ISO 9001: ultimate guide to the core quality management standard
If you want to establish a holistic and functional quality management system from scratch, ISO 9001:2015 is the perfect place to begin.

ISO 9001 lays out the core fundamentals of the modern QMS, and the key ingredients for providing products and services that consistently meet the requirements of your customers.

By itself, ISO 9001 compliance won’t provide the niche life science quality management requirements needed for a medical device, pharmaceutical or therapeutic business.

But it will give you the foundational groundwork upon which all your QMS activity is built. Crack ISO 9001, and your business is empowered to move onto any other quality standard – and be recognized as an established, quality-conscious organization as you do so.

Kelly Stanton
Director of Quality, Qualio
Why ISO 9001?

1. Bring quality and continuous improvement into the heart of your business
2. Align your business
3. Secure leadership commitment to quality
4. Harness opportunities as well as risks
5. Establish a business-wide governance and quality tool
6. Boost profitability
7. Leverage an integrated regulatory approach through Annex SL

qualio.com/resources/annex-sl-guide
The case for a robust QMS

Ireland’s thalidomide survivors: ‘The State is only waiting for us to die’

People affected by drug linked to birth defects have called for ‘an apology and a fair deal’

© Mon, Dec 6, 2021, 06:01

June Shannon

Arrow International, LLC (Subsidiary of Teleflex Inc.) Recalls the Arrow-Thrombota Percutaneous Thrombolytic Device Due to Risk of Tip Damage During Use

Thalidomide survivor Maggie Woods lays a white rose outside the Dáil to mark the 40th anniversary of the withdrawal of the drug from international markets in November 1961. Photograph: Fran Veale/Julien Behal Photography

“We are now 60 years of age. As the years go on we are left with the impression that the State is only waiting for us to die, without any intention of meeting with us or coming up with a fair and just settlement.” – Jacqui Browne, Irish thalidomide survivor.

Medtronic Recalls MiniMed Insulin Pumps for Incorrect Insulin Dosing

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injury or death.

Recalled Product

- MiniMed™ FreeStyle Insulin Pumps
- Lot numbers: Refer to the Medical Device Recalls Database entry for each product.
- Distribution Dates:
  - Model 502D - September 2020 to February 2023
  - Model 506D - May 2021 to December 2021

June Shannon

Sackler owners offer up to $6bn to settle Purdue Pharma bankruptcy

Proposal revealed by court mediator comes after a judge rejected earlier deal
How long will implementation take?

The length of your ISO 9001 journey will be unique to you. It will be impacted by:

1. The range of products and services you offer
2. The complexity of the processes you operate
3. The complexity of your supply chain
4. The diversity of your relevant interested parties’ requirements
5. Your starting point: how mature is your current QMS?
6. Your current culture: how quickly can you drive the required changes through?
The seven-year switch: what changed between 2008 and 2015?
Core principles of ISO 9001:2015

1 — Adoption of a quality management system as a strategic organizational tool to:

- Consistently provide products and services that meet customer, statutory and regulatory requirements
- Demonstrate conformity to specified QMS requirements
- Address opportunities to enhance customer satisfaction
- Address both risks and opportunities associated with context, objectives and strategic direction of your business

2 — Embedding of quality management principles:

- Customer focus
- Leadership
- Engagement of people
- Process approach
- Continuous improvement
- Evidence-based decision making
- Risk-based thinking

3 — Implementation of the process approach:

- Incorporating the Plan-Do-Check-Act cycle for repeatable interacting processes

4 — Relationship with other management system standards:

- Annex SL: for consistency
- Aligns with other ISO standards for better integration
4. Context

The context of the QMS and how your business strategy supports this. Clause 4 determines why your organization is here.

A. Understanding the organization and its context (new requirement!)
B. Understanding the needs and expectations of interested parties (new requirement!)
C. Determining the scope of the management system
D. The management system

2. Normative References

Provides details of the reference standards or publications relevant to the particular standard.

3. Terms & Definitions

Details terms and definitions applicable to the specific standard in addition to any formal related terms and definitions standard. Main changes from ISO 9001:2008:

- Risk
- Innovation
- Management responsibility › Leadership
- Purchasing and outsourcing › Externally provided processes, products and services
Clause breakdown

5. Leadership

Concerns the role of “top management”: the group of people who direct and control your organization at the highest level.

A. Leadership and commitment (new requirement!)
B. Policy
C. Organizational roles, responsibilities, and authorities: Enhanced requirement

6. Planning

How your organization plans actions to address both risks and opportunities.

1. Actions to address risks and opportunities
2. Management system objectives and planning to achieve them
3. Planning of change
Clause breakdown

7. Support
Get the right resource to the right people and the right infrastructure in place
A. Resources
B. Competence
C. Awareness
D. Communication
E. Documented information

8. Operation
How to meet customer requirements and execute plans and processes. Consider risks associated with a product or service, customer requirements, customer feedback, and any statutory requirements.
A. Operational planning and control
B. Requirements for products and services
C. Design and development of products and services
D. Control of externally provided processes, products and services
E. Production and service provision
F. Release of products and services
G. Control of non-conforming output

9. Performance evaluation
Measure and evaluate your QMS to ensure that it is effective and to determine what, how and when things are to be monitored, measured, analyzed and evaluated.
A. Monitoring, measurement, analysis and evaluation
B. Internal audit
C. Management review

10. Improvement
Determine and identify opportunities for continual improvement of the QMS
A. Non-conformity and corrective action
B. Continual improvement
The ingredients of an ISO 9001 QMS
It can be sensible to work your way through each clause one a time, using the structure of ISO 9001 itself as a guiding step-by-step ‘checklist’.

Clauses 2 and 3 are reference and guidance clauses and require no action from you.

Clause 1, ‘Scope’, and Clause 4, ‘Context’, can form a useful interacting first step as follows.
Clauses 1 & 4: Scope & context

1. Define the context of your business with a SWOT and PESTLE analysis
2. Identify, monitor and review internal and external factors that impact the business, including your interested parties
3. Define who and what is relevant to the QMS
4. Use this information to set the scope and boundaries of your QMS
5. Plan, control and operate your QMS processes – with mechanisms for measuring, maintaining and improving them
6. Document plans, procedures, checklists, processes
7. Demonstrate planned process operations align with actual results
Context of the organization

Clause 4.1: Understanding the organization and its context.

- Identify, monitor, and review external and internal issues that are **relevant** to your QMS’ **purpose** and **strategic direction**

- What has the ability to impact the quality management system’s intended results?

![Diagram showing the flow of internal issues, external issues, interested parties, and regular review and monitoring.]

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**Internal issues** → **External issues** → **Interested parties** → **Regular review and monitoring**
**Internal issues**

Continually identify, monitor and review internal issues, such as:

- Strategies to conform to your policies and achieve your objectives
- Relationship with your staff and stakeholders, including partners and suppliers
- Resources and knowledge (capital, people, processes and technologies)
- Risk appetite
- Assets
- Product/service
- Standards, guidelines and models adopted by the organization
- Information systems
External issues

Continually identify, monitor and review external issues such as social, technological, environmental, ethical, political, legal and economic environment.

May include:

- Demand for your product
- Government regulations and changes in the law
- Economic shifts in your market, such as exchange rates
- Your competition
- Events that may affect your corporate image
- Changes in technology
How can you determine your internal/external issues?

- Strengths, weaknesses, opportunities, threats (SWOT)
- Political, economic, social, technological, legal and environmental factors touching your business (PESTLE)

**Strengths**
- Expertise
- Reputation
- Culture of excellence, engaged teams
- Quality management system
- Loyal customer base

**Weaknesses**
- Outdated/inaccurate documented info
- Risk training
- Innovation
- Silos
- Poor IT infrastructure
- Manual QMS

**Opportunities**
- Diversification
- Market penetration
- Standards
- Outsource risk
- Business continuity management
- Physical security
- Malware protection

**Threats**
- Competitors
- Regulations
- Supply chain buying power
- Value of dollar
- Substitute products
- Bargaining power of buyers
Interested parties

Continually identify, monitor and review the needs and expectations of interested parties who have the ability to impact the organisation’s ability to consistently supply products and services that meet customer and applicable statutory and regulatory requirements.

May include:

- Customers
- Suppliers
- Shareholders
- Board members
- Staff
- Competitors
Regular review and monitoring

Document planned process operation and show it is in line with the actual operation.

May include:

- Plans
- Procedures
- Checklists
- Standards
- Menus
- Websites
- Designs
- Evidence
Clause 5: Leadership

1. Clearly organize and structure your operational hierarchy with clear roles and responsibilities
2. Demonstrate leadership commitment to quality
3. Ensure customer, statutory and regulatory requirements are understood, systematized and met
4. Communicate quality policy and QMS requirements
5. Identify vulnerabilities and issues
6. Enhance customer satisfaction
7. Set and review short-, medium- and long-term objectives
Role of leadership

Leadership needs to ensure that responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization.

Leaders need to ensure the integrity of the ISO 9001 quality management system is maintained when changes are planned and implemented.

It is management’s responsibility to ensure these tasks are planned, implemented and achieved.
Cascading roles & responsibilities

As a process owner

I must document and manage our processes thoroughly

So that risks and opportunities are well managed

As a technology owner

I must document changes to procedures

So that I can be confident we are compliant

As a manager

I must encourage my team to talk about risk, quality and improvement opportunities

So that everyone engages with our ISO 9001 system
Get your leaders involved in your ISO 9001 activities

Do your leadership team...

- Inform everyone of the importance and benefits of a certified QMS?
- Tell everyone why they should participate in its effective implementation?
- Ensure the quality policy and objectives are compatible with the strategic direction and context of your organization?
- Promote risk-based thinking in respect of the organization's quality management system?
- Make sure the management system achieves its intended outcome?
- Ensure there are adequate resources to maintain the quality management system?
- Ensure the effectiveness of the quality management system?
Clause 6: Planning

1. Establish processes for systematically managing risk, embedding risk-based thinking and following a risk-based approach

2. Set and measure quality objectives for functions, processes and levels within the QMS

3. Ensure the integrity of the QMS is preserved as changes happen
Quality incidents are usually preventable - planning is key!

Source: Association of Insolvency & Restructuring Advisors
Clause 7: Support

1. Control, measure and monitor infrastructure and equipment
2. Capture, preserve and maintain internal knowledge
3. Identify and fix competency deficiencies
4. Communicate to internal and external stakeholders the consequences of non-conformance with the QMS
5. Control the creation and updating of information streams, including documentation
Train train train!

- Get a mechanism in place for training staff on processes and confirming understanding
- Check the training completion rate for each and every process
- Ensure training records are maintained with integrity like any other QMS documentation
Clause 8: Operation

1. Control inputs, outputs, resources and controls
2. Review requirements related to product and service delivery
3. Measure output
4. Control the design and development of your products and services
Customer centricity is key: let requirements distill into your processes

- Requirement A
- Requirement B
- Requirement C
- Requirement D
Clause 9: Performance evaluation

1. Continually monitor and measure performance
2. Perform thorough and frequent audits and management reviews
3. Report performance in a consistent, actionable way
Set a handful of ‘North Star’ KPIs for Clause 9 - and stick to them!
Business process KPI examples

- % of processes where completion falls within +/- 5% of the estimated completion
- Sum of costs of “killed”/stopped active processes
- Average process age
- Average process overdue time and % of overdue processes
- % of processes where assigned resources exceeds planned number
- Average time to complete tasks
- Defects and NCRs
Service quality KPI examples

- Cycle time from request to delivery
- Complaint resolution time
- Number of escalations
- Number of reminders
- Number of alerts
- Customer feedback (NPS)
- Number of customer complaints
- Number of late tasks
Compliance KPI examples

- Internal and external audit non-conformances
- NCR resolution time
- Frequency of compliance reviews (audits/inspections) per quarter
- Quality standards
- Quality management department budget
- Cost of poor quality (COPQ)
Clause 10:
Improvement

1. Actively seek and realise improvement opportunities
2. Address issues and resolve them
3. Correct and control non-conformances
Build ‘As-Is’ into your ISO 9001 audit program

**AS IS**
- How are current processes executed?
- Where are the areas of weakness/variation?
- What is working well and why?

**TO BE**
- How can processes be improved? How can steps, systems and tasks be minimized?

**TO DO**
- Which SOPs, policies and instructions need to be created?
- How will staff be trained?
(Use subsequent audits to check progress.)
All together now...

Quality Management System (4)

Support & operation (7,8)

ISO 9001:2015

Planning (6)

Performance evaluation (9)

Improvement (10)

Plan

Do

Act

Check

Customer satisfaction

Results of the QMS

Product & services

Organization and its context (4)

Customer requirements

Needs and expectations of relevant interested parties (4)
Use the ISO 9001 checklist in your toolkit for an even more detailed step-by-step requirement list!
The importance of risk in ISO 9001
## Where does ISO 9001 talk about risk?

<table>
<thead>
<tr>
<th>Clause</th>
<th>Risk focus</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clause 4: Context</td>
<td>Determine the processes required for operation of the quality management system and the risks and opportunities associated with these processes</td>
</tr>
<tr>
<td>Clause 5: Leadership</td>
<td>Top management must ensure that the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed</td>
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<tr>
<td>Clause 6: Planning</td>
<td>To give assurance that the quality management system can achieve its intended results, prevent or reduce, undesired effects and achieve continual improvement</td>
</tr>
<tr>
<td>Clause 8: Operation</td>
<td>The organization is required to implement processes to address risk and opportunities</td>
</tr>
<tr>
<td>Clause 9: Performance evaluation</td>
<td>The organization is required to monitor, measure, analyse and evaluate risk and opportunities</td>
</tr>
<tr>
<td>Clause 10: Improvement</td>
<td>The organization is required to continually improve processes whilst responding to changes in risks and opportunities</td>
</tr>
</tbody>
</table>
Risk-based thinking:

Determine, consider, and take action to address any risks and opportunities that impact your organization’s ability to deliver its intended results
The risk-based approach to ISO standards

Risk-based thinking:

- Improves governance
- Establishes a proactive culture of improvement
- Assists with statutory and regulatory compliance
- Assures consistency of quality of products and services
- Improves customer confidence and satisfaction
Meeting ISO 9001’s risk-based demands
Risk stakeholders: what do they do?

**Understanding** — Risk stakeholders should strive to understand the risks which are being discussed.

**Informing** — Risk stakeholders may be required to provide specialist information to other stakeholders.

**Identifying** — Risk stakeholders may help to identify risk.

**Providing** — Some stakeholders may be expected to provide the necessary resources for the chosen action plan.

**Training** — If an action plan requires education of staff or customers, someone must carry out the training.

**Communicating** — Information may need to be widely spread as part of the risk management process.

<table>
<thead>
<tr>
<th>External examples</th>
<th>Internal examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Government</td>
<td>Contractors</td>
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<tr>
<td>Authorities</td>
<td>Business partners</td>
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<tr>
<td>Regulators</td>
<td>Management</td>
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<td>Customers</td>
<td>Quality &amp; compliance</td>
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<tr>
<td>Trade bodies</td>
<td>Health &amp; safety</td>
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<tr>
<td>Emergency services</td>
<td>Risk management teams</td>
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<td>Staff dependents</td>
<td>Business development</td>
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<td>Competitors</td>
<td>Marketing</td>
</tr>
<tr>
<td>Suppliers</td>
<td>HR</td>
</tr>
<tr>
<td>Business owners</td>
<td>Finance</td>
</tr>
<tr>
<td>Bankers/investors</td>
<td>Purchasing</td>
</tr>
<tr>
<td>Business partners</td>
<td>Facilities &amp; estates</td>
</tr>
<tr>
<td>Contractors</td>
<td>Manufacturing</td>
</tr>
<tr>
<td>Procurement</td>
<td>Manufacturing</td>
</tr>
</tbody>
</table>

*Qualio*
Make a repeatable, business-wide framework for managing risk
How to assess risks in your ISO 9001 QMS

- Establish & maintain risk criteria
- Risk acceptance criteria
- Asset inventory
- Causes & sources of risk
- Identify risks
- Identified risks
- Risk owners
- Analyze the risks
- Determined level of risk based on consequences & likelihood
- Evaluate risks
- Risks prioritized for treatment
- Documented information of risk assessment process
How to treat risks in your ISO 9001 QMS

1. Risks prioritized for treatment
   - Select appropriate risk treatment options
   - Determine all controls necessary to implement risk treatment options
   - Compare controls with controls in Annex A to verify that no necessary controls have been omitted
   - Produce statement of applicability
   - Formulate risk treatment plan
   - Obtain risk owner’s approval
   - Justification for inclusion (all controls)
   - Justification for exclusion (Annex A)

2. Controls from other sources
   - Designed controls

3. Annex A

4. Risk owners

5. Documented information of risk treatment plan

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*Source: [Qualio](https://www.qualio.com)*
Look beyond ISO 9001 for risk inspiration...

- ISO 31010 (general supporting standard to ISO 31000)
- ISO 14971 (medical devices)
- ICH Q9 (pharmaceutical)
- Failure mode and effect analysis (FMEA)
- HAZOP
- Cause and effect analysis
- Delphi technique: structured, interactive forecasting
- Scenario analysis
- Root cause analysis
- Risk indices
- Cost/benefit analysis
... and ensure that your risk-based activities:

- Enable your quality and compliance activities to be met
- Are straightforward and logical without overt complication
- Are cost-effective
- Give consistent, repeatable results
- Are applied uniformly across functions that share risks
- Are underpinned by documentation, training and support
What are the top risks to your ISO 9001 QMS journey?

1. Making inappropriate adjustments
2. Underestimating the extent of required changes
3. Insufficient support from top management
4. Insufficient effort in planning your transition
5. ‘Business as usual’ suffers while you’re focused on getting accredited
6. Acting on bad advice from your consultant/certification body
7. Disengaged colleagues
8. Failing to communicate intentions/benefits to your stakeholders
9. Leaving it too late
10. Lack of resources: personnel, budget, manual legacy quality approach which complicates compliance
Building your ISO 9001 QMS
Implementing the process approach

“Consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes that function as a coherent system.”

— Introduction to ISO 9001:2015

Clause 4.4, ‘the QMS and its processes’, strongly suggests the adoption of a process approach for building and maintaining your ISO 9001 quality management activities.

The process approach focuses on how your QMS processes interlink and impact each other, and coordinating them into an ‘integrated and complete system’ underpinned by Plan Do Check Act.

Read more about the process approach in ISO/TC 176, ‘Guidance on the concept and use of the process approach for management systems’.
Why do we need a process approach?

- Organizations are typically structured into departments which are managed by a department head.
- The head is responsible for what comes out of the department.
- Most departmental heads never interact with the customer, only internal stakeholders.
- As such, they are divorced from how the ultimate customer really feels.
- If KPIs are set by department this compounds the problems.
- Heads will try to maximize the performance of their departments to the possible detriment of other departments further down the line.
Most enterprises are organized by functions – sales, marketing, operations, maintenance, engineering, finance – that are managed independently.

Functions are typically islands of competency ruled by jealous kings, populated by antagonistic armies and separated by shark-filled seas.

These disconnects are a significant weakness.

John S. Mitchell,
Operational excellence: journey to creating sustainable value
A better way of working

The process approach introduces horizontal management, controlling processes which flow across departmental boundaries:

- Someone is accountable for the process from start to finish.
- They understand what the stakeholders in the process want and have delegated authority to act to realize this.
- First loyalty is to their assigned projects, products or services, not their own departments.

“Quality people are the needle and thread stitching the whole end-to-end together.”

<table>
<thead>
<tr>
<th><strong>01</strong></th>
<th>Involve staff in building the process-based QMS, including the initial definition of processes and subsequent P-D-C-A steps</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>02</strong></td>
<td>Train individuals so they understand their roles and accountabilities in respect of the core processes</td>
</tr>
<tr>
<td><strong>03</strong></td>
<td>Ensure staff see their processes end-to-end</td>
</tr>
<tr>
<td><strong>04</strong></td>
<td>Restructure the audit program around processes, not functions</td>
</tr>
<tr>
<td><strong>05</strong></td>
<td>Train auditors to follow processes across departments, paying particular attention to interdependencies and interactions</td>
</tr>
<tr>
<td><strong>06</strong></td>
<td>Provide documented information to support the operation of processes</td>
</tr>
<tr>
<td><strong>07</strong></td>
<td>Test your processes are effective</td>
</tr>
<tr>
<td><strong>08</strong></td>
<td>Rebrand your processes</td>
</tr>
</tbody>
</table>
Where should I start?

- Focus on your core processes: the ones which keep you awake at night.
- Ask yourself which processes play a significant role in ensuring:
  - You are constantly providing products and services which meet customer, statutory and regulatory requirements
  - You are enhancing customer satisfaction

1. Change management
2. Risk management
3. Incident management
4. Documentation
5. Compliance
6. Governance
7. Feedback
8. New supplier
9. Equipment management
10. Customer onboarding
11. Audit
12. Data retention
13. Competence management
An example from our own quality manual
Auditing your ISO 9001 system: questions to ask yourself

Have we determined the external and internal issues that are relevant to our business and its strategic direction?

Have we determined the inputs required and outputs expected from our QMS processes?

Have we determined the quality risks and opportunities that need to be addressed?

Have we considered the purpose of any changes to the QMS and their potential consequences?

Have we determined the knowledge necessary for the operation of our processes?
Auditing your ISO 9001 system: questions to ask yourself

Does the QMS scope exist as documented information? Are exclusions recorded and justified?

How are top management demonstrating a hands-on approach to the management of our quality management system?

Where is there evidence that top management have created the quality policy and are implementing and maintain it?

Where is there evidence that top management have assigned responsibility and authority for preserving the integrity of our organization’s quality management system?

How are we applying a systematic methodology for consistently and effectively determining risks and opportunities?
Auditing your ISO 9001 system: questions to ask yourself

How are leadership demonstrating commitment to the quality management system?

How are we ensuring processes are managed, not procedures?

Have groups or individuals been identified and their relevant requirements been documented?

Who assigns process owners?

How are we managing the required inputs / expected outputs for each process?

How have process risks and opportunities been addressed?

How are we monitoring and measuring process performance?
# ISO 9001 blockers

<table>
<thead>
<tr>
<th>Blocker</th>
<th>Solution</th>
</tr>
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<tbody>
<tr>
<td>No direct line to leadership</td>
<td>Secure access to the executive team by pushing for quality presence at board meetings, through an appointed quality director or at least a dedicated quality representative. In larger organizations, the executive team focus is on commercial effectiveness and productivity without necessarily addressing the link between implementation of an effective quality management system and operational performance. Be clear what you want leadership to do.</td>
</tr>
<tr>
<td>Leadership sees quality as a cost</td>
<td>Demonstrate how quality improves customer and patient experience and reduces churn. Introduce quality awareness programs.</td>
</tr>
<tr>
<td>Not speaking the language of the business</td>
<td>Train all quality staff on the broader commercial and patient impacts of their work. Ensure quality-specific language is only used within and between members of the quality department.</td>
</tr>
<tr>
<td>Not knowing who is engaging with quality</td>
<td>Move away from manual paper-based quality management and consider a digital eQMS that unlocks data about engagement with and awareness of quality, such as document acknowledgements and completed training.</td>
</tr>
</tbody>
</table>

# ISO 9001 blockers

<table>
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</tr>
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<tr>
<td>Different objectives / drivers</td>
<td>Couple the Voice of the Customer (VoC) with management engagement initiatives. For instance, complaint trends and subsequent CAPA plans might be used to fulfil a quarterly management objective or get closer to a company BHAG.</td>
</tr>
<tr>
<td>Lack of tangible objectives</td>
<td>Raise awareness of quality and centralize all quality initiatives. If no other objectives exist, continuous improvement of the business by optimizing your QMS will always exist as a operational goal for any business.</td>
</tr>
<tr>
<td>No single source of truth</td>
<td>Pull your quality data into a single area, ideally in a controlled digital repository. Use a centralized quality platform as a place to access and interrogate company-wide data and take action accordingly.</td>
</tr>
<tr>
<td>Not communicating</td>
<td>Schedule weekly and monthly meetings demonstrating ISO 9001 objectives and results. Emphasize quality successes as much as shortcomings and failures.</td>
</tr>
<tr>
<td>Talking the language of leadership</td>
<td>Many senior management figures appreciate a certificate on the wall. Tap into this desire and use to your advantage. Explain how to use the ISO 9001 standard to benefit the company (not the certification body).</td>
</tr>
<tr>
<td>Lack of accountability</td>
<td>Use layered process audits driven by top management so they can see real acts of non-compliance in day-to-day activity.</td>
</tr>
<tr>
<td>Defining leadership</td>
<td>Have confidence in the value and importance of your role as a quality professional and sharpen your leadership skills. Leadership books, quality and compliance blogs and industry updates will all help keep you in the know with clear objectives.</td>
</tr>
</tbody>
</table>
# Conclusion: some top tips from the Qualio quality team

## Common ISO 9001 challenges

- Managing expectations
- Ensuring leaders lead
- Combatting unrest and addressing queries
- Sufficient resource allocation
- Ongoing success
- Amount of documentation
- Managing outsourced services
- Handling audits

## Tips

- Perform training & education
- Spend time to make the requirements clear
- Foster regular communication
- Measure the ROI
- Invest in a centralized quality system for monitoring/review
- Use an eQMS, not paper
- Structure your supplier base with robust quality agreements
- Make audits a natural, automatic part of the business culture with frequent internal audits
Connect teams to a single source of quality truth and build a living, robust eQMS.

See our quality management software in action today.

Request a demo