



ISO 9001: 2026 is Officially Here

What Changed, What It Means, and How ComplianceQuest Helps Organizations Prepare

From ISO 9001:2026 readiness to Connected Quality, Risk, and Compliance





Executive Summary

ISO 9001:2026 is the sixth edition of the world's most widely adopted quality management standard. Published in September 2026, it replaces ISO 9001:2015. The revision is an evolution rather than a reinvention, with greater emphasis or clarity in areas such as leadership and quality culture, ethical behavior, risks and opportunities, management of quality system changes, climate considerations, and the interpretation of requirements.

For organizations with an effective ISO 9001:2015 Quality Management System (QMS), the transition will not be a big stretch to evolve to the changes. You should focus first on understanding the revised requirements, identifying meaningful gaps, and determining where current practices need to mature. It also places the right perspective that the quality system should be for the customer, not just getting certified. A greater emphasis on quality outcomes are shaped by decisions involving suppliers, people, processes, risk, change, training, operations, and continual improvement. When the information behind those decisions is fragmented, the organization loses context and visibility.

This revision further supports the need for most organizations to expand their QMS to a Connected Quality, Risk, and Compliance, or Connected QRC. This addresses the challenge by bringing related disciplines and information together across the entire enterprise and value streams.

ComplianceQuest provides a cloud-based system that connects quality processes with risk management, supplier oversight, audits, training, document control, change, and continual improvement. This connected approach can help organizations address ISO 9001:2026 while building a QMS that reflects how the business actually operates.

For those in Life Sciences and have recently dealt with the new QMSR you may notice ISO 90001:2026 has focused on some of those changes. Specifically, they align on more emphasis on leadership and culture.



Understanding the Evolution of ISO 9001

The operating environment has changed considerably since ISO 9001:2015 was published. Supply chains are more complex and interconnected, organizations face new operational and geopolitical risks, experienced workers are retiring, and competition for specialized skills is increasing. At the same time, digital technologies and artificial intelligence are changing how work is performed and how decisions are made, while climate-related issues can affect suppliers, infrastructure, operations, and customers.

ISO 9001:2026 retains the familiar structure and principles of the 2015 edition but provides greater clarity in areas that influence how organizations lead and manage quality. The revision places stronger emphasis on leadership, quality culture, and ethical behavior; separates risks and opportunities more clearly; reinforces expectations for managing change; incorporates the climate considerations introduced through the 2024 amendment; and adds Annex A guidance on the intent and application of requirements.

Together, these refinements reinforce a practical point: an effective QMS is not simply a collection of procedures and records. It is a management system that connects people, processes, decisions, risks, evidence, and improvement across the organization.



Seven areas of refinement layered around a proven foundation, not a reinvention.

What Has Changed in ISO 9001:2026?

Area of emphasis	What it means for organizations
 Quality culture and ethical behavior	Leadership has a more explicit role in establishing and promoting a quality culture which now includes ethical behavior. Leadership must enable employees to understand how their work contributes to QMS effectiveness.
 Risks and opportunities	The revision separates risks from opportunities more clearly. Organizations need to consider what could prevent intended QMS results and what could improve performance.
 Management of change	Requirements for managing QMS changes are strengthened, reinforcing the need to consider purpose, potential consequences, resources, communication, implementation, and review for any changes to the QMS.
 Climate considerations	The climate considerations introduced through the 2024 amendment are incorporated. Organizations must determine whether climate change is relevant to their context and recognize related interested-party requirements.
 Organizational knowledge	The standard continues to emphasize the knowledge needed to operate processes and achieve intended QMS results, reinforcing the value of retaining and sharing critical knowledge.
 Expanded implementation guidance	A new Annex A adds guidance on the intent and application of requirements, supporting more consistent interpretation without adding requirements.
 Management system integration	Closer alignment with other ISO management system standards can make it easier for organizations to integrate quality with other management disciplines and existing enterprise management systems.

The result is not a fundamentally different ISO 9001. It is a more focused version of the management system organizations already know, with clearer expectations for how quality is led, how uncertainty and change are managed, and how the QMS responds to a changing business environment.

Quality Touches Everything

Most leaders know that Quality cannot be inspected into a product or service at the end of a process. It is shaped by the many decisions made throughout the organization. Supplier selection affects incoming quality; process changes can introduce new risks; training gaps can contribute to nonconformances; audit findings may expose systemic weaknesses; and customer complaints can reveal problems that began much earlier in the product or service lifecycle.

The difficulty is that the systems supporting these decisions are often disconnected. Quality may operate in one system, risk in another, supplier information somewhere else, training in a learning platform, documents in shared repositories, and important decisions in spreadsheets or email. Each process may appear to work independently, yet visibility is lost at the points where they intersect.

Effective QMS such as ISO 9001 must now be a connected QRC recognizes that quality, risk, and compliance are related disciplines. Risk influences decisions across the organization. Quality processes provide the clarity of what to maintain control of, evidence, and improvement mechanisms used to manage those risks. Compliance depends on the ability to show that requirements are understood, implemented, monitored, and effective. When quality, risk, and compliance information shares a connected data model, an organization can see relationships that are difficult to recognize when processes and data are managed in separate systems. ISO 9001:2026 gives organizations a timely reason to examine whether those connections are visible and working as intended.



What Organizations Should Do Now

Read the new revision from the ISO standard, not a third-party interpretation

Use the published ISO 9001:2026 standard rather than earlier drafts or summaries. Identify where requirements changed, were clarified, or received greater emphasis.

Perform a focused gap assessment

Compare current practices with the revised requirements, paying particular attention to leadership and culture, risks and opportunities, change, organizational context, climate considerations, and Annex A guidance. More than likely the gap will be with leadership and culture.

Examine how quality works across the business

Look beyond documented procedures to determine whether people across departments, locations, and suppliers can see the information and risks required for effective decision making.

Review the connection between quality and risk

Assess how risks relate to suppliers, processes, audits, nonconformances, Root Cause Analysis, CAPAs, changes, and improvement activities, and whether those relationships are visible to decision-makers.

Evaluate QMS change management

Review how changes are proposed, risk-assessed, approved, communicated, implemented, and checked for effectiveness. The test is not whether a process exists, but whether significant changes are consistently controlled.

Prepare people as well as documents

Identify affected roles and provide appropriate awareness and training, with specific attention to leadership expectations for quality culture and ethical behavior.

Verify readiness

Use internal audits, performance measures, management review, and corrective action processes to confirm that transition changes are operating as intended before the transition audit.



A practical, sequential path from final requirements to verified readiness.

ISO 9001:2026 Transition Readiness Path

Putting ISO 9001:2026 into Practice with Connected QRC



Building Quality into Everyday Work

Quality culture cannot be created by software, but technology can make it easier for people to follow established processes, understand responsibilities, access current information, complete required training, escalate problems, and participate in improvement.

ComplianceQuest connects controlled documents, training, audits, quality events, CAPAs, changes, and improvement activities in a common environment. Leaders gain a more practical way to turn quality policy and expectations into consistent everyday practice.



Connecting Quality and Risk

The clearer treatment of risks and opportunities creates an opportunity to move beyond a static risk register. In ComplianceQuest, risks can be associated with processes, suppliers, audits, quality events, corrective actions, and other operational activities. A supplier issue, for example, can be assessed for risk, linked to corrective action, evaluated against supplier performance, and reviewed for recurrence.

Connected QRC provides the context needed to understand not only that an event occurred, but how it relates to risk, quality performance, compliance obligations, and future decisions.



Managing Change with Greater Control

ComplianceQuest supports structured change processes that can include impact assessment, risk evaluation, configurable approvals, implementation activities, document updates, training assignments, and effectiveness review.

Connecting these activities provides traceability from the reason for change through implementation and verification, helping organizations reduce the likelihood that change creates unintended quality or operational consequences.



Strengthening Supplier Quality and Operational Resilience

Organizations increasingly depend on suppliers, contract manufacturers, service providers, and other external partners. A supplier issue can quickly affect quality, customers, production, or continuity.

ComplianceQuest brings supplier qualification, audits, performance monitoring, supplier corrective action, and supplier risk management together with the broader QMS. The value is not simply better supplier records, but earlier visibility into supplier conditions that could affect quality, risk, compliance, or operations.



Preserving Organizational Knowledge

When experienced employees retire, change roles, or leave, organizations risk losing more than documents. They can lose the decisions, investigations, corrective actions, audit history, training, and lessons learned that explain how the QMS operates.

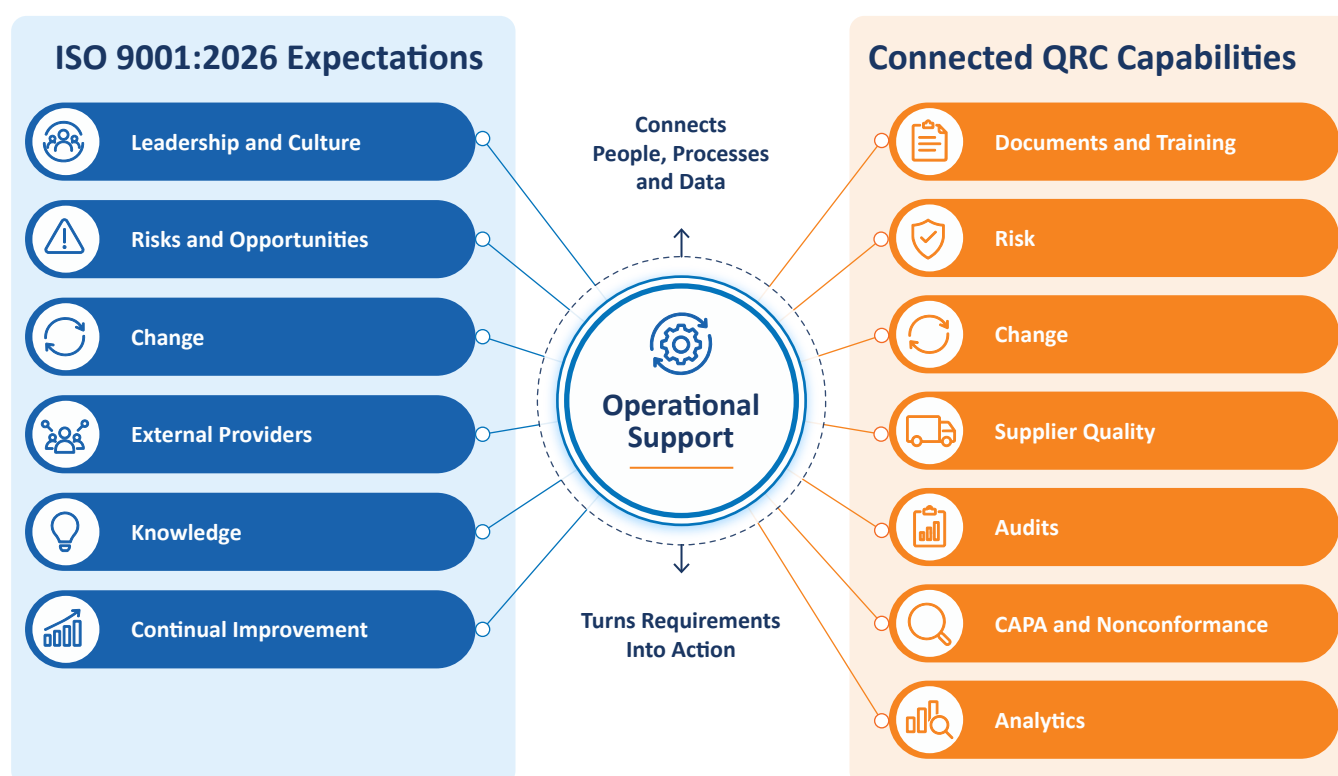
ComplianceQuest brings these records into a connected environment, allowing quality history to become part of the organization's institutional knowledge rather than remain scattered across systems, spreadsheets, shared drives, and inboxes.



Turning Audits and Quality Events into Improvement

Continual improvement depends on understanding relationships across QMS data. An audit finding may relate to earlier nonconformances; a CAPA may address a risk identified elsewhere; repeated supplier issues may reveal a trend; and a change may solve one problem while introducing another.

ComplianceQuest connects audits, findings, nonconformances, CAPAs, risks, changes, and effectiveness reviews, with analytics that help identify patterns. The point is not simply to close records. It is to understand what those records are telling you about the organization.



Operational support for what the standard expects, not a one-to-one compliance checklist.

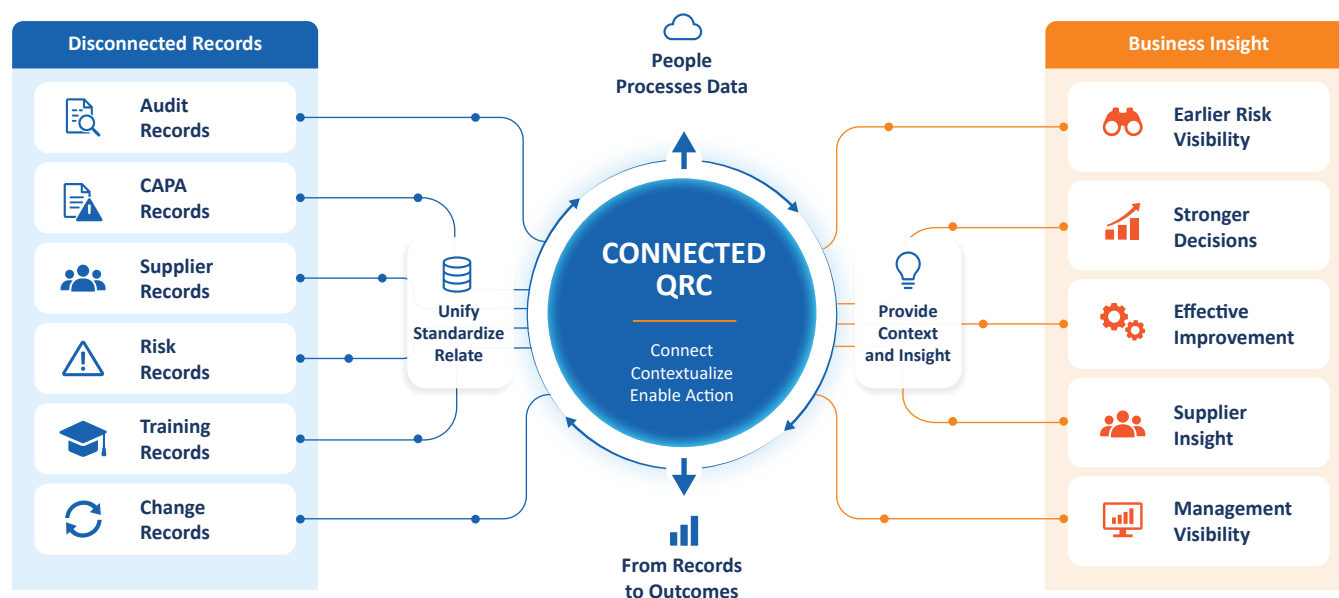
From ISO 9001:2026 Expectations to Connected QRC Capabilities

Beyond Certification: The Connected QRC Opportunity

Most organizations will begin with a practical question: what is required to move from ISO 9001:2015 to ISO 9001:2026?

That question matters, but the transition also creates an opportunity to evaluate whether the QMS provides the visibility and insight the business needs. Leaders should be able to see emerging quality risks, understand the potential business impact of supplier issues, determine whether corrective actions prevent recurrence, assess the quality and risk implications of change before implementation, reuse lessons from audits and investigations, and make management review a source of insight rather than a compliance exercise.

These questions go beyond certification because they address how effectively the organization manages quality. **Quality, risk, and compliance have often been supported by separate processes, systems, and organizational structures.** Connecting them makes relationships visible that are difficult to identify when information remains fragmented. ISO 9001:2026 does not require a Connected QRC platform, but its emphasis on leadership, risk, change, context, knowledge, evidence, and continual improvement makes those connections increasingly valuable.



Connected records become insight; results depend on how the platform is used.

Beyond Certification: From QMS Records to Business Insight



Conclusion

ISO 9001:2026 updates a proven standard for the environment in which organizations now operate. Its stronger focus on leadership and quality culture, clearer treatment of risks and opportunities, reinforced approach to change, climate considerations, and expanded guidance reflect the continued evolution of quality management. Organizations with an effective ISO 9001:2015 QMS should begin by understanding the changes, assessing their effect on current processes, and identifying where practices need to mature.

The larger opportunity is to examine whether the QMS is connected to the decisions that shape business performance. Decisions about people, suppliers, processes, risk, change, and improvement ultimately influence the quality of products and services. Quality, risk, and compliance therefore cannot deliver their full value when they operate as disconnected disciplines.

Connected QRC brings those relationships together. ComplianceQuest connects quality management, risk, supplier quality, audits, training, document control, change, and continual improvement so organizations can see how decisions and events in one area affect another. That can help organizations address ISO 9001:2026 while building a management system that reflects how the business actually operates. The goal is not simply to update a certificate, but to use the transition to answer a more important question: Is the QMS helping the organization run better?

Ready to Move Beyond ISO 9001:2026 Readiness?

ISO 9001:2026 is an opportunity to do more than prepare for your next audit. See how a Connected QRC approach can help bring quality, risk, suppliers, people, processes, and compliance together so your organization has the context and visibility to make better-informed decisions.



[See Connected QRC in Action](#)

Talk with a ComplianceQuest quality expert about your ISO 9001:2026 transition and Connected QRC strategy.

Trusted by Global Teams. Proven with ROI

-80%



Cost of IT Infra
Management

-37%



CAPA raised per Year

-48%



Cost of Quality

-50%



Change Request

-24%



Cost of Labor

+54%



Employee Engagement

-32%



Customer Complaints

-70%



Employee Training Time

-46%



Audit Findings

+37%



Customer Satisfaction



About ComplianceQuest

ComplianceQuest is the #1 AI-powered Quality, Risk, and Compliance (QRC) system that connects Product, Quality, Manufacturing, People, Suppliers and Customers in a single system. Built on Salesforce, the system delivers end-to-end visibility, AI-driven intelligence, and enterprise-scale execution, enabling organizations to manage risk, ensure regulatory compliance, and turn quality into a driver of growth.



ComplianceQuest is pre-validated and easy to implement, use, and maintain, allowing for streamlined communication and collaboration across the product value chain.

For more information, or to request a demo with a ComplianceQuest Expert, contact us today:

- Visit www.compliancequest.com
- Email us at marketing@compliancequest.com
- Call us at **408-458-8343**

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