ISO 9001: ultimate guide to the core quality management standard

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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

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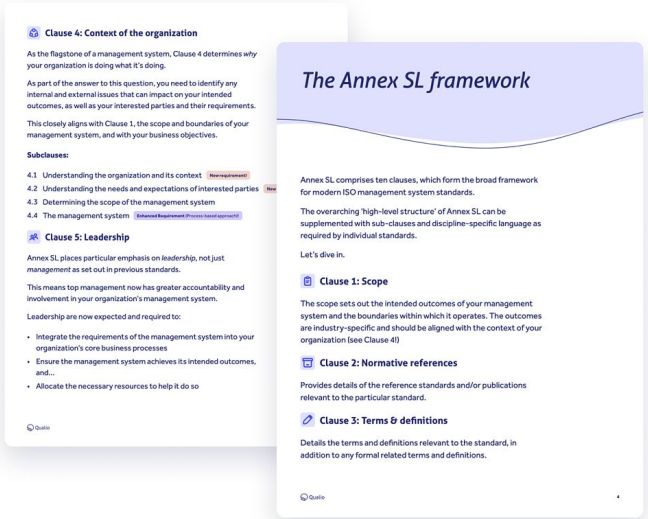
Why ISO 9001?

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

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The case for a robust QMS

U.S. FOOD & DRUG ADMINISTRATION

Home / Medical Devices / Medical Device Safety / Medical Device Recalls / Medtronic Recalls MiniMed Insulin Pumps for Incorrect Insulin Dosing

Medtronic Recalls MiniMed Insulin Pumps for Incorrect Insulin Dosing

Medical Device Recalls
2022 Medical Device Recalls
2021 Medical Device Recalls
2020 Medical Device Recalls

October 5, 2021 UPDATE: Medtronic updated this recall with information that Medtronic will replace any MiniMed™ 600 series insulin pump that has a clear retainer ring with one that has the updated black retainer ring at no charge. A replacement insulin pump will be provided even if the clear retainer ring is not damaged and regardless of the warranty status of the pump. If you have questions about this recall, call Medtronic's 24-Hour Technical Support line: 1-877-585-0166.

Content current as of: 10/05/2021
Regulated Product(s): Medical Devices

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

Recalled Product

- MiniMed™ 600 Series Insulin Pumps
- Lot codes: Refer to the Medical Device Recalls database entry for each product.
- Distribution Dates:
  - Model 630G - September 2016 to February 2020
  - Model 670G - May 2015 to December 2020

U.S. FOOD & DRUG ADMINISTRATION

Home / Medical Devices / Medical Device Safety / Medical Device Recalls / Arrow International, LLC (Subsidiary of Teleflex Inc.) Recalls the Arrow-Trerotola Percutaneous Thrombolytic Device Due to Risk of Tip Damage During Use

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

Content current as of: 02/23/2022
Regulated Product(s): Medical Devices

Recalled Product

- Product Names: Arrow-Trerotola Percutaneous Thrombolytic Device (PTD)
- Model Number: See Recall Database Entry
- Manufacturing Dates: January 1, 2020 to December 31, 2021
- Distribution Dates: February 1, 2020 to December 31, 2021
- Devices Recalled in the U.S.: 24,895

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

Thalidomide survivor Maggie Woods lays a white rose outside the Dáil to mark the 60th 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.

FINANCIAL TIMES

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US opioid epidemic + Add to myFT

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

Proposal revealed by court mediator comes after a judge rejected earlier deal

Purdue, maker of the painkiller OxyContin, filed for bankruptcy in New York in 2019 © REUTERS

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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?

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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:

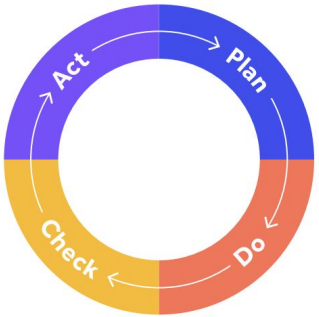
- Customer focus
- Leadership
- Engagement of people
- Process approach
- Continuous improvement
- Evidence-based decision making
- Risk-based thinking

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



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Clause breakdown

1. Scope

The scope sets out the intended outcomes of your management system. The outcomes are industry-specific and should be aligned with the context of your organization (Clause 4).

- Demonstrate ability to consistently supply products and services that meet customer and applicable statutory and regulatory requirements.
- “Output resulting from product realization” has been removed from ISO 9001:2008 to reflect changes to the definition of process and output.

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

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

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Clause breakdown

5. Leadership

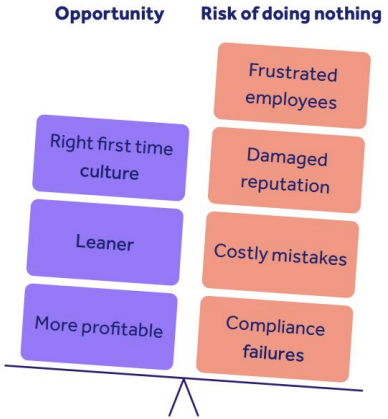
Concerns the role of “top management”: the group of people who direct and control your organization at the highest level.

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



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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

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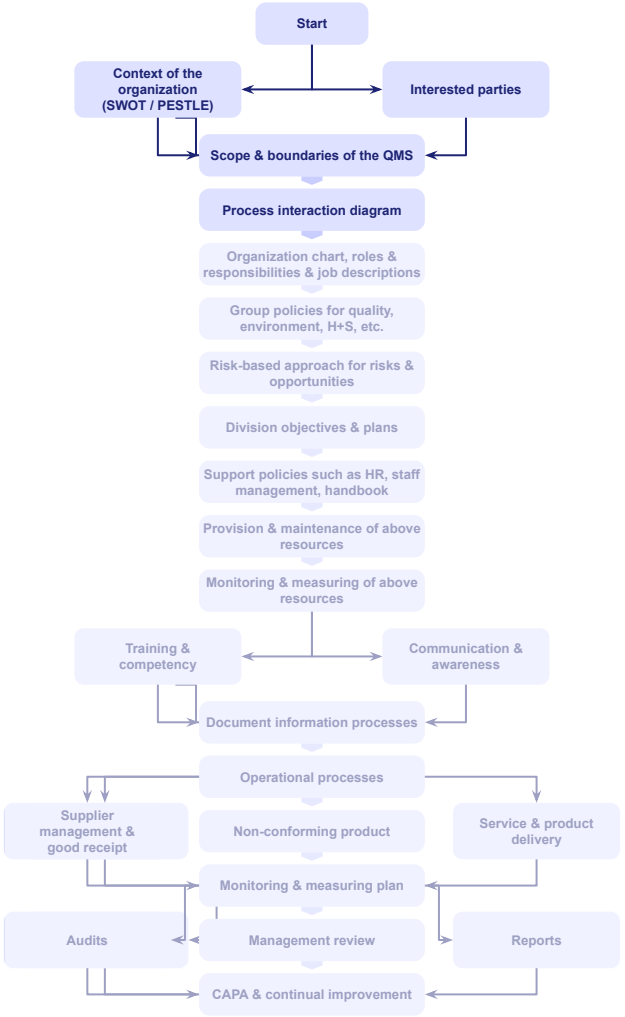
It can be sensible to work your way through each clause one a time, using the structure of ISO 9001 itself as a guiding step-by-step ‘checklist’.

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

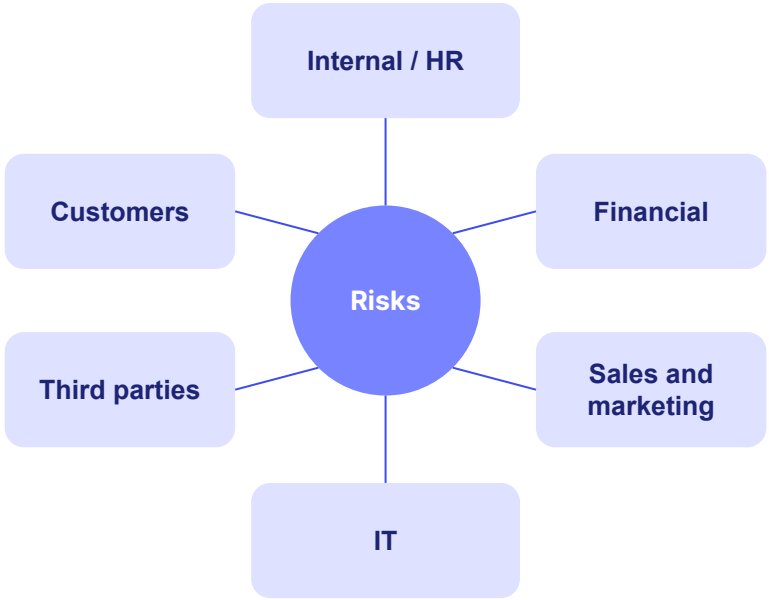
Clause 4.1: Understanding the organization and its context.

- 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?

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

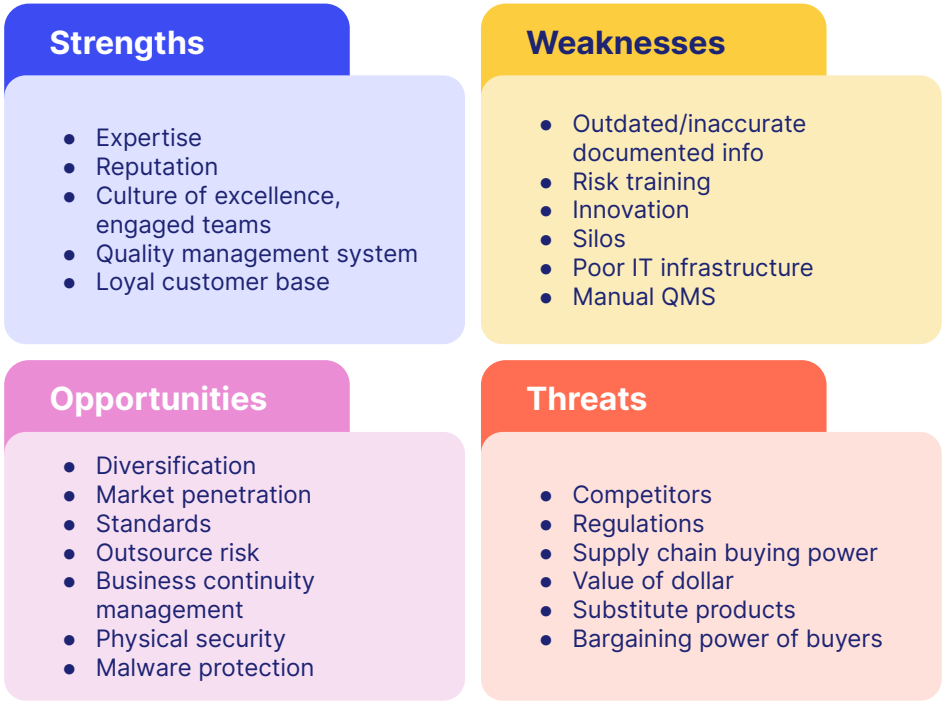
Continually identify, monitor and review external issues such as social, technological, environmental, ethical, political, legal and economic environment.

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)



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

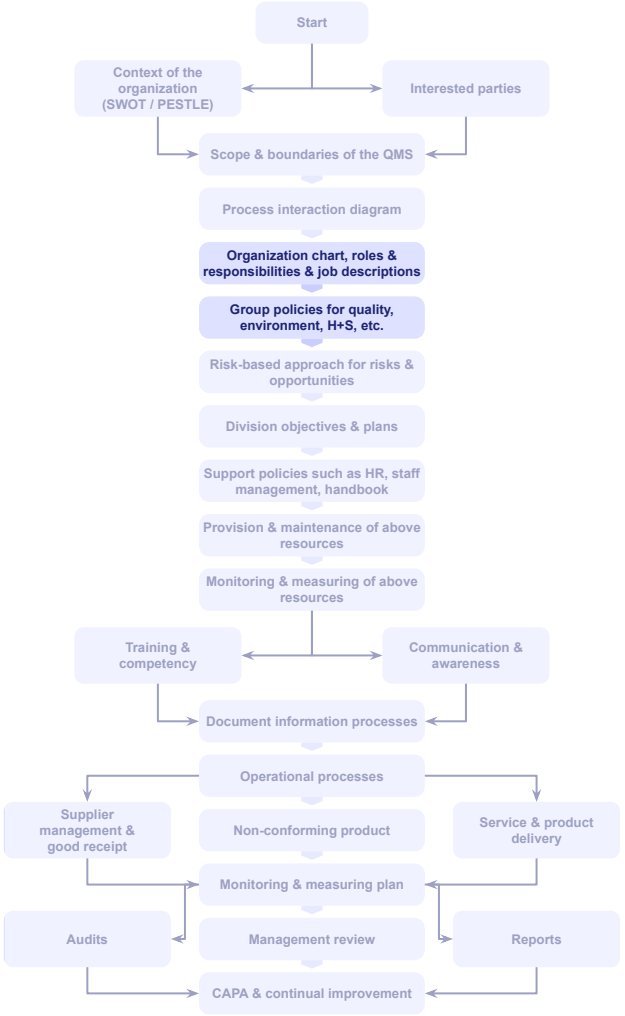
Document planned process operation and show it is in line with the actual operation.

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

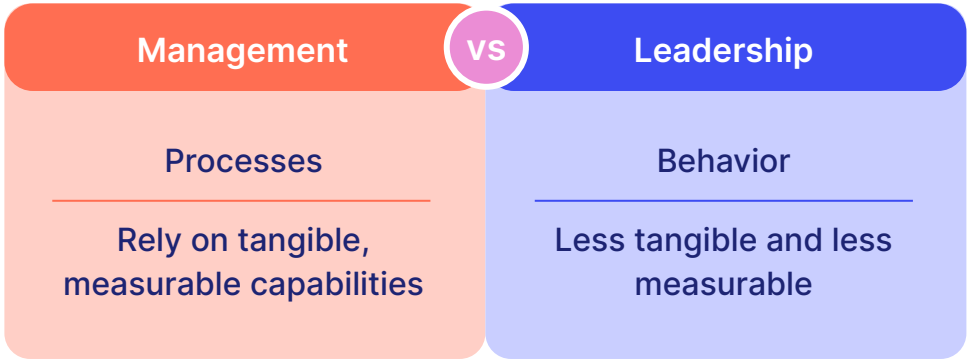


Role of leadership

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?

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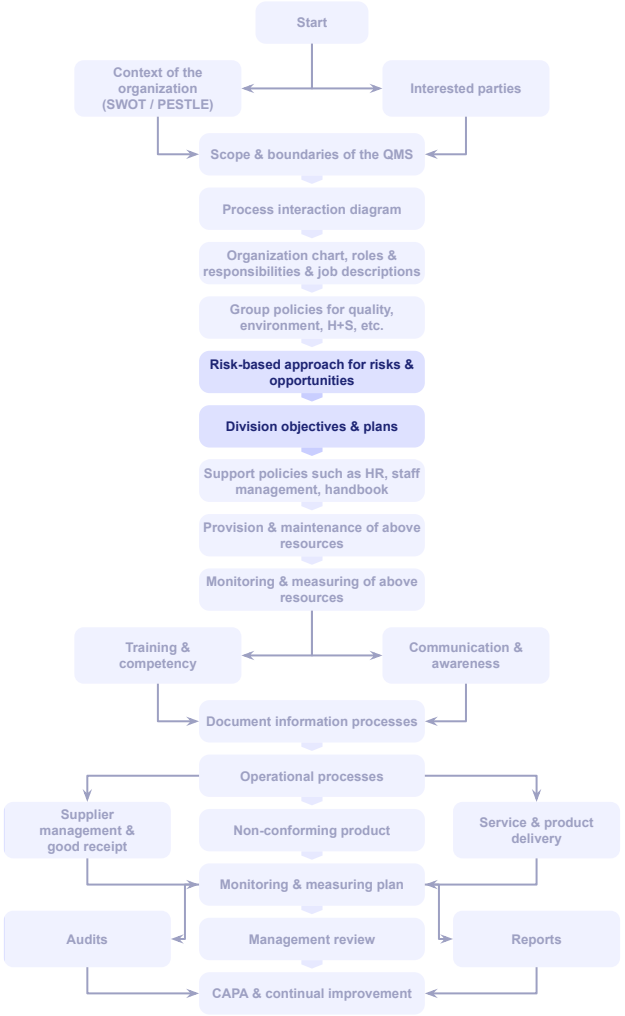
Clause 6: Planning

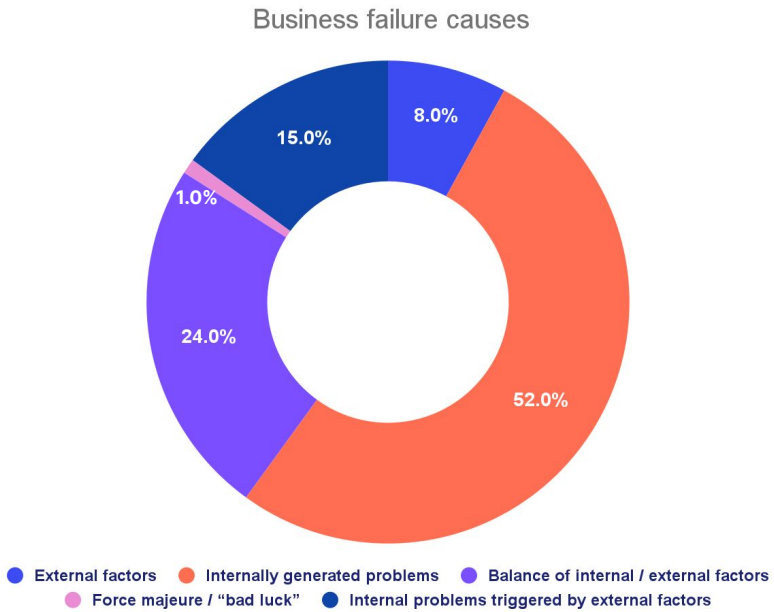
1. Establish processes for systematically managing risk, embedding risk-based thinking and following a risk-based approach

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

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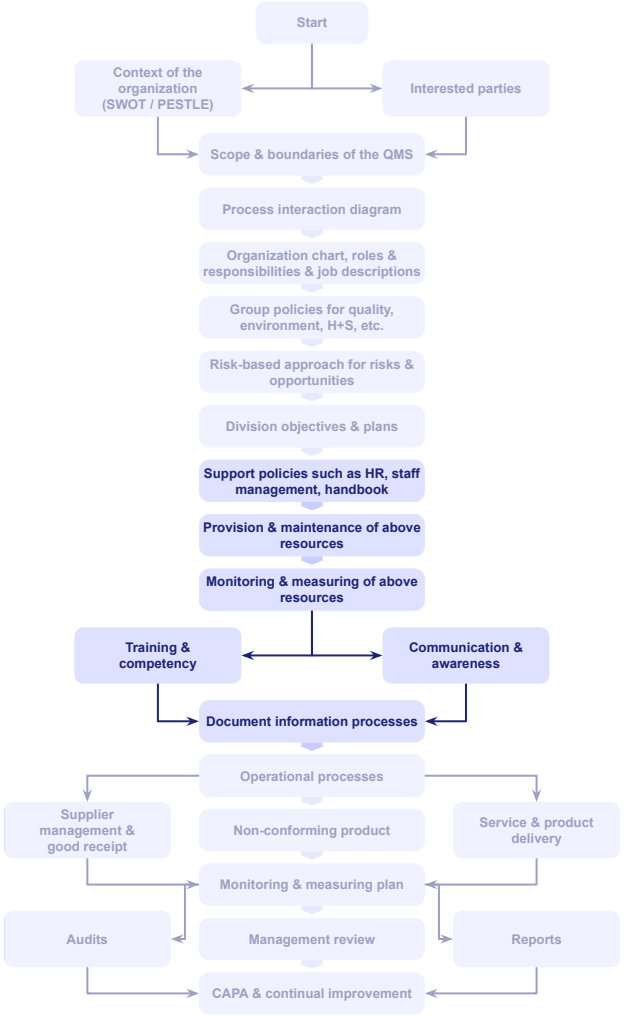
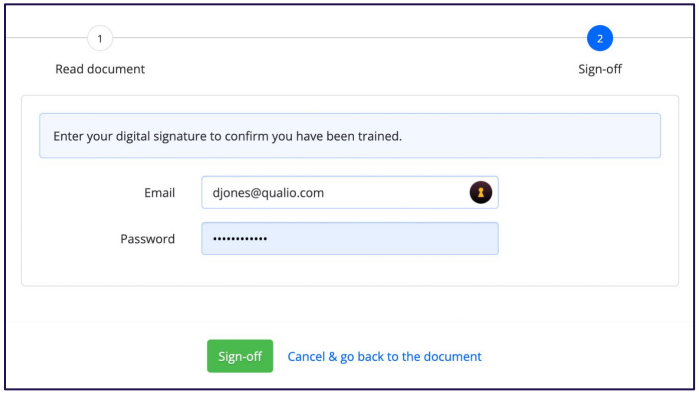
Clause 7: Support

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



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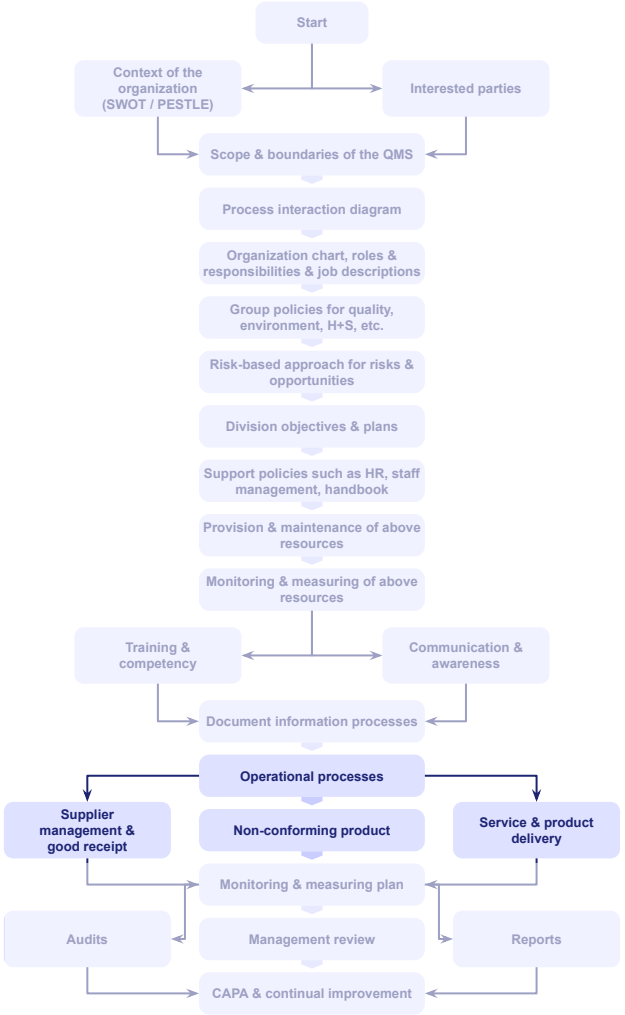
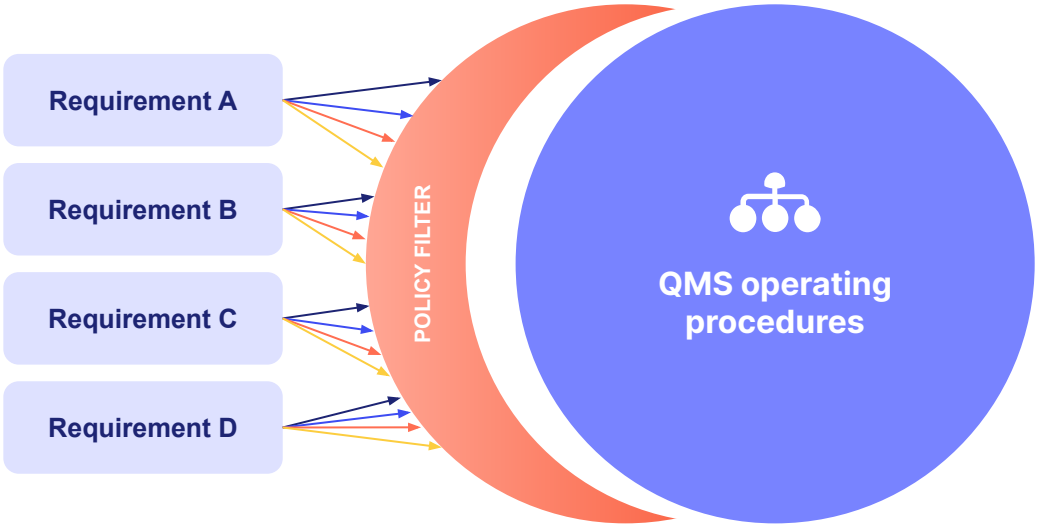
Clause 8: Operation

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



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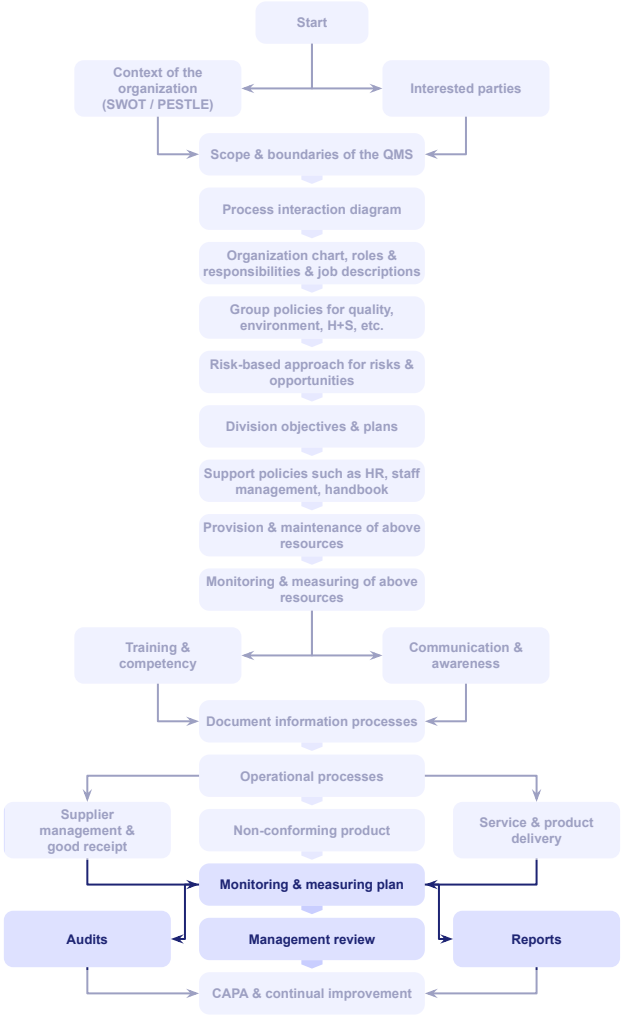
Clause 9: Performance evaluation

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!

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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

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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

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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)

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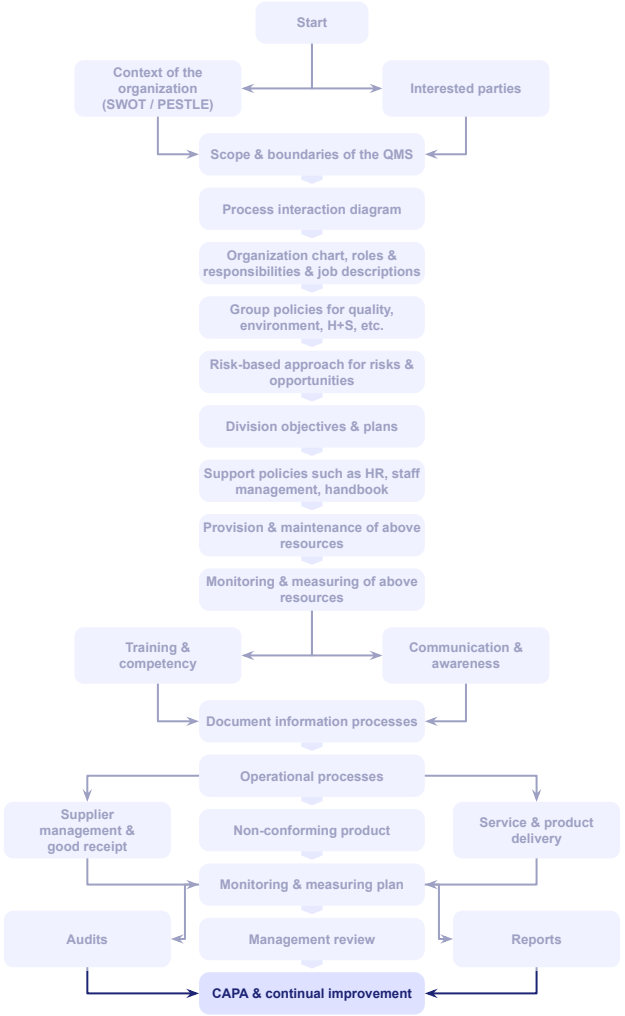
Clause 10: Improvement

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.)

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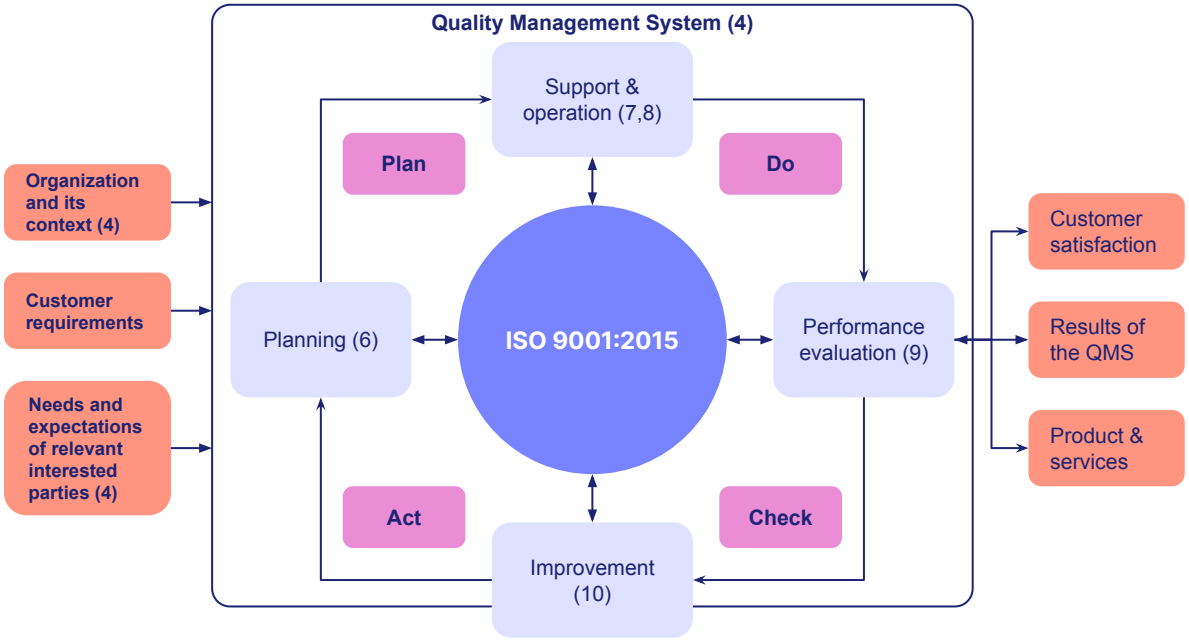
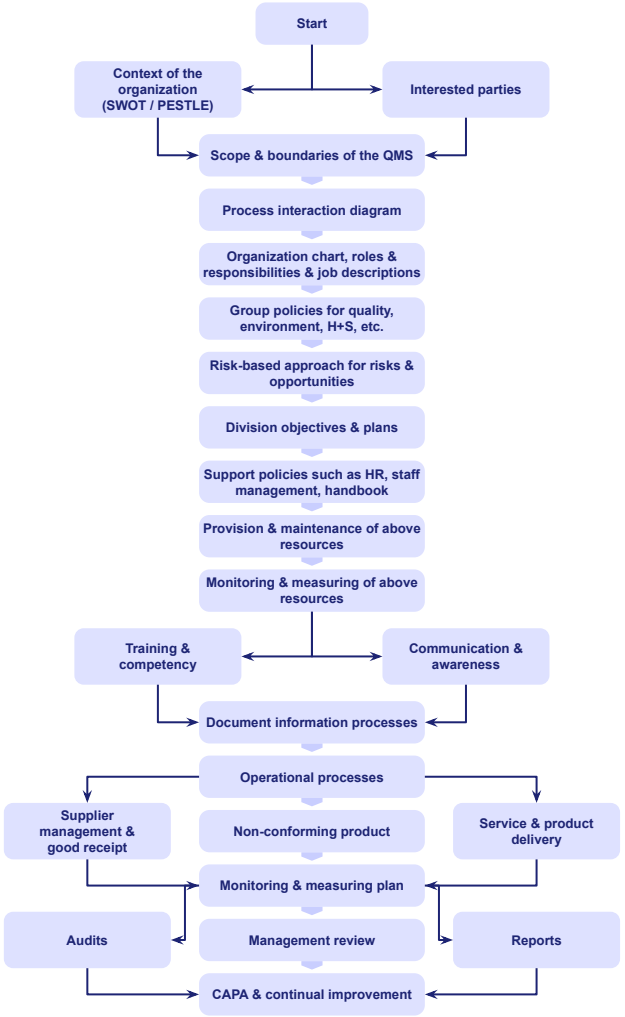
All together now...





Use the ISO 9001 checklist in your toolkit for an even more detailed step-by-step requirement list!

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The importance of risk in ISO 9001

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Where does ISO 9001 talk about risk?

Clause	Risk focus
Clause 4: Context	Determine the processes required for operation of the quality management system and the risks and opportunities associated with these processes
Clause 5: Leadership	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
Clause 6: Planning	To give assurance that the quality management system can achieve its intended results, prevent or reduce, undesired effects and achieve continual improvement
Clause 8: Operation	The organization is required to implement processes to address risk and opportunities
Clause 9: Performance evaluation	The organization is required to monitor, measure, analyse and evaluate risk and opportunities
Clause 10: Improvement	The organization is required to continually improve processes whilst responding to changes in risks and opportunities

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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

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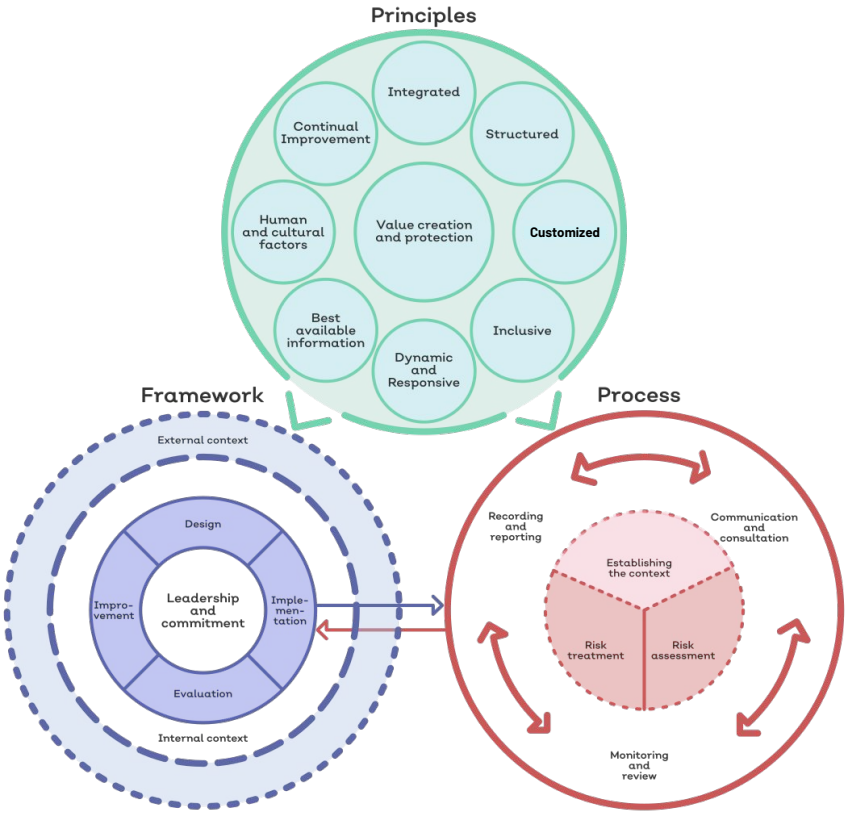
Meeting ISO 9001's risk-based demands



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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

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

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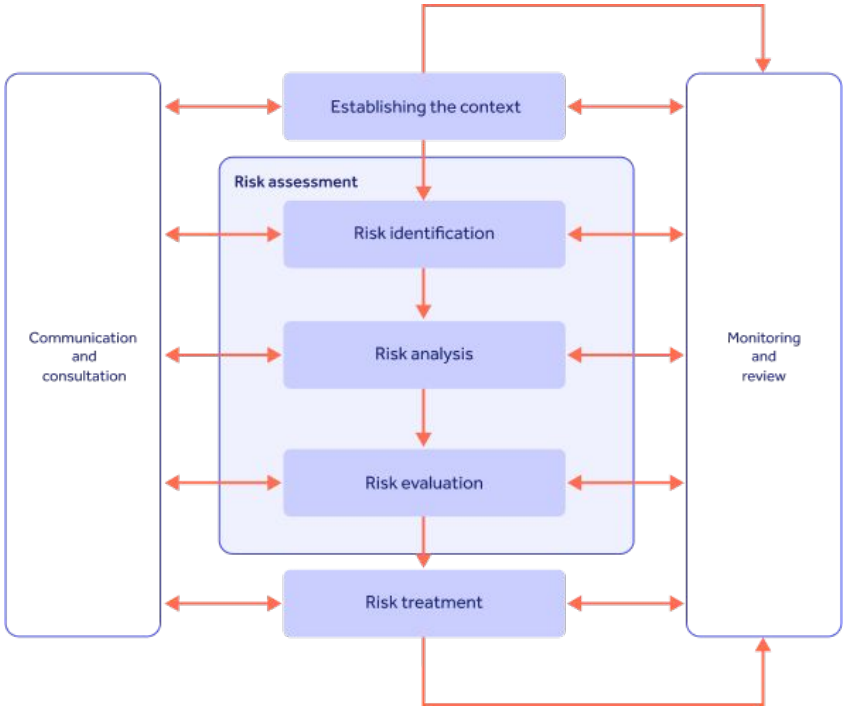
Make a repeatable, business-wide framework for managing risk



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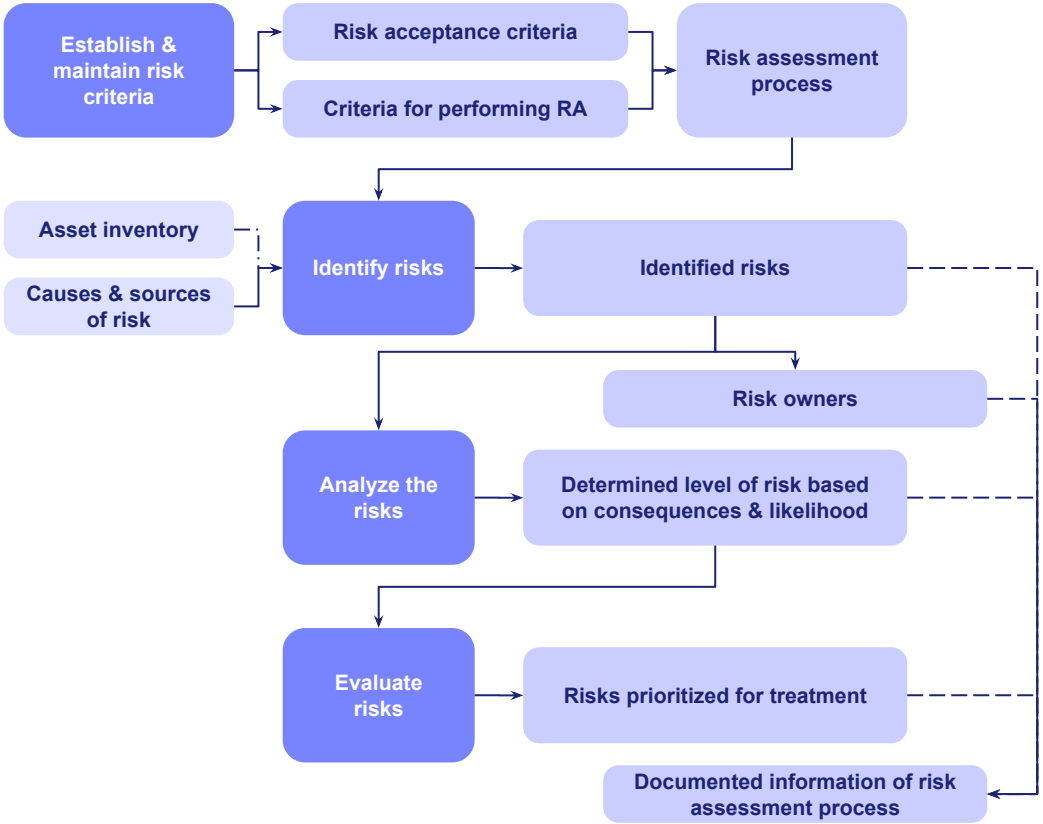
How to assess risks in your ISO 9001 QMS



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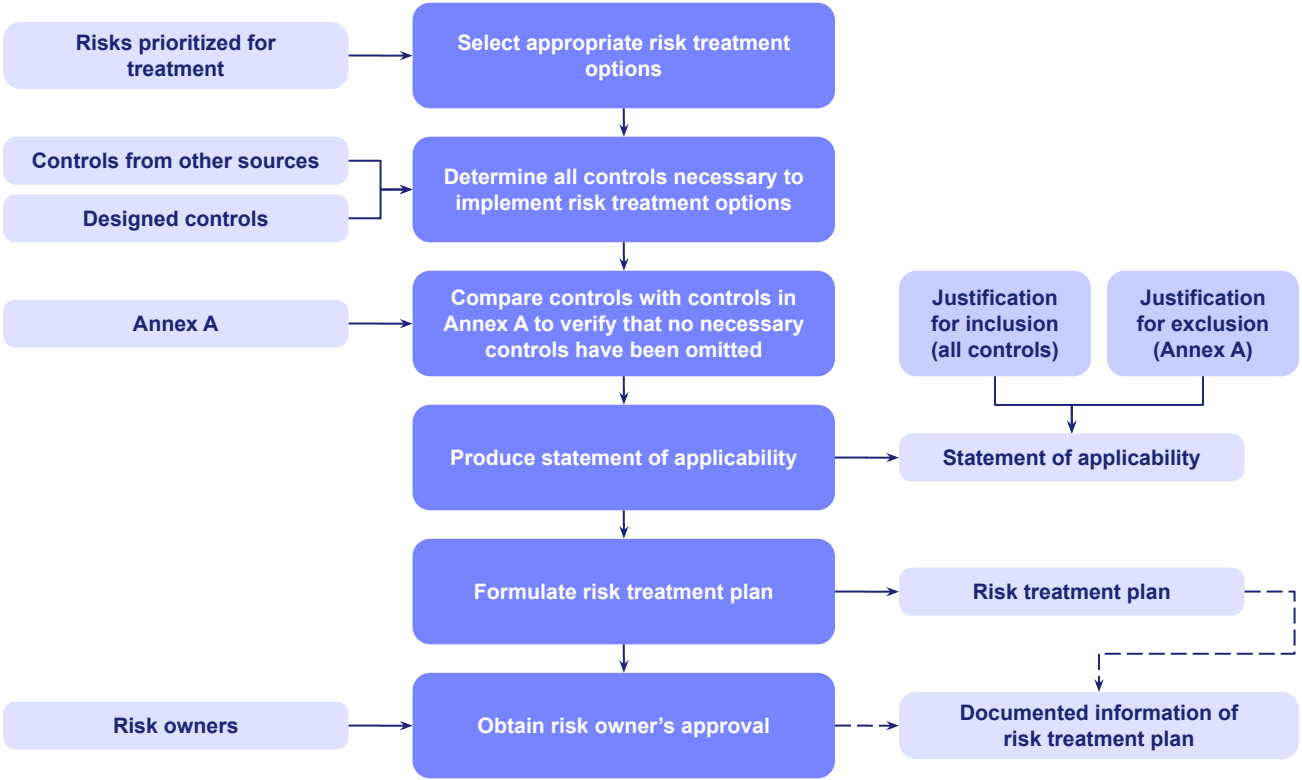
How to treat risks in your ISO 9001 QMS



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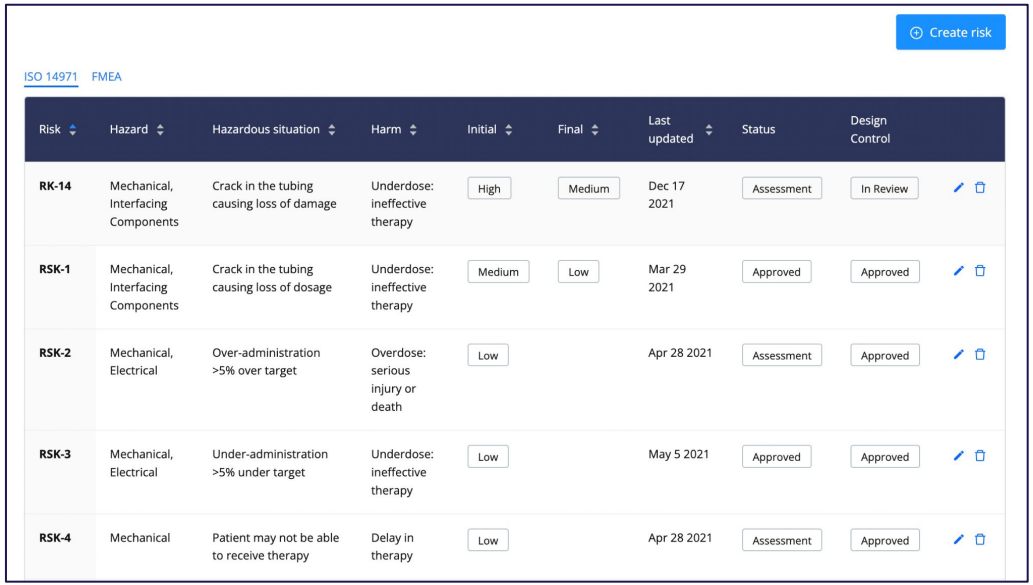
Look beyond ISO 9001 for risk inspiration…

- 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



Risk	Hazard	Hazardous situation	Harm	Initial	Final	Last updated	Status	Design Control
RK-14	Mechanical, Interfacing Components	Crack in the tubing causing loss of damage	Underdose: ineffective therapy	High	Medium	Dec 17 2021	Assessment	In Review
RSK-1	Mechanical, Interfacing Components	Crack in the tubing causing loss of dosage	Underdose: ineffective therapy	Medium	Low	Mar 29 2021	Approved	Approved
RSK-2	Mechanical, Electrical	Over-administration >5% over target	Overdose: serious injury or death	Low		Apr 28 2021	Assessment	Approved
RSK-3	Mechanical, Electrical	Under-administration >5% under target	Underdose: ineffective therapy	Low		May 5 2021	Approved	Approved
RSK-4	Mechanical	Patient may not be able to receive therapy	Delay in therapy	Low		Apr 28 2021	Assessment	Approved

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… 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

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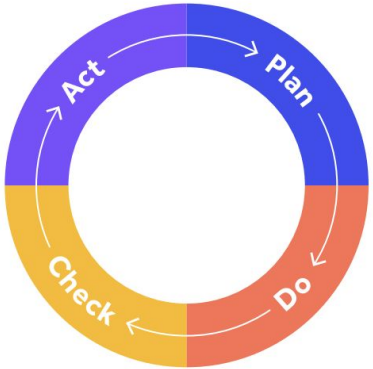
Implementing the process approach

“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."

"Leading quality in the 21st century":
CQI & Oakland research report

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8 tips for an ISO 9001 process approach

01

Involve staff in building the process-based QMS, including the initial definition of processes and subsequent P-D-C-A steps

02

Train individuals so they understand their roles and accountabilities in respect of the core processes

03

Ensure staff see their processes end-to-end

04

Restructure the audit program around processes, not functions

05

Train auditors to follow processes across departments, paying particular attention to interdependencies and interactions

06

Provide documented information to support the operation of processes

07

Test your processes are effective

08

Rebrand your processes

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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

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An example from our own quality manual

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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?

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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?

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ISO 9001 blockers

Blocker	Solution
No direct line to leadership	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.
Leadership sees quality as a cost	Demonstrate how quality improves customer and patient experience and reduces churn. Introduce quality awareness programs.
Not speaking the language of the business	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.
Not knowing who is engaging with quality	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.

ISO 9001 blockers

Blocker	Solution
Different objectives / drivers	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.
Lack of tangible objectives	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.
No single source of truth	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.
Not communicating	Schedule weekly and monthly meetings demonstrating ISO 9001 objectives and results. Emphasize quality successes as much as shortcomings and failures.
Talking the language of leadership	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).
Lack of accountability	Use layered process audits driven by top management so they can see real acts of non-compliance in day-to-day activity.
Defining leadership	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.

Conclusion: some top tips from the Qualio quality team

Common ISO 9001 challenges	Tips
Managing expectations	Perform training & education
Ensuring leaders lead	Spend time to make the requirements clear
Combatting unrest and addressing queries	Foster regular communication
Sufficient resource allocation	Measure the ROI
Ongoing success	Invest in a centralized quality system for monitoring/review
Amount of documentation	Use an eQMS, not paper
Managing outsourced services	Structure your supplier base with robust quality agreements
Handling audits	Make audits a natural, automatic part of the business culture with frequent internal audits

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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