WHITE PAPER

elevate MEDTECH

HealthTech Activator

# Building a Quality-Driven Culture in Medical Device Organisations for ISO 13485

## Executive Summary


ISO 13485 is the leading global standard for quality management systems and is required, or explicitly demanded, by most regulatory authorities worldwide.

For medical technology companies, compliance is therefore not only a matter of patient safety but also a regulatory necessity.

Nevertheless, companies frequently treat quality management as merely the responsibility of individual departments or specialists. In practice, however, quality runs through every task and every stage of the product lifecycle.

If this lifecycle is not consistently aligned with quality, the requirements of the standard can scarcely be met. The consequences are significant: product defects, regulatory sanctions and, above all, risks to patient safety.

What is missing in many cases is a fundamental principle: Quality management must be part of the corporate culture as a whole, not confined to isolated functions.

Only when it is embedded across the organisation can ISO 13485 achieve its purpose of safeguarding both compliance and lives.

A quality-driven culture moves beyond minimum compliance. It embeds quality into every decision, every process, and every role, from executive leadership to front-line teams.

It transforms ISO 13485 from a set of obligations into a strategic asset that drives innovation, operational excellence, and trust.

This whitepaper examines how medical device organisations can build, sustain, and measure a culture of quality that meets and exceeds ISO 13485 requirements. Drawing on best practices, regulatory expectations, and industry case studies, it outlines:

- **Leadership's role** in setting the tone, allocating resources, and modelling quality behaviours.
- **Employee engagement strategies** to foster ownership, accountability, and continuous improvement.
- **Operational integration** of quality into everyday workflows, risk management, and product lifecycle decisions.
- **Metrics and feedback loops** to track cultural progress and sustain momentum

Organisations that cultivate a quality-driven culture experience fewer compliance issues, stronger customer loyalty, and improved market competitiveness.

More importantly, they create medical devices that meet the highest standards of safety and effectiveness, earning the trust of regulators, healthcare professionals, and patients alike.

## 1. Introduction

The medical device industry operates in a uniquely high-stakes environment. Products are not merely consumer goods, they are instruments that diagnose, treat, or support the health and lives of patients. For this reason, regulators worldwide require robust quality management systems (QMS), with ISO 13485 standing as the internationally recognized standard for ensuring product safety and regulatory compliance.

While ISO 13485 provides a comprehensive framework for quality management, achieving certification alone does not guarantee consistent product excellence. All too often, organisations regard quality management as the responsibility of individual departments or specialists instead of a guiding principle for decision-making and innovation. This mindset can result in fragmented processes, reactive problem-solving, and missed opportunities to improve both product performance and organisational resilience.

A quality-driven culture addresses these challenges by embedding quality into the fabric of the organisation. It ensures that:

- Leadership sets a clear vision for quality and allocates the necessary resources to achieve it.
- Every employee, regardless of role, understands their impact on product quality and patient safety.
- Continuous improvement is not merely an initiative but a mindset that guides both daily operations and strategic planning.

In the context of ISO 13485, culture is a measurable, operational driver that influences audit readiness, regulatory outcomes, and market reputation. A strong quality culture is more important than ever, since regulators assess both documented procedures and the attitudes, behaviours, and decision-making patterns that support them.

This whitepaper explores the practical steps medical device organisations can take to develop and sustain a quality-driven culture, with ISO 13485 as the structural backbone. Through leadership alignment, employee engagement, process integration, and cultural measurement, organisations can shift from compliance-focused thinking to a proactive, quality-first mindset—ultimately leading to safer products, stronger market performance, and lasting trust.

## 2. Understanding a Quality Driven Culture

A medical device, whether it is a physical product or a piece of software, passes through many stages before it reaches the patient. From product design through management, manufacturing and distribution, the entire organisation carries responsibility for ensuring quality. This is why quality management cannot be limited to those who formally work in a quality function. For a quality management system to be truly effective, it is not enough to implement the requirements of ISO 13485 as written. Quality must become part of the organisation's culture, shaping every decision, large and small.

The difference between compliance and culture lies in how people think and act. Compliance focuses on whether processes are documented and followed in line with the standard. Culture is broader: it is the shared mindset, the everyday behaviours, and the values that people bring to their work. A company can show auditors that the right procedures exist and still lack a culture where staff naturally take responsibility for quality in their daily tasks.

This distinction is often blurred by a persistent misconception: that quality belongs to the Quality Assurance team. If quality is treated as a separate function, others may feel exempt from responsibility. But quality is not a department. It is the outcome of choices made at every level. Engineers deciding on materials, managers setting project timelines, and service teams handling customer feedback all shape whether a product is safe and effective.

When organisations embrace quality as a collective duty, certain patterns emerge. Risk is managed proactively rather than retrospectively. Transparency replaces silence, with staff confident to raise concerns without fear. Continuous improvement becomes an instinct, with teams learning from each issue and refining processes before failures occur.

The opposite patterns are just as telling. In a weak culture, compliance is treated as a minimum hurdle. Employees may do the bare minimum to prepare for audits, without addressing deeper issues.

Mistakes can lead to blame, discouraging staff from speaking up. Problems are solved reactively, often under pressure, instead of being prevented in the first place. Such an environment creates hidden risks that eventually surface as regulatory findings, costly recalls, or damage to reputation.

## 3. Regulatory and Business Drivers

The regulatory environment for medical devices underscores that leadership is central to quality management. ISO 13485 establishes the foundation, while regulators in multiple jurisdictions reinforce it by holding senior management directly accountable for the effectiveness of the quality system.

Organisations that show authentic leadership commitment achieve not only compliance but also measurable business benefits.

### Culture vs Compliance in Practice

| | COMPLIANCE MINDSET | QUALITY DRIVEN CULTURE |
|---|---|---|
| RESPONSIBILITY | “The audit report is handled by QA, I just focus on my shift.” | “I highlight a deviation in my shift log so QA and production can address it together.” |
| MOTIVATION | “We tidy up documents the week before the audit.” | “We update records as part of daily work to keep them accurate at all times.” |
| RISK MANAGEMENT | “We perform the risk analysis once the design is almost finished.” | “We add risk assessment as a standing point in every design review meeting.” |
| HANDLING ERRORS | “I keep quiet about a small mistake to avoid blame.” | “I report a mistake right away so the team can learn and prevent recurrence.” |
| LEADERSHIP | “Management signs the quality policy once a year and leaves QA to it.” | “The CEO attends monthly quality reviews and asks teams about their challenges.” |
| IMPROVEMENT | “We launch a corrective action project right before an external audit.” | “Teams suggest process changes during toolbox talks and see them implemented quickly.” |

## ISO 13485 Requirements and Leadership Responsibility

The core requirements of ISO 13485:2016 include a documented **quality manual** that defines the scope of the system, outlines the process structure, and describes the organisation's approach to quality.

Companies must establish **standard operating procedures** covering areas such as document control, supplier management, process validation, corrective and preventive actions, and internal audits.

These procedures form the operational backbone of the system and ensure that activities are performed consistently and effectively.

Another central expectation is the integration of **risk management** across all processes, not limited to product development. Manufacturers must apply risk-based thinking in supplier qualification, process design, post-market surveillance, and the handling of complaints and nonconformities.

## Regulatory Requirements & Leadership


This principle ties into ISO 14971 for product safety but extends further, requiring management to consider organisational and quality risks in decision-making.

ISO 13485:2016 also mandates structured processes for **feedback, complaints, and post-market surveillance.** Information from clinical use, adverse event reports, and customer feedback must feed into corrective and preventive actions, as well as updates to risk management and product design. These requirements ensure that the quality management system remains a living framework that adapts to real-world performance and feedback.

**Clause 5** of ISO 13485:2016 **focuses on management** responsibility, and outlines specific leadership obligations. It positions management not only as the sponsor of the system but as an active participant who must review its performance, allocate resources, and ensure that regulatory requirements are met at every level.

## Medical Device Single Audit Program (MDSAP)

Within MDSAP, the very first process audited is the management process. Auditors examine whether top management has established a quality manual, aligned quality objectives with the quality policy, assigned responsibilities so that quality is safeguarded, and committed sufficient resources and infrastructure.

The appointed management representative is assessed against specific duties: ensuring system requirements are implemented, reporting to top management, and promoting awareness of regulatory requirements.

Leadership is also expected to apply risk-based thinking in planning and decision-making. The programme is explicit that without leadership commitment, other quality system processes cannot be effective.

## European Union MDR and IVDR

Under both the European Regulation (EU) 2017/745 on Medical Devices (MDR) and the Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices (IVDR), manufacturers must establish and maintain a quality management system that covers the entire lifecycle of a device. Article 10 MDR/IVDR requires the system to include organisational structure, defined responsibilities, procedures, processes, and the management resources necessary to ensure ongoing conformity of production.

A further reinforcement of accountability is the requirement for a Person Responsible for Regulatory Compliance (Article 15 MDR/IVDR). This role must be held by an individual with defined qualifications who ensures that regulatory tasks such as technical documentation and post-market surveillance are properly carried out. Even small and micro-enterprises must have access to such expertise. Notified bodies audit not only documentation but also the practical functioning of the system, meaning that leadership cannot restrict its role to paper compliance but must ensure continuous and effective application.

## United States FDA

The United States is aligning its regulatory expectations with ISO 13485 through the new Quality Management System Regulation (QMSR), which will replace the current Quality System Regulation in February 2026. The QMSR incorporates ISO 13485:2016 by reference, which means the leadership requirements in Clause 5 will be directly enforceable. Until that date, firms remain subject to the current version of 21 CFR Part 820, which already obliges management to define responsibility and authority, appoint a management representative, and provide adequate resources under §820.20. The forthcoming harmonisation demonstrates a shared international understanding that leadership accountability is the central driver of quality management.

## The business case for leadership commitment

The regulatory focus on leadership reflects the reality that effective management commitment delivers measurable business benefits. Organisations with strong systems experience fewer recalls and can respond more effectively if corrective actions are required. Harmonisation of standards shortens approval timelines when leadership ensures consistent, risk-based execution across markets. A visible quality-driven culture enhances trust among customers, clinicians, and partners, reinforcing loyalty and strengthening reputation. In competitive markets, organisations that treat leadership engagement in quality as a strategic priority achieve greater resilience, operational efficiency, and sustainable advantage.

| FRAMEWORK | ADDITIONAL LEADERSHIP REQUIREMENTS |
|---|---|
| **ISO 13485:2016** | · Internal communication on QMS effectiveness<br>· Management representative must also promote regulatory awareness |
| **MDSAP** | · Management is the first process audited<br>· Leadership must demonstrate commitment in practice<br>· Risk-based decision-making explicitly assessed |
| **MDR / IVDR** | · Lifecycle-wide QMS (Article 10)<br>· Person Responsible for Regulatory Compliance with defined qualifications (Article 15) |
| **US FDA** | · Current Part 820: roles, resources, management rep required<br>· From 2026: QMSR adopts ISO 13485 Clause 5 duties directly |

## 4. The Leadership Role in Culture Building

Culture does not emerge by chance. In medical device companies working under ISO 13485, it is leadership that sets the conditions for how people think about quality and how they act in daily work. Executives and managers define the tone, provide the resources and decide whether quality is part of strategic ambition or treated as an afterthought. Their choices influence not only compliance outcomes but also patient safety, market access and organisational credibility.

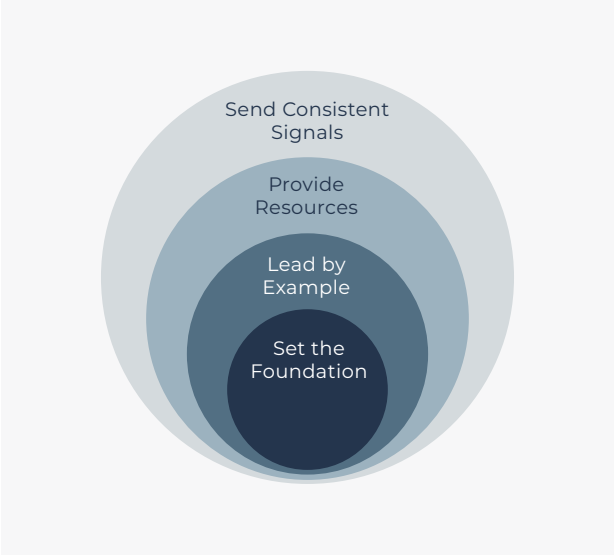
### Leadership Responsibilities in ISO 13485

ISO 13485 clearly defines management responsibilities. Section 5 outlines several obligations directly linked to corporate culture. Managers must establish a quality policy that is clear, meaningful, and understood across the entire organisation.

- **Clause 5.1 and 5.2** require top management to demonstrate commitment to the system and to ensure a customer and regulatory focus across the organisation.
- **Clause 5.3 and 5.4** require leaders to establish a quality policy and to translate this into measurable objectives that are maintained and reviewed at different levels of the organisation
- **Clause 5.5.1** requires clear definition and communication of roles, responsibilities, and authorities.
- **Clause 5.5.2** requires the appointment of a quality management representative with responsibility for maintaining the system, reporting on its performance to management, and promoting awareness of regulatory requirements.
- **Clause 5.5.3** requires management to establish internal communication processes regarding the effectiveness of the quality system.
- **Clause 5.6** requires planned management reviews with defined inputs, audit results, customer feedback, process performance, and resource adequacy. Outputs must include decisions on system improvement, effectiveness, and resource needs.

These requirements make leadership accountable for whether the quality system functions in practice. A policy that exists only on paper, objectives that are not measured, or reviews that do not result in actions quickly become visible in audits and, more importantly, in patient outcomes.

### Leadership Checklist




### Tone from the Top

Formal responsibilities are necessary, but culture is shaped by behaviour. Employees take their cues from what leaders do. The “tone from the top” is therefore decisive.
When executives speak about quality in company-wide meetings, when they review nonconformities or complaints openly, and when they link their own performance evaluations to quality metrics, they send a strong message. Staff see that quality is central to the identity of the organisation. Conversely, when leaders focus exclusively on financial targets or treat quality as the domain of the QA department, the message is equally clear: quality is secondary. And most other staff will very likely take their cue from this negative example.

## Aligning Quality with Strategic Goals

Aligning Quality with Strategic Goals
Culture becomes durable when quality is embedded in strategic decision-making. If quality is isolated from business goals, it remains fragile. Successful organisations integrate quality into innovation planning, market access strategies, risk management and brand positioning.

This integration is visible in board-level discussions where product pipeline decisions are evaluated not only for market potential but also for quality risks. It is visible when investment proposals include quality impact assessments alongside financial projections. Quality has to become the measure of success.

## Resource Allocation

No culture can thrive without resources. ISO 13485 Clause 6 requires management to provide the people, training, infrastructure and environment necessary to operate an effective quality system. This means budgets must be sufficient to support internal audits, supplier oversight, corrective and preventive actions, regulatory monitoring and continuous improvement initiatives. It also means staff must have the tools, equipment and systems that allow them to work reliably and in compliance.

Training is particularly critical. It must go beyond technical skills to include awareness of how individual roles affect patient safety and regulatory outcomes. Regular refreshers are necessary as standards evolve. When leaders allocate resources consistently, they show that quality is non-negotiable. When quality is the first item cut from budgets, the culture erodes quickly.

## Avoiding Mixed Messages

Perhaps the most damaging influence on culture is inconsistency between what leaders say and what they reward. Employees notice when incentive schemes focus solely on speed or cost while ignoring defect rates or compliance. They notice when teams are pressured to cut corners to meet deadlines. They notice when managers praise cost savings but remain silent about quality improvements.

To avoid such contradictions, leaders must embed quality metrics into performance reviews and KPIs across the organisation. They must recognise and reward behaviours such as transparency, problem reporting and continuous improvement. And when trade-offs between cost, speed and quality occur, leaders must explain how quality was protected in the decision. Only then can staff trust that the stated commitment to quality is genuine.

## Leadership Checklist

To build and sustain a quality-driven culture under ISO 13485, leaders should:

**Set the foundation**

- Establish a clear and meaningful quality policy.
- Define measurable objectives that track performance against that policy.
- Appoint a management representative with authority and visibility.

**Lead by example**

- Speak about quality in broad company forums, not just technical settings.
- Review complaints and nonconformities openly, showing that they matter at the highest level.
- Link leadership performance reviews to quality outcomes and communicate them.

**Align quality with strategy**

- Integrate quality into strategic planning, product development and risk management.
- Treat quality as a measure of success alongside growth, cost and innovation.

**Provide resources**

- Allocate sufficient budget for audits, training, supplier oversight and continuous improvement.
- Ensure staff have the tools, infrastructure and systems to meet quality requirements.
- Maintain training programmes that build both competence and awareness.

**Send consistent signals**

- Include quality metrics in KPIs across the organisation.
- Reward transparency, reporting of problems and improvement efforts.
- Avoid incentives that prioritise speed or cost over patient safety and compliance.

## 5. Engaging the Whole Organisation

For a culture of quality to take root across every level of the company and in every stage of production, the entire organisation must be involved in what is nothing less than a mammoth project of quality management.

### Communicating Objectives in Clear, Role-Relevant Terms

Quality objectives often appear in strategic plans or audit reports, but they only gain traction when translated into the language of daily work. A corporate goal to “improve complaint handling” becomes relevant for a service team when it is expressed as an explicit commitment to register every complaint within 24 hours and to escalate unresolved cases within a week. A target to “reduce nonconformities” becomes tangible for production staff when expressed as a goal to lower rework rates by a set percentage on a defined line.

Clear communication requires managers to interpret objectives for their teams, use examples that reflect daily routines, and repeat the messages until they become familiar reference points. Dashboards in workshops, short updates during shift briefings or team meetings that review performance against objectives can all reinforce this connection.

### Quality Champions as Cultural Ambassadors

One method that helps spread quality culture is the appointment of quality champions.
These are staff members selected from different functions who act as local points of contact for quality-related questions.

They connect high-level objectives with daily practice, raise concerns early and share lessons across departments.

Champions are most effective when they are not seen as auditors but as peers who support their colleagues. By choosing champions from varied roles such as engineering, manufacturing, regulatory affairs and customer service, organisations demonstrate that quality belongs to everyone.

### Recognition and Rewards for Positive Behaviours

Incentives shape culture. If only speed or cost savings are celebrated, quality loses visibility. Recognition of quality-oriented behaviour shows employees what really matters. This recognition can take many forms: a manager publicly thanking a team for identifying and addressing a potential nonconformity, a small award for a process improvement idea, or promotion criteria that value contributions to quality as much as financial results.
Gestures do not need to be expensive. What matters is that they are consistent. If reporting a deviation or contributing to an audit is recognised as valuable, staff will repeat those behaviours.

### Building Psychological Safety

Employees must feel safe to speak up when they see risks, errors or near misses. In organisations where mistakes are met with blame, silence becomes the norm. Under ISO 13485, this silence is dangerous. It hides problems that regulators expect to be addressed through CAPA, training or process changes.
Creating psychological safety means leaders respond constructively when issues are raised, focus on the problem rather than the individual, and show through actions that reporting is valued. Anonymous reporting channels and open-door policies help, but the strongest signal comes from how managers react in everyday situations. When staff see that reporting leads to learning and improvement rather than punishment, they trust the system.

### Training that Builds Ownership

ISO 13485 requires that organisations define competence needs, provide training, and maintain evidence that staff are qualified (Clause 6). Too often this becomes a paperwork exercise: attendance lists, signatures, and files that satisfy auditors but do little to change behaviour. Training of this type may show compliance, but it rarely creates ownership.

Ownership develops when training makes the purpose of procedures clear and connects them directly to patient safety. A production operator is more likely to document parameters accurately if they know how a missing value could compromise device performance. A service employee handling a complaint will log the details more diligently when they understand how these records feed into CAPA and help prevent recurrence.

Training is most effective when it is practical, participatory and reinforced over time. Organisations that succeed in this area often combine different approaches:

- Contextual training: Sessions that link procedures to real risks and regulatory outcomes, using examples from past audits, complaints or recalls.
- Case-based learning: Review of actual nonconformities, design changes or adverse events to show how small oversights have large consequences.
- Interactive methods: Role-plays of audit interviews, workshops where staff map risks in their processes, or simulations of CAPA investigations.
- Continuous reinforcement: Short refresher sessions, toolbox talks, and micro-learning modules that keep awareness alive between formal training cycles.
- Leadership involvement: Executives who attend training themselves or reference training content in meetings signal that learning is a priority, not an afterthought.

The cultural signal is just as important as the content. When training is treated as a formality, staff will respond accordingly. When it is invested with meaning, relevance and visible support from leadership, employees begin to see themselves not just as followers of procedures but as guardians of product quality.

Effective training therefore becomes a cornerstone of culture. It transforms the QMS from a framework that is documented into one that is understood, valued and actively sustained by the people who make it work every day.

## 6. Embedding Quality in Daily Operations

For quality management to become part of the corporate culture, it has to be lived in everyday work across the organisation. This requires embedding it in all operational activities and ensuring that processes and documents are designed so compliance with quality standards is realistic and integrates naturally into workflows.

### Aligning SOPs with Reality

Standard operating procedures are meant to guide, but they lose authority when they do not match operational practice. Staff often invent workarounds if procedures are outdated, cumbersome or misaligned with workflow. These shortcuts may seem harmless but introduce risk and can damage credibility with regulators.

Embedding procedures into real workflows requires active involvement of those who use them. Drafting SOPs with input from operators, technicians, engineers and QA staff ensures that instructions reflect equipment, environment and time pressures. Procedures also need regular review and clear version control so that staff do not rely on obsolete instructions.

Leaders should view workarounds as signals. Instead of punishing staff for deviating, organisations can ask why the workaround exists. Is the procedure impractical, too slow,

or unsupported by resources. Adjusting SOPs in response to these findings strengthens both compliance and trust.

## CAPA as a Learning Tool

Corrective and preventive action is one of the most scrutinised areas of any quality system. In many organisations it is viewed with suspicion, associated with blame and punishment. This perception discourages reporting and slows improvement.

The alternative is to use CAPA as a learning tool. Companies that distinguish between routine, low-risk issues and serious safety problems can resolve minor items quickly while focusing full investigations where they matter most. Pilot studies by the Medical Device Innovation Consortium[1] show that this approach reduces backlogs, accelerates resolution and improves trend detection.

To build a learning culture, CAPA investigations must ask not only what went wrong but also why. Root-cause analysis should be thorough, and corrective actions must be tested for effectiveness. Outcomes should be shared openly so staff see that reporting problems leads to improvements. In this way, CAPA becomes a driver of transparency rather than a source of fear.

## Risk-Based Thinking in Decisions

ISO 13485 explicitly references ISO 14971 for risk management. ISO 14971 requires risk management across the entire device lifecycle: hazards must be identified, analysed, evaluated, and controlled, with post-production information feeding back into the risk file. In line with ISO 13485, this approach must extend beyond documentation to shape daily decisions, embedding risk awareness throughout the organisation.

This means operational choices, whether about process changes, supplier selection, or scheduling, should include risk considerations. Minor deviations may need a brief risk check, while significant design or supplier changes require full analysis. Risk files must be updated with complaints, field data and post-market surveillance.

Embedding risk thinking into daily work also requires tools and habits. Templates, checklists and standing agenda items in project reviews make it natural to ask what could go wrong, how serious the impact would be, and how to control it. Over time, this becomes reflexive rather than procedural.

## Feedback Loops from Post-Market Surveillance into R&D

Too often, post-market surveillance is treated as an end point: complaints are logged, analysed and closed. Yet ISO 14971 explicitly requires post-production information to flow back into the risk management file, and regulators expect to see evidence of design changes informed by field data.

Effective organisations close this loop. Service teams channel complaint trends to design engineers. Adverse event data is reviewed alongside development plans. Patterns such as recurring user errors trigger usability reviews, while component failures drive supplier reassessment.

Formal mechanisms help. Scheduled meetings where R&D teams review post-market data, clear documentation of design updates linked to surveillance findings, and cross-functional ownership of corrective actions ensure that learning from the field translates into safer and more reliable devices.

MDIC. (2023). Overview of New CAPA Framework and Pilot Results. In MDIC. https://mdic.org/wp-content/uploads/2023/05/2022-MDIC-Make-CAPA-Cool-Whitepaper_v16.pdf.

## Extending Culture to Suppliers and Partners

In recent years, international regulations have steadily expanded corporate responsibility to include suppliers and partners, placing the entire supply chain under scrutiny.

From a quality management perspective, this is consistent: just as every internal work step affects outcomes, the full supply and production chain determines whether the final product meets quality standards. Under ISO 13485 and ISO 14971, these relationships are defined as part of the quality system and must be addressed through risk management and surveillance.

Companies must therefore choose suppliers and partners with care, assessing more than cost alone. An inexpensive supply chain that results in defects and forces a product withdrawal ultimately proves far more costly than selecting reliable partners from the beginning.

To ensure resilience, organisations should embed the supply chain into their quality concept, for example through the following measures:

- Include quality and risk criteria in supplier selection
- Require suppliers to share data on nonconformities and corrective actions
- Conduct audits that assess behaviour and transparency, not just paperwork
- Run joint workshops or improvement initiatives that strengthen processes on both sides.

## 7. Measuring and Sustaining Quality Culture

Whether a culture of quality is truly taking hold in a company should not be left to gut feeling. What matters are measurable facts. Organisations should therefore establish specific metrics to assess how firmly a culture of quality is embedded across the business. Sustaining that culture requires ongoing monitoring, structured measurement, and the readiness to address resistance before it undermines engagement.

### Methods for Gauging Culture

Counting defects or audit findings tells little about whether a culture is strong. To understand culture, organisations need methods that look at behaviour and perception. Culture audits are one way. These combine surveys, interviews and focus groups to capture how staff view leadership, whether they feel safe to raise concerns and how they respond when quality, cost and speed collide. Anonymous surveys that ask, “How often do you see procedures bypassed?” or “How confident are you that issues will be acted upon?” often reveal more than any dashboard.

Quantitative indicators add another layer. The volume of near-miss reports, the time it takes to resolve a problem, or the uptake of training all show whether people are engaged or disengaged. Looking at these trends alongside qualitative insights gives a more reliable picture than either alone.

Here are some metrics that are especially helpful in understanding culture:

| METRIC | WHAT IT INDICATES ABOUT CULTURE |
|---|---|
| Reporting behaviour (near misses, quality concerns) | Willingness to surface problems rather than hide them |
| Training uptake & skill retention | How seriously staff take quality; whether investments in training are used and kept alive |
| Number / rate of employee suggestions / improvement | Evidence of engagement and ownership |
| CAPA closure time and recurrence rates | Whether problems are remedied thoroughly and lessons are learned |
| Audit trend metrics (internal, supplier, regulatory) | What systemic patterns emerge; whether audits lead to real change |
| Supplier quality metrics (defects, deviations, responsiveness) | Whether culture of quality extends beyond internal boundaries |

### Management Reviews as Checkpoints

Clause 5 of ISO 13485 requires management reviews at planned intervals. Used properly, they can be cultural checkpoints. Leaders should ask not only whether performance indicators are met but whether behaviours align with the organisation’s values. Did staff raise issues promptly? Did corrective actions lead to visible improvement? Were suggestions acted on or quietly dropped? A management review that confronts these questions helps leadership see whether culture is thriving or fading.

## 8. Common Pitfalls and How to Avoid Them

Even well-designed quality systems can fail if cultural and behavioural pitfalls are left unaddressed. The following are recurring challenges in organisations working with ISO 13485 and related frameworks, together with ways to avoid them.

### Overemphasis on Documentation over Meaning

Some organisations allow their quality systems to grow into complex bureaucracies, where different departments defend their own territory and information flows are restricted.

This undermines collaboration, slows response times, and creates inconsistency.

**How to avoid it:**

- Design procedures that are streamlined and easy to follow, avoiding duplication.
- Encourage cross-functional teams to handle audits, CAPAs, and risk reviews together, breaking down silos.
- Use digital systems where appropriate to improve visibility and access to shared information.

### Leadership Inconsistency

Inconsistencies in corporate management can rapidly erode the progress achieved in building corporate culture.

If leaders speak about quality but reward speed or cost-cutting, staff quickly learn what really matters. This mixed messaging damages trust and undermines compliance.

**How to avoid it:**

- Align performance incentives with quality objectives, not only financial or delivery targets.
- Ensure leaders at all levels act consistently, from boardroom to line management.
- Publicly recognise behaviours that reinforce quality culture, such as transparent reporting or successful corrective actions.

### Lack of Communication and Underestimating Resistance

Another common pitfall is to underestimate how change affects people. Silence from leadership, or one-way announcements without dialogue, leaves staff uncertain and disengaged. Resistance grows quietly, sometimes expressed through non-compliance or passive workarounds.

**How to avoid it:**

- Establish two-way communication channels: town halls, team discussions, anonymous feedback tools.
- Anticipate resistance as normal and plan for it. Provide explanations, training, and visible support.
- Monitor early signals of disengagement, such as missed training or lower reporting rates, and intervene promptly.

## 9. Case Studies

The following case studies of quality-driven culture illustrate varying stages of maturity, the challenges encountered, and the results achieved.

### Case Study 1: Reducing Audit Findings Through Cross-Functional Quality Champions

**Background:**
A mid-sized European manufacturer of Class IIb orthopaedic implants was struggling with repeated minor nonconformities during ISO 13485 surveillance audits. Audit reports consistently pointed to inconsistent documentation practices and gaps in employee awareness of quality procedures.

**Intervention:**
The organisation launched a "Quality Champion" initiative, selecting representatives from each department (R&D, production, regulatory affairs, customer service) to act as cultural ambassadors. Champions received additional training in ISO 13485 requirements, internal auditing, and process improvement tools. They held monthly cross-functional meetings to share insights and escalate risks before they became findings.

**Outcome:**
Within 12 months, the company reduced audit findings by 68%. Employee surveys showed a 40% increase in understanding of how individual roles contributed to quality objectives. The initiative also improved interdepartmental communication, reducing process delays and increasing first-pass yield by 15%.

### Case Study 2: Embedding Risk Management into Product Development

**Background:**
A medical device startup developing a Class III cardiovascular device was preparing its first submission under the EU MDR. Initial project reviews revealed that risk management activities were being performed as a compliance step at the end of development rather than throughout the lifecycle. This led to late design changes, increased costs, and potential delays in market entry.

**Intervention:**
The leadership team worked with the Quality and Engineering departments to embed ISO 14971 risk management processes into every design control stage. Risk assessments became a standing agenda item in all design review meetings, and cross-functional teams were trained to proactively identify and mitigate risks.

**Outcome:**
The integration reduced late-stage design changes by 50% and improved the completeness of the technical documentation package for MDR submission. The Notified Body auditor specifically noted the company's "mature and proactive risk management culture" during the conformity assessment, helping accelerate approval timelines.

### Case Study 3: Transforming CAPA from Punishment to Learning

**Background:**
A large North American diagnostics company faced chronic issues with CAPA backlog and a culture of fear around reporting nonconformities. Employees were reluctant to raise issues, perceiving CAPA as a tool for blame rather than improvement.

**Intervention:**
The Quality Director initiated a cultural reset by rebranding CAPA as a "Continuous Improvement" process. All managers were trained to frame CAPA discussions as opportunities for learning, and success stories were shared company-wide to highlight positive outcomes from reporting issues. KPIs shifted from "number of CAPAs closed" to "percentage of CAPAs resulting in preventive changes."

**Outcome:**
Over 18 months, the volume of voluntarily reported issues increased by 60%, while repeat nonconformities dropped by 45%. The organisation's last MDSAP audit contained zero CAPA-related findings, and internal engagement surveys showed a marked increase in trust between operational teams and the Quality department.

## Key Takeaways Across Case Studies:

- Leadership visibility and commitment are essential for shifting behaviours.
- Cross-functional engagement breaks down silos and improves process alignment.
- Reframing compliance processes as enablers of improvement fosters trust and participation.
- Embedding quality into daily operations reduces late-stage issues and audit findings.

| CASE STUDY | ORGANISATION PROFILE | CHALLENGE | INTERVENTION | OUTCOME |
|---|---|---|---|---|
| **1. Reducing Audit Findings Through Cross-Functional Quality Champions** | Mid-sized European manufacturer of Class IIb orthopaedic implants | Repeated minor nonconformities in surveillance audits; inconsistent documentation; low quality awareness | Appointed cross-functional "Quality Champions" in each department; monthly meetings; additional ISO 13485 and process improvement training | 68% reduction in audit findings; 40% improvement in staff quality understanding; 15% increase in first-pass yield |
| **2. Embedding Risk Management into Product Development** | Startup developing Class III cardiovascular device (EU MDR submission) | Risk management done late in development, causing costly design changes | Integrated ISO 14971 risk management into every design stage; trained cross-functional teams; risk review in all design meetings | 50% reduction in late design changes; faster MDR approval; praised by Notified Body for proactive risk culture |
| **3. Transforming CAPA from Punishment to Learning** | Large North American diagnostics company | CAPA backlog; fear of reporting issues; low trust in quality processes | Rebranded CAPA as "Continuous Improvement"; trained managers in constructive problem-solving; shifted KPIs to preventive changes | 60% increase in voluntary reporting; 45% drop in repeat nonconformities; zero CAPA-related MDSAP findings; improved trust in Quality department |

## 10. Roadmap for Implementation

Building a culture of quality under ISO 13485 is a deliberate, staged process that involves leadership commitment, systematic assessment, and integration into daily work.

Organisations that treat culture as a long-term project, not a short-term initiative, are more likely to achieve lasting results. The following roadmap offers a structured approach that organisations can adapt to their own size, maturity, and regulatory environment.

### Step 1. Leadership Alignment

The starting point is agreement among senior leaders. Executives must share a common understanding of what quality means for the organisation, why it matters for patient safety and market success, and how they will model the behaviours expected of others. Alignment includes clarifying responsibilities under ISO 13485 Clause 5, defining how the management representative will report to the leadership team, and agreeing on how quality objectives will be monitored.

### Step 2. Culture Baseline Assessment

Before an organisation can strengthen its culture, it needs to know where it stands. A baseline assessment uses surveys, interviews, and data from audits and CAPA records to map perceptions and behaviours. The goal is to identify strengths, such as openness to reporting, and weaknesses, such as a tendency to bypass procedures. This assessment provides the reference point for future measurement. It also gives employees a voice in the process, signalling that culture is not imposed from above but shaped collectively.

### Step 3. Define and Communicate Vision

Once leadership is aligned and the baseline is clear, the next step is to articulate a vision. This vision should connect quality directly to the organisation's mission and strategy. It must be simple enough to be remembered and specific enough to be acted upon. Communication is key here. Leaders must repeat the core message consistently, reference it in decisions, and link it to outcomes such as patient safety, regulatory approvals, or customer trust.

For management it is vital to avoid sending mixed signals through words or actions. A clear thread from guiding principles to communication and personal conduct is essential if a culture of quality is to take root throughout the organisation. Culture begins at the top: when leaders fail to set the right example, the entire effort to build quality culture is unlikely to succeed.

### Step 4. Integrate into Processes

A vision only gains traction when it is embedded in the way work is done. This means aligning SOPs with real workflows, ensuring CAPA functions as a learning tool, and making risk-based thinking part of daily choices. It also means integrating quality criteria into supplier management, investment decisions, and performance evaluations. Integration requires close cooperation between quality teams and operational staff. The views and experience of the responsible team members must be considered to ensure that the principles reflect workplace realities and can be put into practice. Processes should be tested against real use and revised where necessary. The aim is to eliminate gaps between policy and practice, making quality the natural outcome of how work is structured.

### Step 5. Train and Empower

ISO 13485 requires that organisations provide training, and maintain evidence that staff are qualified. Training should combine procedural knowledge with an understanding of why procedures matter. Interactive methods, case studies, simulations, peer learning, help transform compliance into ownership.

However, training is only effective when employees are trusted to act on it. They need the authority to stop a process, raise concerns, or propose improvements without fear of reprisal. When such behaviour is recognised and supported by managers, quality becomes part of everyday work rather than an obligation imposed from outside.

### Step 6. Monitor and Adjust

Continuous monitoring ensures that progress is tracked and that emerging risks are addressed. This involves combining quantitative metrics, such as CAPA closure rates or supplier defect trends, with qualitative insights from surveys or interviews.
ISO 13485 requires regular management reviews, and these are the right place to test whether culture is holding. Leaders need to ask whether behaviours match the vision they have set, and whether problems raised are dealt with openly. When adjustments are required, they should be explained and shared across the organisation so that learning is collective, not confined to a single team.

### Suggested Timeline and Checkpoints

The pace of implementation depends on the maturity of the organisation, but a phased approach over 12–18 months is typical:

**Months 1–3:** Leadership alignment, appointment of management representative, culture baseline assessment.

**Months 4–6:** Definition of vision, communication strategy, initial integration into selected processes.

**Months 7–12:** Expanded integration across operations and suppliers, rollout of targeted training, establishment of quality champions.

**Months 13–18:** First full cycle of measurement and management review focused on culture, adjustments based on findings, reinforcement of leadership commitment.

Checkpoints at quarterly intervals help maintain focus and prevent drift. At each point, leadership should ask whether objectives are being communicated clearly, whether staff feel engaged, and whether processes reflect both regulatory requirements and operational reality.

## 11. Conclusion

ISO 13485 provides the quality framework that every medical device manufacturer must follow. It defines the processes, responsibilities and documentation that regulators expect. Yet compliance with the standard is only the beginning. What distinguishes resilient organisations is the culture that surrounds these requirements. When quality is treated as a shared responsibility, embedded in daily practice and championed by leadership, the framework becomes a living system rather than a static set of rules.

Throughout this white paper, the same theme has surfaced: leadership determines whether quality remains a theoretical concept or becomes part of the organisation's identity. Leaders set the tone, allocate resources, and integrate quality into strategy. Employees, in turn, carry that commitment into design, production, service and supply chains. Culture flourishes when everyone recognises their role in safeguarding patients and meeting regulatory expectations.

The benefits of this approach reach far beyond compliance. A strong quality culture reduces the risk of recalls, strengthens regulatory trust, and shortens approval timelines. It builds confidence among customers, clinicians and partners. Over time, it becomes a competitive advantage: organisations with robust cultures are more trusted, more innovative and more sustainable.

The call to action is clear: Leadership must remain visibly committed, reinforce consistent messages, and ensure that resources support quality at every level. By doing so, they not only meet the demands of ISO 13485 but also create lasting trust in their products and their organisation. Quality culture is not a project with an end date. It is the foundation for patient safety and the measure by which long-term success in the medical device sector is defined.

## Quick Start Checklist for Building a Quality-Driven Culture

### 1. Align leadership

- ☐ Leadership has agreed a shared commitment to quality
- ☐ Responsibilities under ISO 13485 Clause 5 are clearly assigned
- ☐ A management representative has been appointed and empowered

### 2. Assess the baseline

- ☐ Culture audit or survey completed
- ☐ Staff perceptions of quality collected through interviews or focus groups
- ☐ Strengths and weaknesses identified

### 3. Define and communicate vision

- ☐ A concise quality vision statement is created
- ☐ Vision is linked to patient safety, compliance and strategy
- ☐ Leaders communicate the vision regularly and consistently

### 4. Integrate into processes

- ☐ SOPs reviewed and aligned with real workflows
- ☐ CAPA approach reframed as a learning tool
- ☐ Risk-based thinking included in daily decision-making

### 5. Train and empower

- ☐ Training explains not only procedures but their purpose
- ☐ Employees feel safe to raise concerns
- ☐ Recognition systems in place for positive quality behaviours

### 6. Suppliers and Partners

- ☐ Quality expectations included in supplier selection and contracts
- ☐ Supplier audits test culture as well as compliance
- ☐ Improvement initiatives involve key partners

### 7. Monitor and adjust

- ☐ Metrics tracked (reporting behaviour, CAPA recurrence, training uptake)
- ☐ Management reviews include culture as well as performance
- ☐ Adjustments made based on findings, with lessons communicated

## Appendix: ISO 13485 Clauses Related to Culture

| CLAUSE | TITLE | WHAT IT REQUIRES / HOW IT RELATES TO CULTURE |
|---|---|---|
| **4.1 – General requirements** | Quality Management System, including risk-based thinking | Requires establishing, implementing and maintaining a QMS. Cultural requirement: processes must be defined in a way that everyone understands how they contribute; risk awareness must be part of process design. |
| **4.2 – Documentation requirements** | Control of documents and records | Cultural relevance: ensures shared understanding; clear and usable documents; prevents confusion and workarounds. |
| **5 – Management responsibility** | Overall leadership duties (subclauses including 5.1 through 5.6) | This is the core culture-clause: top management must show commitment, establish quality policy, set objectives, define roles & authority, appoint a management representative, ensure communication, and conduct reviews. These requirements are directly about leadership behaviour and culture. |
| **5.1 – Management commitment** | Leadership demonstration of commitment | Requires top management to actively support the QMS, regulatory compliance, and awareness of responsibilities. Cultural relevance: sets the tone from the top and shows quality is non-negotiable. |
| **5.2 – Customer focus** | Focus on regulatory and customer needs | Requires leadership to ensure customer and regulatory requirements are identified and met. Cultural relevance: embeds accountability to patients, users, and regulators. |
| **5.3 – Quality policy** | Establish and maintain policy | Requires a documented and communicated policy that is reviewed for suitability. Cultural relevance: acts as a visible anchor of values and direction. |
| **5.4.1 – Quality objectives** | Define measurable goals | Requires measurable objectives aligned with the quality policy. Cultural relevance: links everyday work to long-term quality ambitions. |
| **5.4.2 – QMS planning** | Plan for maintaining and adapting QMS | Requires planning so that the QMS remains effective during changes. Cultural relevance: ensures adaptability and embeds quality in business decisions. |

| CLAUSE | TITLE | WHAT IT REQUIRES / HOW IT RELATES TO CULTURE |
|---|---|---|
| **5.5.1 – Responsibility and authority** | Clear definition of roles | Requires roles and responsibilities to be defined and communicated. Cultural relevance: avoids ambiguity and fosters accountability. |
| **5.5.2 – Management representative** | Appoint a quality representative | Requires a leader with authority to maintain the QMS, report performance, and promote regulatory awareness. Cultural relevance: creates a visible advocate for quality with leadership weight. |
| **5.5.3 – Internal communication** | Ensure effective communication | Requires processes for communication about QMS effectiveness. Cultural relevance: supports transparency, trust, and shared understanding. |
| **5.6 – Management review** | Regular reviews at planned intervals | Requires structured reviews with defined inputs (audits, feedback, performance data, complaints, CAPA, resources) and outputs (decisions, improvements, resourcing). Cultural relevance: provides a formal checkpoint where leadership reinforces values and drives improvement. |
| **6 – Resource management** | Competence, infrastructure, work environment | Culture depends on adequate resources; employees must have training; the work environment must support quality behaviour. Without resource commitment, culture falters. |
| **7 – Product realisation** | Design and development, supplier controls, process validation etc. | Culture is reinforced in how the organisation realises product; design reviews, change control, supplier relationships require cooperation, shared responsibility, and openness to feedback. |
| **8 – Measurement, analysis and improvement** | Monitoring, CAPA, audits, data-driven improvements | Sustaining culture means measuring what matters, using feedback, learning from failures. This clause mandates corrective and preventive actions and continuous improvement. |

**Author | Anne Arndt CEO**
Elevate Med Tech New Zealand Limited

+64 (0) 20 4183 1943
anne.arndt@elevate-med.tech

1/103 Qb Studios | 235 High Street
Christchurch CBD 8011
New Zealand

www.elevate-med.tech