

Life science culture of quality playbook

The case for better quality management

U.S. FOOD & DRUG ADMINISTRATION

Medical Device Recalls

Medtronic Recalls MiniMed Insulin Pumps for Incorrect Insulin Dosing

October 5, 2021 UPDATE: Medtronic updated this recall with information that Medtronic will replace any MiniMed™ 600 series insulin pump that has a clear reservoir ring with one that has the updated black reservoir ring at no charge. A replacement insulin pump will be provided even if the clear reservoir 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.

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 2018 to December 2020

Content current as of: 10/05/2021

Regulated Product(s): Medical Devices

U.S. FOOD & DRUG ADMINISTRATION

Medical Device Recalls

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

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

- Product Name: Arrow-Tretrola 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

Content current as of: 02/23/2022

Regulated Product(s): Medical Devices

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

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

Quality:

The totality of features and characteristics of a product or service that bears on its ability to satisfy stated or implied needs.

”

Culture:

The way things are done around here.

”

“

Companies with a highly developed culture of quality spend, on average, \$350 million less annually fixing mistakes than companies with a poorly developed one.

— Harvard Business Review

”

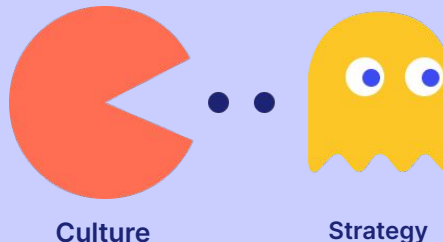
What is quality?

- Products, services, systems and processes that are fit for purpose and constantly improving
- Ensuring the whole organization is fit and effective
- Pursuing excellence
- Eliminating defects and waste
- Satisfying patients and stakeholders

Why does it matter?

- More pressure from new technologies
- Increasingly complex supply chains
- More (and tighter) compliance requirements
- Faster market demands

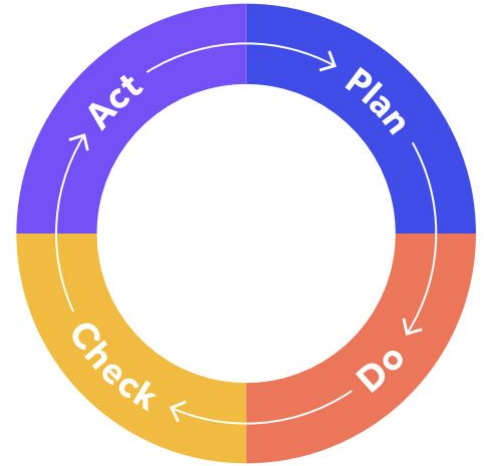
Organizational culture eats strategy for breakfast, lunch and dinner



Tips from quality gurus:

1. Shewhart

1. Create constancy of purpose for improvement of product and service
2. Follow a new philosophy
3. Discontinue dependence on mass inspection
4. Don't award business on price alone
5. Strive always to improve the production and service of the organization
6. Introduce new and modern methods of on-the-job training
7. Devise modern methods of supervision
8. Let go of fear
9. Destroy barriers among the staff areas
10. Dispose of the numerical goals created for the workforce

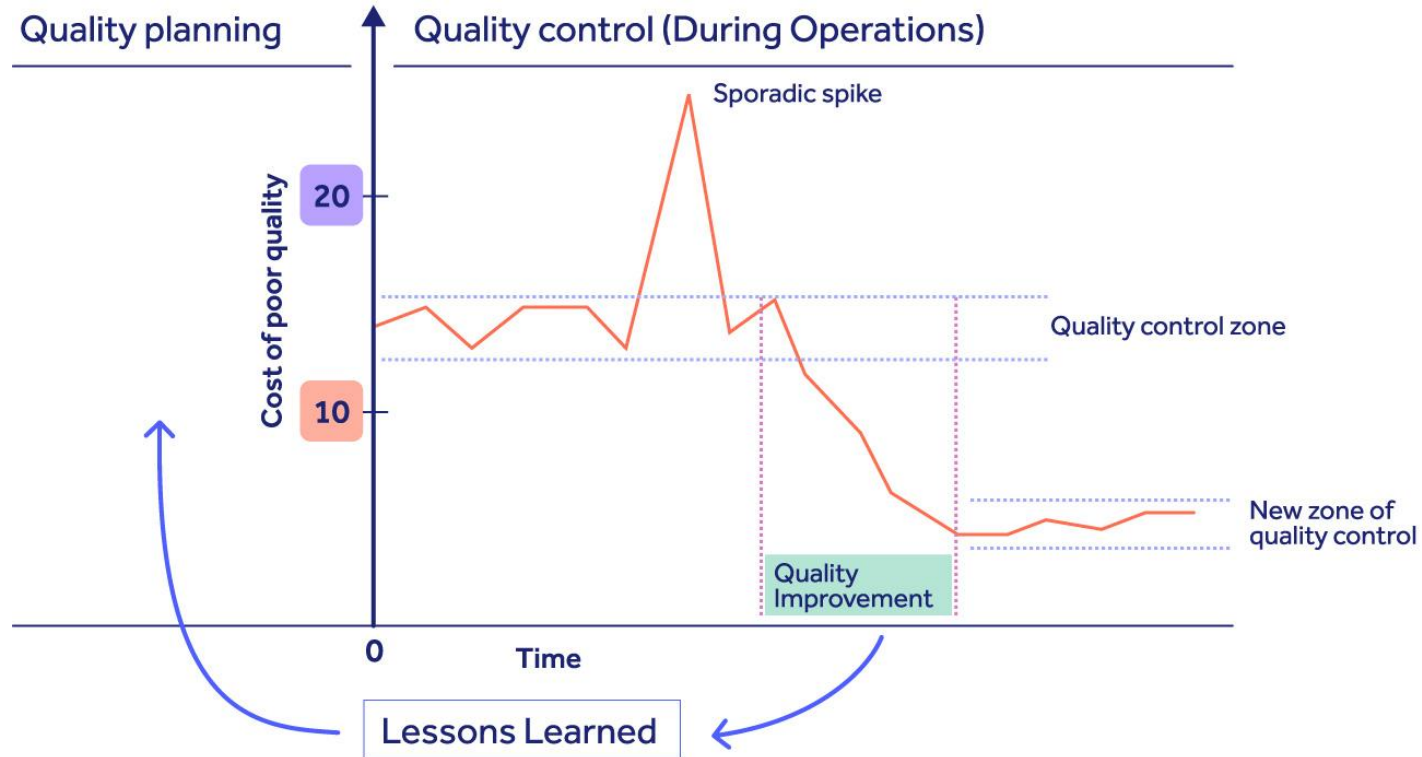


Tips from quality gurus:

2. Juran

1. Establish awareness for the need to improve and the opportunities for improvement
2. Set goals for improvement
3. Organize to meet the goals that have been set
4. Provide training
5. Implement projects aimed at solving problems
6. Report progress
7. Give recognition
8. Communicate results
9. Keep score
10. Maintain momentum by building improvement into the company's regular systems

The Juran Trilogy



Tips from quality gurus:

3. Crosby

1. Make it clear that management is committed to quality for the long term
2. Form cross-departmental quality teams
3. Identify where current and potential problems exist
4. Assess the cost of quality and explain how it is used as a management tool
5. Improve the quality awareness and personal commitment of all employees
6. Take immediate action to correct problems identified
7. Establish a zero-defect program
8. Train supervisors to carry out their responsibilities in the quality program
9. Encourage individuals and teams to establish both personal and team improvements
10. Encourage employees to tell management about obstacles they face in trying to meet quality goals
11. Recognize employees who participate
12. Implement quality controls to promote continual communication
13. Repeat everything to illustrate that quality improvement is a never-ending process

3. Crosby

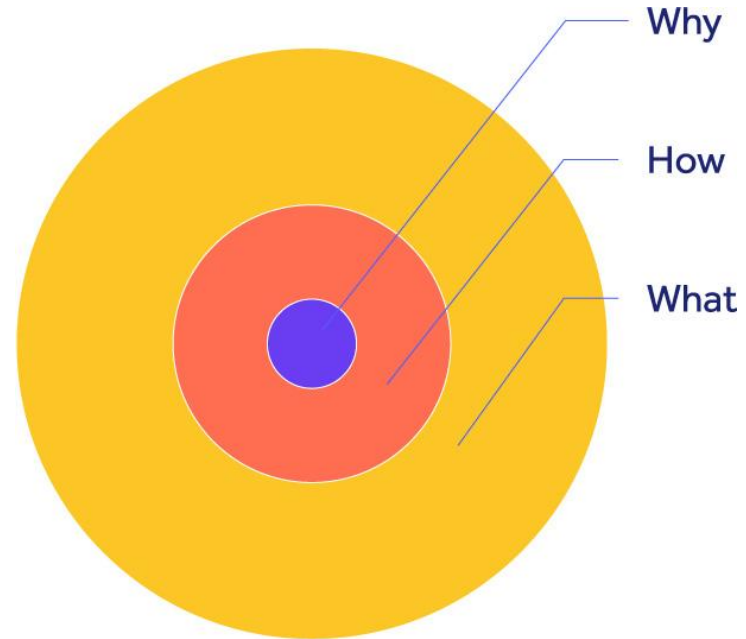
Measurement Categories	Stage 1: Uncertainty	Stage 2: Awakening	Stage 3: Enlightenment	Stage 4: Wisdom	Stage 5: Certainty
Management understanding and attitude	No comprehension of quality as a management tool. Tend to blame quality department for "quality problems"	Recognising that quality management may be of value but not willing to provide money or time to make it all happen	While going through quality improvement programme learn more about quality management; becoming supportive and helpful	Participating. Understand absolutes of quality management. Recognise their personal role in continuing emphasis	Consider quality management as an essential part of company system
Quality organization status	Quality is hidden in manufacturing or engineering departments. Inspection probably not part of organisation. Emphasis on appraisal and sorting	A stronger quality leader is appointed but main emphasis is still on appraisal and moving the product. Still part of manufacturing or other	Quality department reports to top management, all appraisal is incorporated and manager has role in management of company	Quality manager is an officer of company; effective status reporting and preventive action. Involved with customer affairs and special assignments	Quality manager on board of directors. Prevention is main concern. Quality is a thought leader
Problem handling	Problems are fought as they occur; no resolution; inadequate definition; lots of yelling and accusations.	Teams are set up to attack major problems. Long-range solutions are not solicited	Corrective action communication established. Problems are faced openly and resolved in an orderly way	Problems are identified early in their development. All functions are open to suggestion and improvement	Except in the most unusual cases, problems are prevented
Cost of quality as % of sales	Reported: Unknown Actual: 20%	Reported: 3% Actual: 18%	Reported: 8% Actual: 12%	Reported: 6.5% Actual: 8%	Reported: 2.5% Actual: 2.5%
Quality improvement actions	No organised activities. No understanding of such activities	Trying obvious "motivational" short-range efforts	Implementation of a multi-step programme (e.g. Crosby's 14-step) with thorough understanding and establishment of each step	Continuing the multi-step programme and starting other pro-active / preventive product quality initiatives	Quality improvement is a normal and continued activity.
Summary of company quality posture	"We don't know why we have problems with quality".	"Is it absolutely necessary to always have problems with quality?"	"Through management commitment and quality improvement we are identifying and resolving our problems."	"Defect prevention is a routine part of our operation."	"We know why we do not have problems with quality."

Define quality for your organization

How would you define quality in relation to your business?

Lay the foundation for your quality culture by thinking about what you do, how you do it, and why.

Combine the findings into a clear mission, driven by agreed values and promises.



Example:



Mission

Enable teams to launch and scale life-saving products.



Customer promises

Easy • Scalable • Trusted



“

A quality culture exists when all employees seamlessly embed quality improvement into their daily activities.

”

The 4 corners of quality



Planning

Who customers are

Their needs

Potential customers

Developing tools to
meet their needs



Assurance

Confidence goals are
achieved

Error prevention in
practice



Control

Fulfil quality
requirements

Reviews / audits



Improvement

Evaluation and
improvement of
processes

Efficiency,
effectiveness and
flexibility

The 5 building blocks of a quality culture



- 1 Leadership quality advocates
- 2 Employee empowerment
- 3 Customer-centric operation
- 4 Collaborative working is the norm
- 5 Continual improvement is formal and structured

Culture of quality

1 Walk the talk

2 Make quality everyone's job

3 Energize your team

4 Focus on processes

5 Monitor and measure

6 Encourage innovation

	Low complexity	High complexity
High rate of change	Power Fast-paced or changeable work but simple and straightforward	Task High-paced work of a unique or complex nature
Low rate of change	Role Steady, relatively unchanging or patterned work of a predictable nature	Person Steady work of a unique nature at the micro level

Dos and don'ts

Do

Advise and coach leadership

Encourage a 'we're in this together' environment

Foster open, honest communication

Make information accessible

Focus on processes

Encourage learning experiences to be documented

Don't

Assume leadership know what you need to do

Exclude suppliers, customers or employees when planning quality

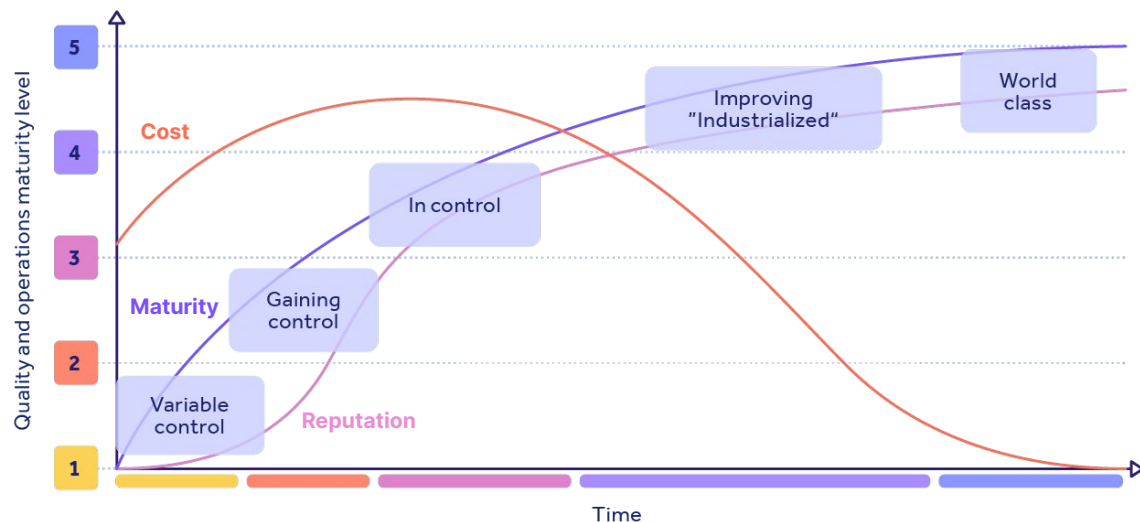
Cut corners to find the root cause of an issue

Follow a one-size-fits-all approach

Blame

Do everything

Where are you on your cultural journey?



"Quality can be hard to attain.
It can be hard to maintain.
And in large and complex
organizations, it can be very
easy to lose."

— Professor John Oakland



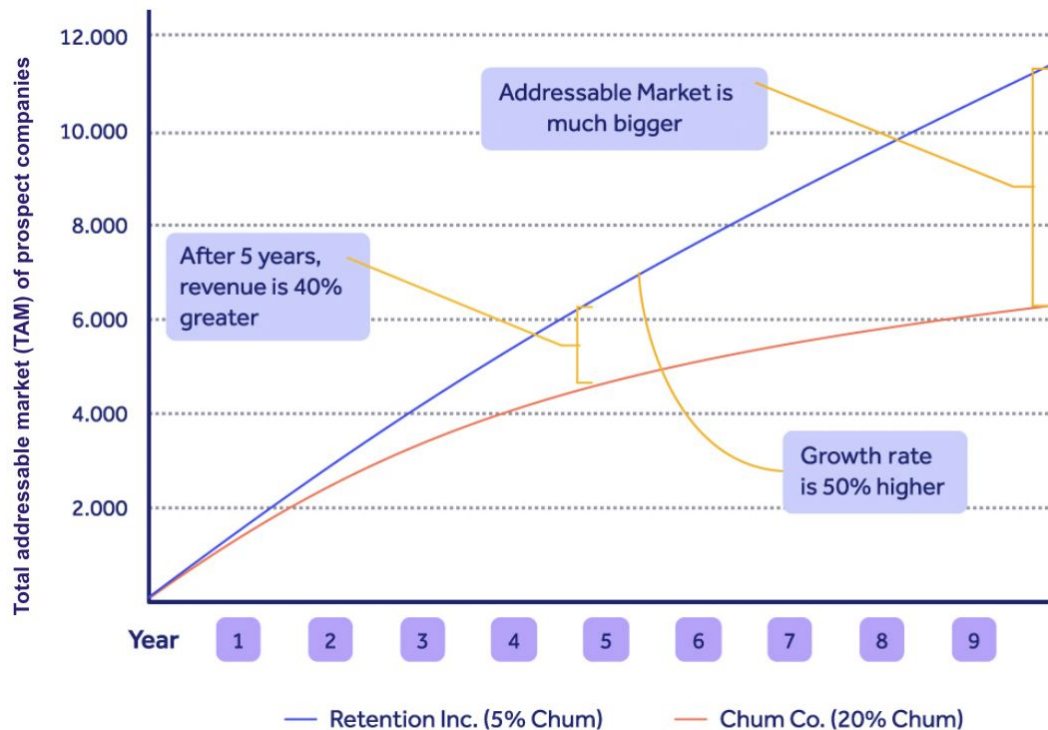
Building a customer and patient focus



Why focus on the customer and patient?

Customer- and patient-centric quality management:

- Maximizes patient safety and satisfaction
- Reduces churn
- Opens your total accessible market
- Encourages growth



Quality service and product as sustainable advantage

Product = what your customers want to achieve

Service = how they want to achieve it

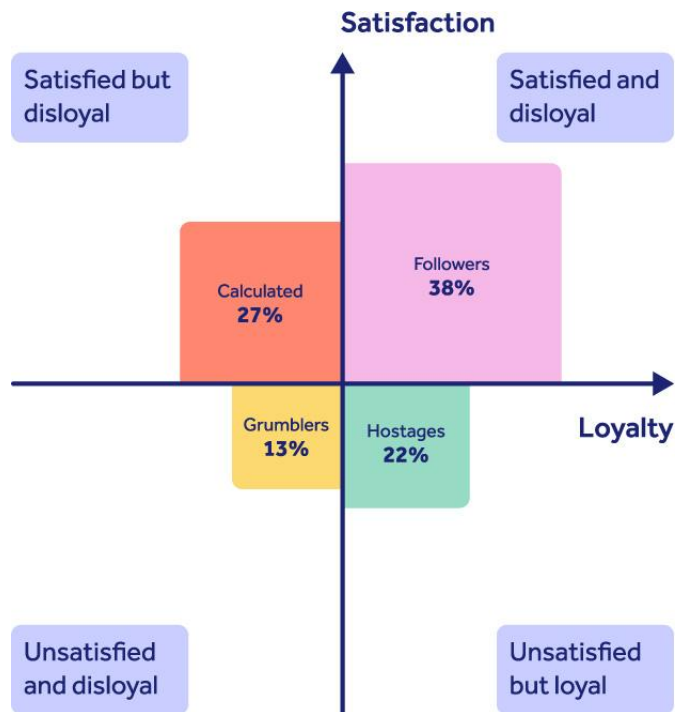
Achieved goals + appropriate service = desired customer outcome

- Get customer feedback on both to drive quality improvement
- Consider capturing Net Promoter Score (NPS) metrics and listen to customer feedback
- End product quality is ultimately decided by the customer, not you. So give your customer a voice.



Satisfaction vs. loyalty

The satisfaction and loyalty of your customers are not necessarily the same thing:



Calculated: satisfied clients who tend to seek an alternative offer

Followers: satisfied and loyal clients

Hostages: unsatisfied clients, who are attached to the offer because there is no alternative

Grumblers: disappointed clients who tend to discourage potential clients

10 characteristics of a customer-centric business

1

Quick (before, during and after the route to market!)

2

Easy and sticky processes

3

Exceed expectations

4

Consistently right first time

5

Deal with disappointment

6

Empower their staff

7

Equip their staff

8

Spot and remove blockages

9

Champion their customer champions

10

Embed 'customer thinking' at every level

6 things you can start doing now



1 Think small

2 Hire carefully

3 Train with culture and customer in mind

4 Rewards

5 Communication

6 Lead by example

Leadership as quality advocates



Management talking the talk...

We asked thousands of life science quality professionals to what extent they agreed with the following statements in our 2024 global survey:



...but not walking the walk?

"The quality department has the resources and support it needs to function properly."

Avg. 6.7

"The quality department is being used to its full potential."

Avg. 6.3

"The quality dept. receives a fair share of investment and spend compared to other areas of the business."

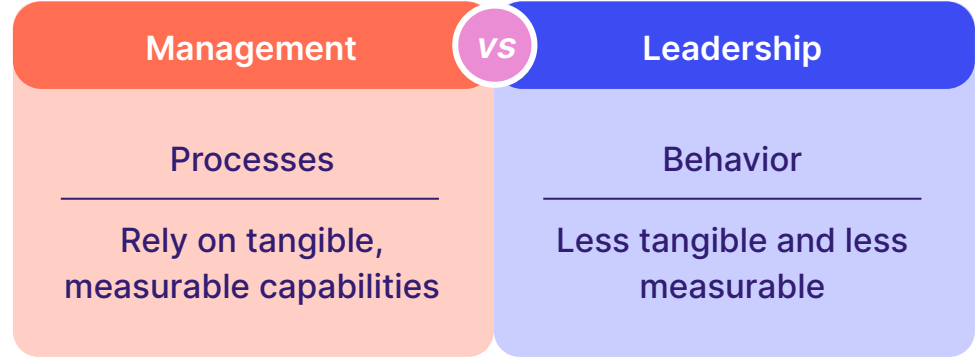
Avg. 6.2

Role of leadership

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

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

It is management's responsibility to ensure these tasks are planned, implemented and achieved.



Active cultural support from leadership

Do your leadership team...



Inform everyone of the importance of the quality management system?



Tell everyone why they should participate in its effective implementation?



Ensure the quality policy and quality objectives are compatible with the strategic direction and the context of your organization?



Promote risk-based thinking in respect of their 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?

9 benefits of leadership for your quality culture

1

People will understand and be motivated towards the organization's goals and objectives

2

Activities are evaluated, aligned and implemented in a unified way

3

Miscommunication between levels of an organisation will be minimized

4

A clear vision of the organization's future is established

5

Challenging goals and targets are set

6

Shared values, fairness and ethical role models are established at all levels of the organization

7

Trust is established and fear is eliminated

8

People are provided with the required resources, training and freedom to act with responsibility and accountability

9

People are inspired, encouraged and their contributions are recognised

5 things to demand from your leaders



1

Clear definition of organizational structure, hierarchy, roles and performance

2

SMART goals and mission

3

Performance monitoring

4

Time to review, every week

5

Clear, collective corporate culture

Common cultural 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.

Common cultural 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 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 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.

How standards support a life science culture of quality

Using quality standards as a cultural anchor

Quality management standards establish a framework for how your business manages its key activities.

They identify an agreed way of doing something: either making a product, managing a process or delivering a service.

Quality standards:

Improve your credibility and image

Improve patient and customer satisfaction

Sharpen process integration

Improve your evidence for decision making

Create a continual improvement culture

Engage employees

Are mandatory for highly regulated environments like life science

ISO 9001:2015: where does it talk about customer centricity? Everywhere!

Clause	Title	Description
Clause 4	Context	The purpose of implementing a quality management system is to consistently provide products and services that meet customer requirements and enhance its customers' satisfaction.
Clause 5	Leadership	Top management to take the lead in demonstrating the organisation's commitment to its customers and maintain a customer focus. Top management must address any risks or opportunities that might impact or enhance customer satisfaction.
Clause 6	Planning	Quality objectives must be relevant to enhancing customer satisfaction. Identifying resources needed to enhance customer satisfaction.
Clause 7	Support	Identifying resources needed to enhance customer satisfaction.
Clause 8	Operation	The organisation must communicate effectively with its customers, covering management of customer feedback.
Clause 9	Performance evaluation	Put in place arrangements to monitor and assess the degree to which customers believe their requirements for products and services have been met.
Clause 10	Improvement	Use layered process audits driven by top management so they can see real acts of non-compliance in day-to-day activity.

ISO 9001 for a culture of quality

ISO 9001 is the core quality management standard around which all others are based, and integrates with other standards through the Annex SL high level structure.

As such, it offers a useful bedrock to build your QMS and quality culture upon. ISO 9001 accreditation not only helps align your business around consistent documented processes, it can be used as a springboard to unlock further standards like ISO 13485.

How to prepare for ISO 9001 certification

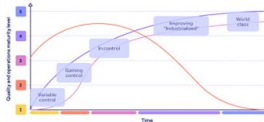
What is ISO 9001 certification?

ISO is an independent, non-governmental, international organization with a membership of 164 national standards bodies. Through its members, it brings together experts to share knowledge and develop voluntary, consensus-based, market-relevant International Standards that support innovation and provide solutions to global challenges.
— ISO (International Organization for Standardization)

ISO 9001 is a certification you can acquire by following specific standards and guidelines for a quality management system with a strong customer-centric focus.

Becoming ISO 9001-certified ensures your customers receive top quality products and services consistently, and allows your organization to begin its journey up the maturity curve to a world class QMS.

The journey to world class
Quality maturity curve



Qualio

11 benefits of ISO 9001:2015 accreditation

01. Bringing quality and continuous improvement into the heart of your organization
02. Aligned business
03. Leadership commitment
04. Opportunity and risk management
05. An integrated approach through Annex SL
06. Profitability
07. Governance tool
08. Adapt to a changing world
09. Greater customer focus
10. Consistent foundation for the future
11. Meet the needs of all interested parties

Qualio

1

Measuring your culture of quality



Measuring your quality culture

Why?

Continual improvement

Efficiency and effectiveness

Business reporting

Risk awareness

Quantified business objectives

Track goals

How?

Analyzing your data

Customer satisfaction

Product conformity

Characteristics/trends of corrective action

Suppliers

Decisions based on evidence

Is collaboration normal and automatic?

Typical indicators include:



Documents:

Notification response rate



Training:

Completed training requirements



Events:

Overdue issue resolutions



Design controls:

Device risk statuses



Suppliers:

rejected suppliers

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 level agreement (SLA) KPI examples



% of service requests resolved within agreed timeframe



Cost of service delivery as defined in SLA by month/quarter



Average time (e.g. in hours) between the occurrence of an incident and its resolution



Downtime



Availability



% of correspondence replied to on time



Number of complaints received within the measurement period

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

Efficiency KPI examples



Volume of tasks per staff



Task completion speed (document approval, training completion, event close-out, etc.)



Number of staff involved



Number of process errors



Number of human errors



Time allocated for administration, management, training

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)

Empowering your teams



“

Empowerment: the idea that giving employees skills, resources, authority, opportunity, motivation, responsibility and accountability will contribute to their competence and satisfaction.

”

What is empowerment?

A quality management technique of sharing:



with employees, so they can take initiative and make decisions to solve problems and improve service and performance.

Benefits of empowerment



Sense of ownership



Quality centricity



Improved performance



Organizational responsiveness



Increased productivity

12 empowerment tips

1

Give employees generous boundaries

2

Listen intently

3

Connect your employees to a single source of shared truth

4

Forgive mistakes

5

Provide growth paths

6

Praise effort

7

Ask powerful questions

8

Earn and demonstrate trust

9

Give employees time

10

Set your own ego aside

11

Identify common goals with SMART objectives

12

Use big data to get buy-in

Celebrate quality!

Consider ways to reward your team for contributing to your quality culture

Set friendly competitions around your quality KPIs: reward the site with the least wastage or the department with the best turnaround time

If employees suggest an improvement and it's implemented, reward and encourage further suggestions



“

Operational excellence: the execution of your business strategy more consistently and reliably than the competition

”

What does operational excellence mean?

An operationally excellent company will have the following characteristics:



Lower operational risk



Lower operating costs



Increased revenues relative to competitors, creating value for customers and shareholders



Systematic management of business and operational processes



Investment in quality culture

8 operational excellence principles



3 operational excellence techniques from the manufacturing world

Many life science businesses neglect traditional quality management techniques developed in the manufacturing world.

Consider:

1

Lean manufacturing

2

Six Sigma

3

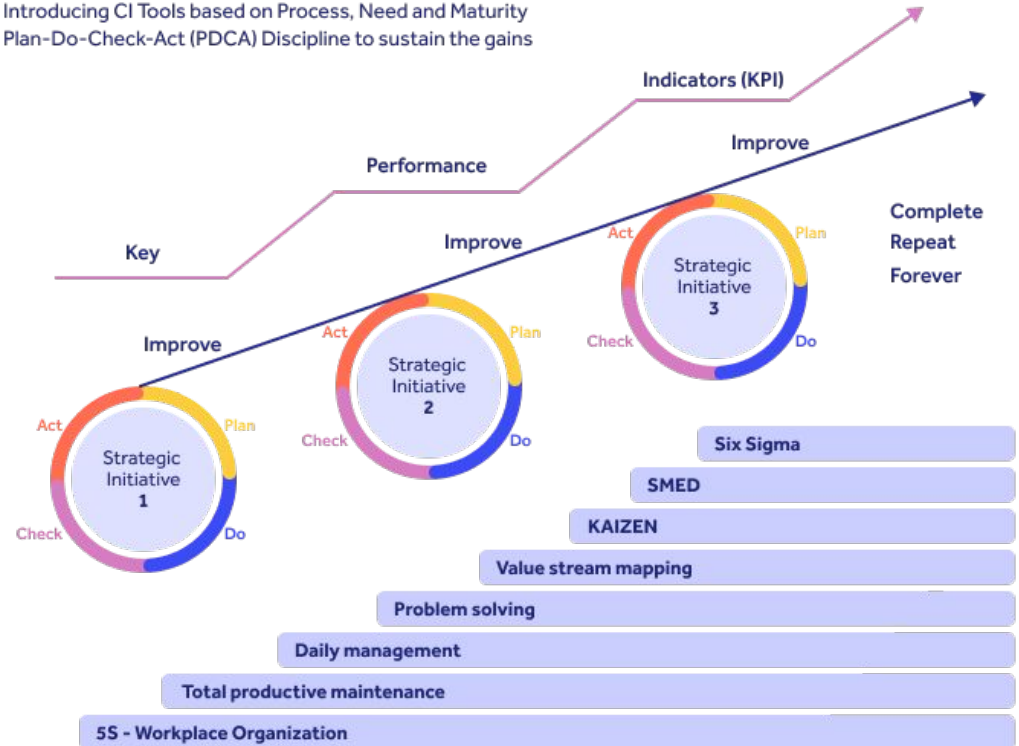
Kaizen

Why embed operational excellence?

- Unifying purpose, strategy and behaviours
- Aligning frontline work with business objectives
- Improving the effectiveness of decision-making
- Identifying the value of your customer base

Continuous improvement thinking

Introducing CI Tools based on Process, Need and Maturity
Plan-Do-Check-Act (PDCA) Discipline to sustain the gains



Conclusion: key points

To achieve a culture of quality

Foster a mentality of "we're all in this together"
(company, suppliers and customers)

Drive open, honest communication

Make quality information accessible

Focus on processes

Understand there are no successes or failures,
just learning experiences

To achieve operational excellence

Attract and retain top talent

Innovate and collaborate

Align strategies and tactics

Track KPIs, connect teams, build a single source of truth and more.

See our quality management software in action today.

qualio.com/demo

