Owner
R-01	Key component shortages due to supplier quality failures or insolvency	Supply Chain	4	6	24 (high)	Dual sourcing for critical parts; supplier audits & scorecard; buffer stock strategy	Procurement Manager
	The actual results show 2 more columns + more rows						

Live Prompt Demos

Demo 2 - (Procedure Draft)

Grok: "You are an ISO 9001:2015 expert. Generate a procedure for documenting a non-conformance event."

After 8 seconds, it responded:

Procedure: Documenting and Handling Nonconformance Events Document Reference: QMS-PROC-010 (Rev 1.0) ISO 9001:2015 Clauses: 8.7, 10.2, 9.1.3, 7.5

1. Purpose
2. Scope
3. Responsibilities
4. Definitions
5. Procedure Steps
6. Records (Retained Documented Information)
7. References

Each numbered item is detailed completely. Download the pdf to review the full response.

Live Prompt Demos

Demo 3 - Root Cause Analysis (specific)

- Open Grok and type: You are an ISO 9001:2015 expert, Generate a root cause analysis for a 20 Ton Trumpf 1000 S19 Large Format CNC Punching Machine that is off tolerance by 15% on .25 inch hole punches

This is a very specific prompt and it is based on a machine type and the specific problem that is occurring.

In 6 seconds, the AI responded:

- **Root Cause Analysis (RCA) ISO 9001:2015 Reference:** Clause 10.2 (Nonconformity and Corrective Action)
- **NCR Reference:** NCR-2026-XXX **Machine:** Trumpf TruPunch 1000 S19 (20 Ton Large Format CNC Punching Machine) **Problem:** .25" (6.35 mm) round holes consistently out of tolerance by $\pm 15\%$ (actual hole size deviation $\approx 0.0375"$ / 0.95 mm) **Detected:** In-process / Final inspection **Impact:** Scrap / Rework on affected sheets, potential customer rejection, schedule delay

Download the pdf to review the full response.

Prompt Engineering Basics

5 Golden Rules of Prompt Engineering

1. Be specific & assign a role
2. Provide context (industry, clause, format)
3. Ask for structured output (tables, steps)
4. Iterate (refine in follow-up prompts)
5. Always verify against latest ISO 9001 requirements

Common Pitfalls

Avoid These Common Mistakes

- Accepting output without verification
- Using vague prompts
- Sharing confidential company data (some AI's keep your prompts)
- Assuming AI is always up-to-date with any amendments
- Over-reliance (*AI is a powerful assistant, **not** a replacement for competent quality professionals*)

End of Module 2

Key Takeaways

- AI ≠ Automation
- Generative, Predictive & Agentic AI each serve different QMS needs
- Prompt engineering is your new core competency

Module 3

Using AI to Build and Maintain a Quality Management System

AI Across the ISO 9001 Clauses – High-Level Mapping

Learning Objectives

By the end of this module you will be able to:

- Use a practical framework to map AI capabilities to ISO 9001 clauses
- Identify high-impact AI use cases for each major clause
- Prioritize AI opportunities based on effort vs. benefit
- Complete a personal QMS AI Opportunity Map

Framework: How to Map AI to ISO 9001

AI Mapping Framework

1. Identify the clause requirement
2. Assess current pain points & manual effort
3. Match to AI type (Generative / Predictive / Agentic)
4. Evaluate benefit, risk & compliance impact
Prioritize & pilot

AI + ISO 9001 Heat Map

Clause	Generative	Predictive	Agentic	Overall Impact
4 Context	High	Medium	Medium	5/5
5 Leadership	Medium	Low	High	4/5
6 Planning	High	High	High	5/5
7 Support	High	Medium	High	5/5
8 Operation	High	High	Very High	5/5
9 Evaluation	Medium	Very High	High	5/5
10 Improvement	High	High	High	5/5

Clause 4: Context of the Organization

Clause 4 – Context & Interested Parties

- AI Use Cases:
 - Auto-generate SWOT / PESTLE analysis
 - Map interested parties & expectations
 - Monitor external issues (regulatory, climate)
- Note: Climate change context (amendment alignment)
- Benefit: Reduces 4–6 hours of manual research to <30 minutes

Example - Grok: “For our ISO 9001:2015 standard, prepare a SWOT analysis to conform to clause 4. ‘Context of the Organization’ mapping interested parties, and expectations for our metal stamping production line.” *...add your company specifics...*

(see attached pdf for the results: Grok-Prompt-for-Clause-4-SWOT-Analysis.pdf)

Clause 5 – Leadership & Commitment

- AI Use Cases:
 - Draft management review agendas & minutes
 - Generate policy deployment cascades
 - Ethics & AI governance statements
- Benefit: Frees leaders to focus on strategy instead of documentation

Clause 6: Planning

Planning (Actions to Address Risks)

- High-Impact AI Opportunities:
 - Automated risk & opportunity registers
 - Predictive risk forecasting
 - Climate risk integration
- Example: AI turns historical NCR data into proactive mitigation plans

Clause 7: Support

Support (Resources, Competence, Awareness)

- AI Use Cases:
 - Personalized training content & competency matrices
 - Automated document control & version comparison
 - Knowledge base chatbot for employees

Clause 8: Operation (Part 1)

- AI can automate:
 - Design FMEA & design review checklists
 - Supplier scoring & risk-based evaluation
 - Quality gates & inspection planning

Clause 8: Operation (Part 2)

- Real Example:
Prompt → “Create a production quality plan for [product] including critical control points and acceptance criteria for our ISO 9001 QMS and specifically clause 8.”
- Benefit: Consistent, traceable, risk-based outputs

Modify the prompt to provide sufficient detail about your product (a url to your website’s product detail page helps)

Clause 9: Performance Evaluation

- Strongest AI Area: Predictive Analytics
 - KPI trend forecasting
 - Customer satisfaction sentiment analysis
 - Audit finding pattern detection

Prompt: find a pattern in the following customer surveys to help improve customer satisfaction (then paste in the full results)

Clause 10: Improvement

- AI Use Cases:
 - Root cause analysis suggestions (5-Why + Fishbone)
 - Corrective action recommendation engine
 - Lessons-learned knowledge base

Common Implementation Considerations

Key Considerations for Success

- Data privacy & security
- Human oversight & validation
- Change management
- Integration with existing QMS software

Module 4

Real-World Wins & Quick-Start Tools

Case 1

CircuitTech Electronics (PCB Manufacturer)

- Problem
 - High defect rate (8.2%) in surface-mount assembly
 - Manual root cause analysis taking 3-4 days
- AI Solution
 - Predictive AI defect detection + Generative root cause engine integrated with MES (Manufacturing Execution Systems): data directly from machines and sensors on equipment
- Results
 - Defect rate reduced from 8.2% to 6.1% (25% improvement)
 - Root cause time reduced to under 4 hours
 - ROI achieved in 4 months

Case 2

PrecisionDrive Automotive (Tier 1 Supplier)

- Problem
 - Inconsistent supplier performance
 - Risk-based thinking poorly documented for IATF 16949 alignment
- AI Solution
 - Agentic AI for automated supplier scoring and predictive delivery risk
- Results
 - On-time delivery improved by 18%
 - Supplier audit preparation time cut by 65%
 - Enhanced Clause 8.4 compliance

Case 3

MediCore Devices (Medical Device Manufacturer)

- Problem
 - Lengthy design verification and traceability documentation
 - Increasing regulatory compliance burden
- AI Solution
 - Generative AI for automated design FMEA, traceability matrices, and design review checklists (Clause 8.3)
- Results
 - Design review cycle reduced from 6 weeks to 11 days
 - 100% audit-ready documentation output
 - Significant reduction in CAPA related to design

Case 4

- Nexus IT Solutions (Global IT Services Provider)
- Problem
 - Inconsistent internal audit quality across global sites
 - Management review preparation taking several weeks
- AI Solution
 - Generative AI for intelligent audit checklists and automated management review inputs (Clauses 9.2 & 9.3)
- Results
 - Audit report quality score increased by 42%
 - Management review preparation time reduced by 70%

Case 5

- SwiftLogistics Global (Logistics & Supply Chain)
- Problem
 - Poor demand forecasting causing quality and delivery issues
 - Large backlog of corrective actions
- AI Solution
 - Predictive analytics applied to shipment, customer feedback, and sensor data
- Results
 - Forecasting accuracy improved by 30%
 - Corrective action closure rate increased 55% faster
 - Measurable reduction in customer complaints

Case 6

AeroPrecision Machining (Precision Machining Firm)

- Problem
 - Manual inspection planning and heavy reliance on retiring workforce knowledge
- AI Solution
 - Agentic AI combined with enterprise knowledge base for inspection plans and training content
- Results
 - Inspection planning time reduced by 75%
 - Improved knowledge retention and consistency across shifts

Choosing the Right AI Tool for Your QMS

Tool	Best For	Integration Strength	Security
Microsoft Pilot	Office + Teams users	Excellent	High
Claude	Complex document work	Good	High
Grok	Technical & Creative Tasks	Excellent	Enterprise
ServiceNow	Enterprise workflow	Excellent	Enterprise

Library of Prompts

- Click the download link to access the file
- They are arranged by ISO clause

Module 5

Challenges, Ethics & Compliance

AI in QMS: Risk Matrix

- AI Risks in ISO 9001 Environments

Likelihood / Impact	Low	Medium	High
High	Hallucinations in procedures	Bias in supplier scoring	Data privacy breach
Medium	Outdated regulatory references	Explainability gaps	Over-reliance on AI decisions
Low	Minor formatting issues	Model drift	Inaccurate risk predictions

ISO 42001 & ISO 9001 Alignment

ISO 42001 (AI Management System) vs ISO 9001 Alignment

Annex SL Clause	ISO 9001 Focus	ISO 42001 Additional Focus	Integration Opportunity
4 Context	Interested Parties	AI stakeholders & ethical context	Combined context document
6 Leadership	Commitment	AI ethics & accountability	Joint policy statement
6 Planning	Risks & opportunities	AI-specific risks (bias, drift)	Unified risk register
8 Operation	Process control	AI lifecycle management	AI-assisted processes
9 Evaluation	Performance monitoring	AI performance & impact monitoring	Enhanced KPIs
10 Improvement	Continual improvement	AI model retraining & decommissioning	Close-loop improvement

Key Compliance Areas

Critical Compliance Topics

1. Data Privacy – Never input confidential or personal data into public AI tools
2. Bias & Fairness – Regularly test outputs for unintended bias
3. Explainability – Be able to show how AI reached a conclusion
4. Human Oversight – Maintain clear approval gates for all AI-generated outputs

Keeping AI Use Auditable

Maintaining Audit-Ready AI Usage

- Version control of all AI-generated documents
- Log prompts, tool used, date, and reviewer
- Clear approval workflow before release
- Periodic review of AI outputs for accuracy and relevance
- Document human oversight and validation steps

Module Summary & Best Practices

Key Takeaways

- AI introduces new risks that must be actively managed
- ISO 42001 integrates naturally with ISO 9001
- Human oversight and documentation are non-negotiable
- Responsible AI strengthens — rather than weakens — your QMS

Best Practice:

“Trust, but verify” every AI output

Thank you

- Take the exam for your certificate
- Come back to review any module
- 2 minute survey helps us