

Scilife

The 7-step blueprint for Smart Quality transformation

Is your organization
ready?



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Introduction

The Smart Quality Quest

In an increasingly digital, patient-experience, and insight-driven Life Sciences ecosystem, a scatter-shot approach to quality focused on “compliance-only” no longer works.

From design thinking to advanced analytics and data science, digital technologies are converging to accelerate and automate quality. This not only improves quality throughout an organization, it provides an opportunity to completely reimagine processes, ways of working and collaborations with regulatory bodies and different stakeholders.

The purpose of our Smart Quality Transformation Blueprint is to lay out the path forward for Life Sciences organizations to advance their quality capabilities and move from hindsight to foresight, driving insights. It establishes the foundation, frameworks,

and vaults that contain all the knowledge needed to embark on the Smart Quality quest.

With this roadmap in hand, you’ll cross the threshold beyond quality management and processes—far beyond a mere compliance perspective. Our blueprint will guide you through 7 comprehensive chapters detailing everything intrepid quality professionals will need to plan, execute, and orchestrate the Smart Quality model within their organizations.

Soon, you’ll be ready to effectively transition from a linear-based approach to a forward-looking quality approach and create an unbeatable competitive edge in your Life Sciences organization.



Unlock the potential for extraordinary value creation. Let’s start the journey!

Definition

What is Smart Quality?

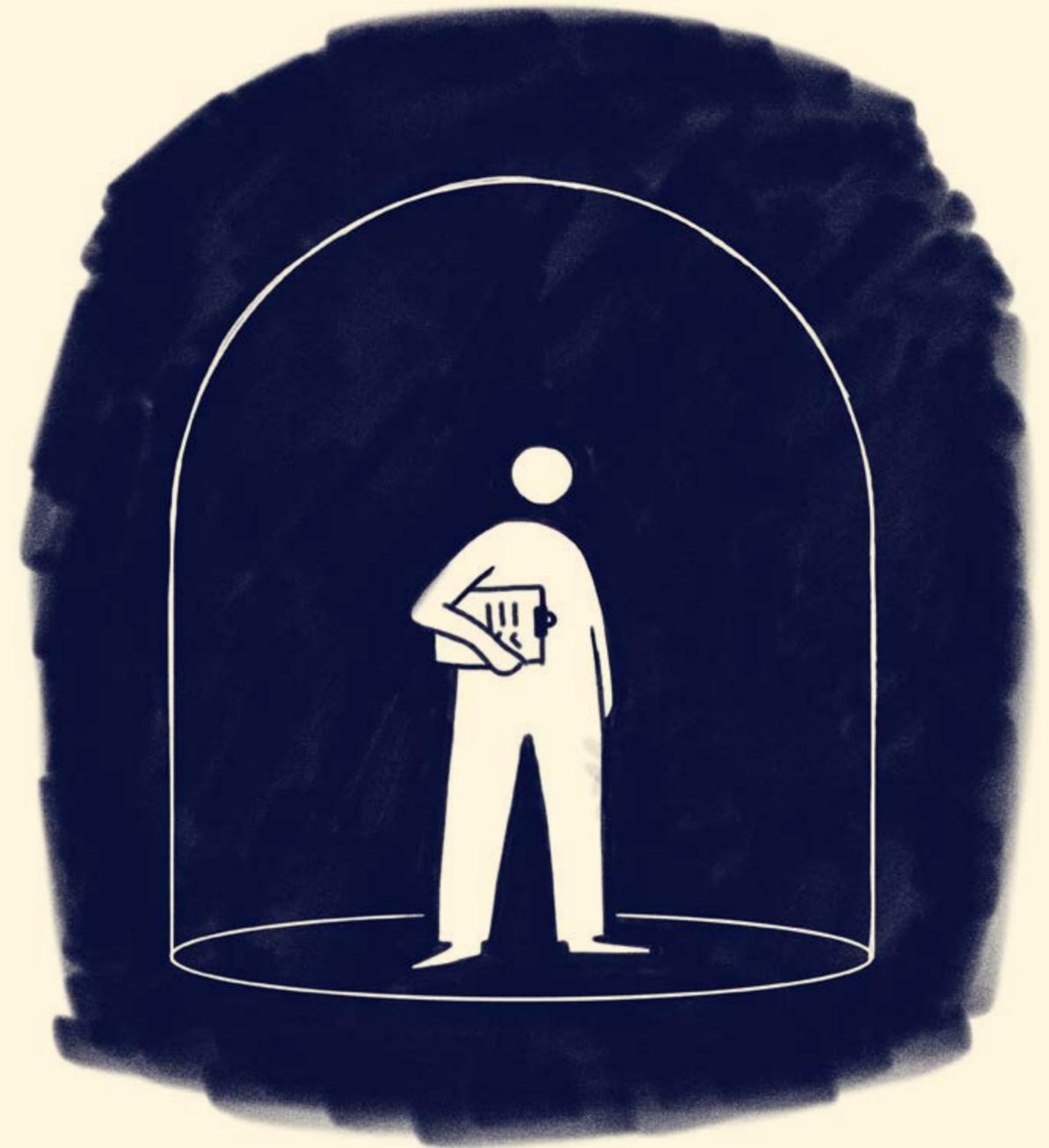
Smart Quality is the new quality model that empowers Life Sciences organizations to **transform quality** into a **key catalyst of value creation**, rather than being merely an unavoidable cost of doing business.

With a **Smart Quality mindset**, employees across an organization are equipped to take ownership of quality, **boost patient experience**, **reduce compliance risk**, reach **peak performance** and seize the emergent **opportunities for innovation** in the dynamic, ever-changing Life Sciences landscape.

By combining advanced data analytics, (personalized) continuous learning, and proven game-like methodologies, our **Smart Quality Platform** helps Life Sciences **accelerate science and improve patients' lives**.

Step 1

Breaking free of the Quality Status Quo



1. Breaking free of the Quality Status Quo

Traditional Quality vs Smart Quality

Traditional quality is based on understanding the customers' needs and requirements and translating these into products and services. In this model, the focus is mainly on the **standardization** of a manufacturing process, producing and delivering according to regulations, reducing variation and learning from errors to improve efficiency.

The final target of traditional quality is verifying the quality of the product or service and using the feedback to continuously improve the processes and products, while ensuring effectiveness and profit.

Smart Quality, on the other hand, is a way of looking at the world of quality with different eyes, empowering organizations to uncover vast troves of added business value.

Our Scilife platform operates with Smart Quality at its core. We redefine what quality means by helping you discover what quality can do.

Smart Quality is a new way of working using digital tools within a digital transformation scenario. We believe that “doing digital” is not enough, and only “being digital” truly leads an organization to excellence.



The following table describes the essential differences between Traditional Quality and Smart Quality.

1. Breaking free of the Quality Status Quo

Traditional Quality	Smart Quality
Compliance	
<ul style="list-style-type: none"> • Meet regulatory requirements • Meet customer requirements • Systems and processes focus on regulatory and paper-work compliance • Product is fit for purpose/intended use • Product is free from defects 	<ul style="list-style-type: none"> • Continuously delivers on patient safety and regulatory requirements at the lowest-possible budget. • Predicts emergent customer needs • Leads to strong collaboration with suppliers and regulatory bodies
Quality Management	
<ul style="list-style-type: none"> • Quality is the responsibility of the Quality Unit • QA with a policing mentality • Controlled and audit-based approach • QA relies on checking, surveillance, inspections and compliance. • Quality is about bottom-line savings • Focus on costs to reduce quality defects and variation • Focus mainly on short-term objectives • Reactive approach to quality with processes and systems that add no value to the product or service • Decisions are based on emotions rather than on facts • Inadequate problem solving capabilities 	<ul style="list-style-type: none"> • Organization-wide ownership of Quality • Embracing Quality Management Maturity principles • Quality as top-line revenue generator • Proactive approach to quality • User-friendly processes built on new technologies • Use of novel digital tools for continuous improvement • Preventive and intelligent systems • Focus on continuous innovation • Focus on problem-solving and increasing process robustness

1. Breaking free of the Quality Status Quo

Traditional Quality	Smart Quality
Technology	
<ul style="list-style-type: none"> • Primarily paper-based system • “Doing digital” to reduce directly identifiable costs • Traditional desktop software 	<ul style="list-style-type: none"> • Completely paperless workflows • Being 100% digital • Digital QA processes (eQMS) • Cloud-based software • Innovative technologies
Documentation & Data	
<ul style="list-style-type: none"> • Manual processes • Silos of information • Existing systems create difficulties in accessing data • Bureaucracy • Manual data collection and trend creation 	<ul style="list-style-type: none"> • QA processes are digitalized and integrated • Automated data pulls • Real-time trends and visualization • Automated metrics and KPIs • Advanced analytics
Value creation	
<ul style="list-style-type: none"> • Low-value-added work: focus on troubleshooting, non-conformances, root-cause analysis investigations, complaints, etc. • Reactive actions and activities with no value added to the product or service proactively • Risk-based approach and risk-averse mindset 	<ul style="list-style-type: none"> • Compliance is integrated into regular operations • High value creation: innovation, product design, prevention of deviations and non-conformances, customer care, data accessibility, and much more. • Focus on solving problems with cross-functional teamwork

1. Breaking free of the Quality Status Quo

Traditional Quality	Smart Quality
Quality Culture	
<ul style="list-style-type: none">• Weak quality culture: focus on what people do and how they do it• Achieve compliance with minimum quality effort• Learn from errors• Little or no acknowledgement or implementation of employee's suggestions for improving quality	<ul style="list-style-type: none">• Quality is everyone's responsibility• Employees own , actively participate and carry out various quality initiatives• Employee accountability but also sense of ownership• Smart Quality behavior, mindsets and beliefs embodied by everyone in the company• High employee engagement• Focus on what people do, how they do it and why they do it• Cross-functional collaboration• Transparency and stability
Training and Education	
<ul style="list-style-type: none">• Manual paper-based training• Inadequate GxP training programs• Fragmented training• Employees need to be 'chased' by managers to complete trainings	<ul style="list-style-type: none">• Digital quality learning management system for the whole organization• Automated training delivery• Role-based training• Personalized learning based on skill needs• Employees determine and lead their own learning journeys.• Automated training reminders

1. Breaking free of the Quality Status Quo

While traditional non-digital Quality Assurance departments concentrate on the tip of the iceberg (direct labor, direct materials, supplies, production costs, testing costs, etc.), avoiding recalls and loss of reputation, they tend to forget about other hidden costs including :

- **Direct cost of ensuring good quality:** validation, quality control, quality system support, auditing, inspection, etc.
- **Direct cost of poor quality:** quality failures, investigations, CAPAs, customer returns, time lost, reprocessing/reworking, complaint handling, equipment failures, inappropriate training, etc.
- **Other indirect quality costs:** unused capacity, excess inventory, overproduction, no added valued technology and IT, revenue loss due to quality failures, etc.

The total direct cost of quality can go up to 10% of industry sales, which is a lot of money down the drain if those costs aren't delivering added value beyond meeting compliance requirements.

The cost pressure that a company is under limits how much can be spent in assuring best quality practices.

Smart Quality empowers Life Sciences organizations to invest in what really matters: adding value in all processes, especially those directly patient-related.

1. Breaking free of the Quality Status Quo

Where are Life Sciences companies today in their Smart Quality journey?

Over the past decades, Life Sciences organizations have approached quality with a policing mentality to demonstrate to regulating bodies that quality was under control with robust processes. The requirements from regulations and guidelines birthed reactive processes that ultimately undermined profits.

Nowadays, organizations can get on board with new technologies and digital transformation initiatives. Although most companies are using digital tools or boasting about digital culture, it doesn't mean they're being fully digital.

So, how can a company get out of its comfort zone and switch to a Smart Quality mindset?

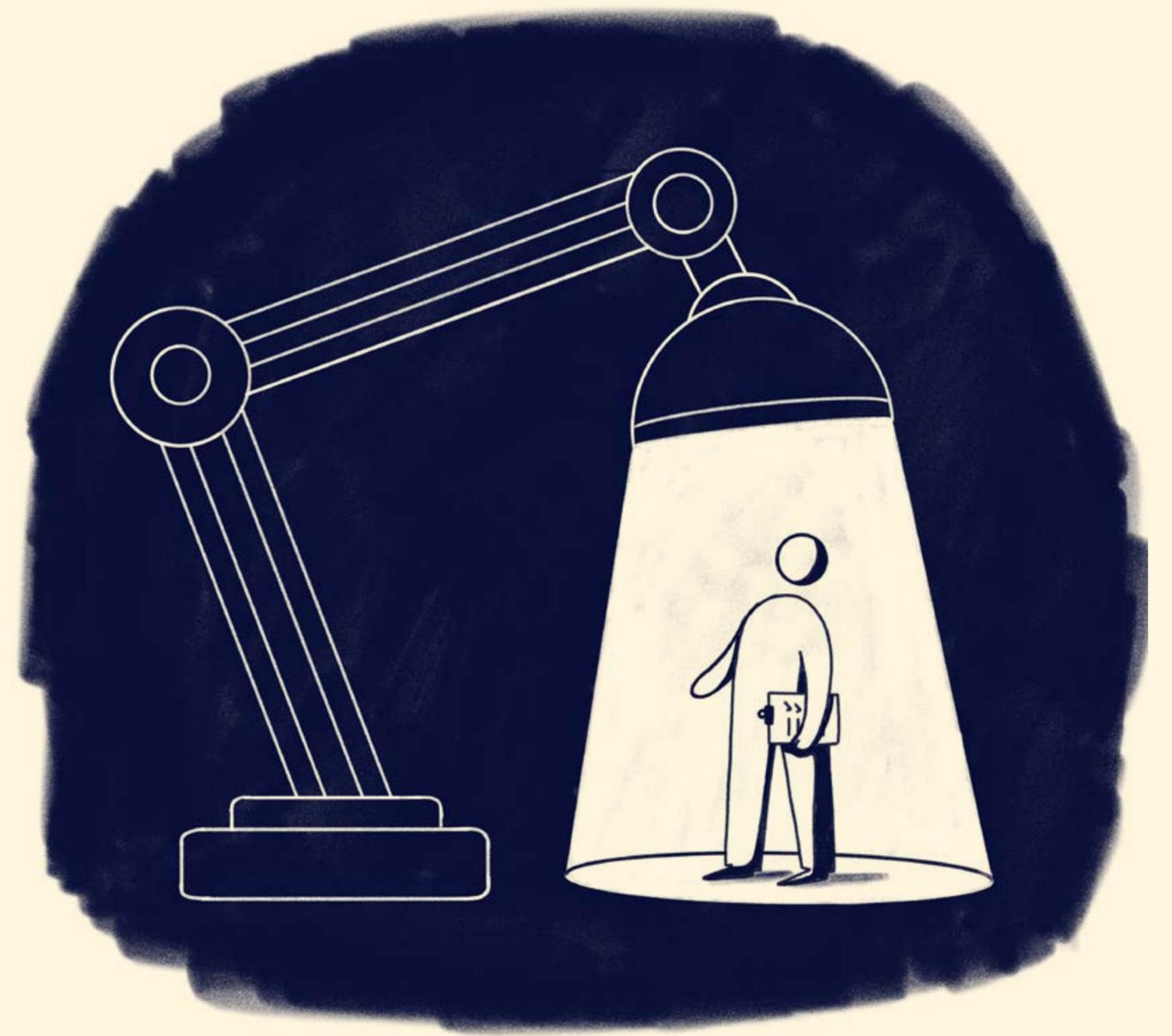
At Scilife we believe it's not just about adopting technology but also about motivating people; **inspiring a holistic quality culture through mindset transformation.**

The real challenge is advancing people's mindsets, behaviors, capabilities, competencies, and outdated ways of working. The transformation to Smart Quality is human-centered and demands open-minded thinking.

When people are prepared to embark on a continuous personalized learning journey to grow skills, such as team collaboration, communication and critical thinking to solve problems, then they're ready to embrace novel technology and get 'smart'. A Smart Quality culture nurtures such skills to flourish, ultimately leading to new opportunities and business success.

Step 2

The call



2. The call

What are the triggers that catalyze Smart Quality in the Life Sciences?

- ✓ Market complexity demanding innovative solutions
- ✓ Visibility and transparency of market forces
- ✓ Increased manufacturing capacity, flexibility and organizational velocity
- ✓ Wanting to go beyond compliance and reduce risks
- ✓ Quality cost reduction demands
- ✓ Seeking to generate positive value
- ✓ Desire for efficiency and effectiveness
- ✓ Seeking employee ownership of quality and empowerment
- ✓ Curiosity to redefine what quality means
- ✓ Desire to improve Quality Culture

Why do we need a different quality paradigm?

- **The approach of traditional quality is suitable according to regulations, but it is not enough to excel.** The processes and workflows need to be streamlined, and sometimes re-designed, in line with a new quality culture, using more efficient and robust processes.
- **At Scilife, we propose a new quality paradigm, going beyond the borders of traditional quality.** A paradigm based on Smart Quality, design-thinking and an organization-wide commitment to quality. Above all, a nurtured quality culture, which we believe is what unites organizations, connecting people through common values.
- Ultimately, this new approach has the potential to empower people to act in a way that involves their hearts and minds, as well as their hands. Smart Quality is a partner that **helps integrate compliance into regular operations and adds value to customers, patients and the business** as a whole.

2. The call

Quality

Qu

- Quality is seen as a top-line revenue generator
- Building quality leadership throughout the organization
- Develop strong problem-solving skills to minimize errors (a zero defects target)
- Integrate compliance into everyday operations

Customer focus

Pa

- Understand and foresee the needs of customers and patients
- Accelerate time to market for capital projects
- Go beyond the pill or medical device: provide added-value services such as training programs and educational materials
- Boost effectiveness of care

Innovation

In

- Focus on product and process innovation
- Accelerate the discovery and design of new products or services
- Use technology for more empowered decision making: upskilling, cross-functional collaboration, innovation, improved workplace safety and employee satisfaction

Growth

Gr

- Use data and analytics to get insights from customers about the way they take decisions and the way they interact with the brand
- Discover completely new products or lines of business
- Invest for profitable, inclusive and sustained growth
- Pick talent, capabilities and resources to turbocharge performance

Continuous improvement

Co

- Continuously strive to improve processes, products, systems, tools and services to boost performance and provide greater value to customers.
- Establish meaningful quality metrics to assess and improve
- Base decisions on insights and trends rather than just “facts”

2. The call

Quality Culture

Cu

- Engage employees with their work and the organization
- Encourage employees to express ideas or opinions and ask questions
- Promote human emotions and curiosity as behaviors that create value
- Foster creative and collaborative ways of working
- Nurture trust to support self-responsibility and self-management
- Take care of human capital within the organization (skills, education, etc.). A culture of learning is the leverage to excellence
- Promote integrity, transparency and accountability
- Train management to be open to new internal and external ideas

Sustainability

Su

- Implement environmental and social initiatives: reduce environmental impact, consume energy, water, and raw-materials more efficiently
- Offer the lowest possible price to products and services: allow more widespread accessibility



At Scilife, we are convinced that if you adopt new technologies and base decisions on advanced analytics, your quality management system will be able to be a rich source of insights.

It will help you to take data-driven decisions with minimum cost and risk. After all, the dream of any QA manager is to take advantage of the power of digital tools to obtain thousands of answers and develop relevant solutions in the minimum time necessary.

Step 3

Gathering allies



**Strategy,
not technology,
drives
(smart) quality**



What do you need when embarking on the journey towards Smart Quality?

This is where having a 'good' ally by your side is key (as in Scilife)!

✓ Have a clear and coherent digital strategy

✓ Build skills on digital trends

✓ Make their company culture less risk averse when it comes to digital capabilities

✓ Use novel technologies and encourage employee buy-in with new digital capabilities

✓ Use benchmarking data and advanced analytics to set goals and take data-driven decisions

✓ Have a communication strategy that engages the whole organization to change and redesign systems

✓ Improve decision-making and innovation

✓ Be agile and adapt to changes

✓ Develop collaborative work environments to foster innovation

✓ Lead by example

Step 4

Crossing the threshold



4. Crossing the threshold

Shifting Mindsets and Business Models from “Compliance-only” to Value Creation

The Smart Quality approach is based on 3 main blocks:

- **Smart Quality Assurance**
- **Smart Processes**
- **Smart Quality Culture**

Smart Quality Assurance

Quality assurance activities are used to create quality value in the whole organization with minimum cost and low risk. Quality flaws are foreseen in advance, before they appear, using data to prevent reoccurrence of past deviations. A risk management approach and change management control are used to minimize deviations and complaints. Deviations are fully investigated using automated data to find the root cause and apply a definitive CAPA action that avoids the recurrence in the future. The circle of improvement is continuous to gain zero defects.

Smart Processes

Real-time data is collected, analyzed and visualized in an automated way. Insights are used to make compliance, operational, business and cross-functional decisions. The goal is to streamline all processes, to improve efficiency, robustness and reduce deviations and costs.

Smart Quality Culture

Activities of an organization can only be effective if the environment in which employees work is quality-oriented. In a Smart Quality culture, people, apart from following quality guidelines, do quality-focused actions all the time: in everyday activities, listening to others talking about quality and feeling quality all around them. Quality is seen as a cultural value where leaders communicate credibility, foster peer involvement and encourage employee ownership of quality issues.

**Change does
not always mean
transformation,
but transformation
by itself changes
everything
fundamentally**

4. Crossing the threshold

What does Smart Quality transformation really mean?

Levels of Smart Quality

There are three main levels where Smart Quality principles can be applied.

Operational Level

Doing what you are currently doing in a better, faster, and cheaper way. Many companies that are “doing digital” fit in this category — they are using new technologies to solve old problems.

A leading life science company implements an eQMS in all its facilities around the world to improve their deviations management, investigations and CAPA actions.

Traditional QMS find difficulty to find an effective problem solving approach, especially one that will guarantee that the problem will be solved effectively and avoid recurrence in the future.

A systematic, ongoing process of ensuring and improving quality is therefore an essential component of an effective, efficient, and responsive quality management system.

Tactical Level

Involves doing what you are doing in a fundamentally different way. There are several key elements of a tactical plan, including focused goals, steps to take to reach those goals, and a timeline.

Smart-quality ways of working: A Life Sciences company automates data collection, analysis, and visualization for its quality management review to improve depth of insight and accelerate cross-functional decision making.

Smart compliance: A Life Sciences company redefines its processes to cover a global integrated approach, using technology to enhance agile processes, making compliance teams more efficient and effective with the objective of adding value for the organization and patient. This framework helps organizations to deploy the most appropriate electronic tools and quality systems, address quality defects and forecast trends in real-time.

4. Crossing the threshold

A full transition to Smart Quality is a significant shift

Smart Quality assurance: A Life Sciences company transforms their paper based system to being fully digital and automates processes to improve their employees' experience. Quality flaws and other nonconformities are foreseen in advance, before they happen, using real-time trends. This initiative reduces the cost of complaint management and recalls.

Smart Quality controls: A Life Sciences company with multiple labs uses an advanced-analytics digital-twin solution to dynamically optimize scheduling in the labs. The scheduling model relies on a continuous feed of production and lab data to automatically generate an optimized allocation of resources such as equipment and employees.

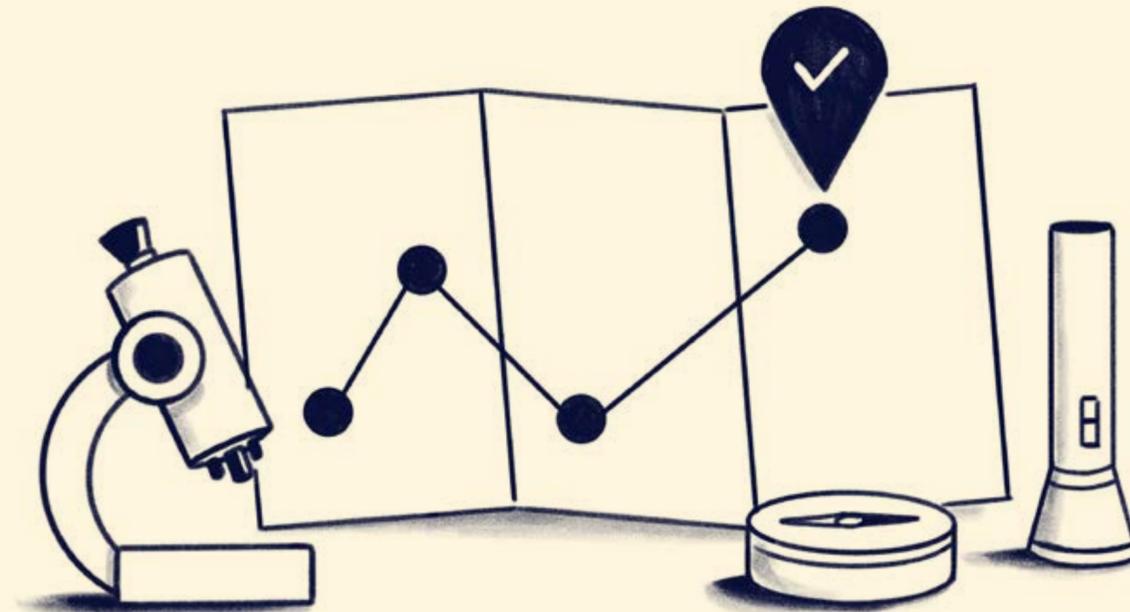
Strategic Level

Changing the essence/mindset of the organization (alignment): Involves using information from external sources to see market trends and the strategies of competing corporations. This level needs information of a predictive nature that allows creation of many different what-if scenarios. It defines the strategy to be followed by the organization with an aligned mindset.

Smart Quality culture: Quality ambassadors, armed with new digital tools and real-time insights from complaints and vigilance, can shift their attention from troubleshooting to engaging with customers and health authorities. All employees can become more engaged in supporting quality, as relevant data is easily accessible and quality-compliance requirements, systems, and processes are more intuitive and user friendly.

Step 5

Smart Quality Roadmap



Smart Quality transformation: Main steps to develop your Smart Quality capabilities

In general, we recommend to carry out the full implementation of a Smart Quality framework in several different steps.

We propose to divide the project in stages according to your business strategy, priorities, key quality processes and resources.

We're sure that by now you're convinced to cross the threshold from quality problem-solvers to quality-creators, and fully ready to embark upon the Smart Quality

quest!! However, crossing the gateway that separates the ordinary world to the next leap of extraordinary excellence will take effort. It may require more than accepting one's fears and weaknesses.



**First things first,
you need a map!
Let's get started!**

Top-down. Quality at the helm of Life Sciences companies' strategy

Start with a diagnosis stage

- Perform an assessment to determine the current quality culture of your organization and the degree to which quality is already present.
- Collect data on employee satisfaction, do surveys, run focus groups, list available human and technological resources, capabilities, business data and history of change.
- Use SWOT technique (strengths, weaknesses, opportunities, and threats) to understand your global weaknesses, as well as your strengths. Identify your threats and pinpoint your opportunities.

Lead transformation

- Design the desired state. Propose what needs to be done to make that vision a reality.
- Develop a corporate mission and vision.
- Prepare to lead the change. Get leaders on board. Define a steering team. Select the team leaders, not bosses, of the transformational change who will take ownership of engagement and support the change. Provide guidance and coach. Teach them leadership skills.
- Set realistic goals and expectations. Show the mission, responsibilities and operating rules. Keep the teams aligned.
- Allocate enough resources to the quality ambassadors and the IT department. Support for best use of resources. The transformation team should be empowered to envision the areas for improvement and lead the commitment to change in the whole organization.
- Benefits and outcomes for Smart Quality transformation must be highlighted in the whole process.

Bottom-up. Employee empowerment

Execute a communication strategy

- This is the “human” side of change management. Organize internal workshops. The goal is to alleviate anxiety, staff resistance, meet training needs and secure buy-in. Show the current quality state and develop a clear vision of the desired state to avoid confusion among employees and help them to understand the scope and size of the initiative. Communicate the consequences of not changing and benefits of adopting the transformational change. Open up employee minds to new ways of doing things.

Use a co-creation leadership style

- Let the whole team participate in the process. Listen to their opinions and concerns. Ask employees what they think. If people believe in the change by seeing incremental and ongoing value realized then the probability of success will jump exponentially.

Transversal management, communication and training path

Promote communication

- Use human resources with different functional expertise, material or financial resources and belonging to different units of the company, to carry out the Smart Quality project.
- Pool resources between departments and business units. Build a transversal culture, team spirit and cohesion.
- Run a community for sharing knowledge or best practices.

Identify skill gaps

- Promote cross-management between teams to enhance the participation of different departments and transformational teams to identify the gaps and main areas of concern in the process flows.
- Identify organizational silos.
- Identify quality activities that can be optimized by technology.

Training

- Provide the employees the knowledge and skills necessary to adopt the change. Personalized learning paths based on skills and competences should be initiated.

Plan and organize for implementation

Start with a pilot plan

- Select one or two key areas for improvement. These areas should be those from which the benefits obtained after the project can be reinvested into subsequent projects.

Implement the change

Test the implementation

- Use Plan-Do-Check-Act methodology in small groups.
- Conduct follow-up meetings to regularly report progress to the hierarchy and general management. It will facilitate recognition of cross-functional actions and the value of individual contributions.
- Giving feedback and recognition at its fair value is key. Assess the contribution of each member and take it into account during the assessment of their performance.

Celebrate, learn, and apply corrections

Celebrate short-term wins

- These wins will build credibility and momentum for the longer-term effort.

Learn and apply corrections

- Share lessons learned across the organization to speed up implementation of next stages and lower risk failure.
- Roll out the framework to more quality systems. It will help to accelerate the overall transformation to Smart Quality.

Step 6

The big pitfalls



What is holding the industry back from evolving Smart Quality capabilities?

✘ **Live in the comfort zone of traditional quality.** They limit their capabilities and skills to strictly interpret data and reports. They are reluctant to prepare themselves for the expectations and demands of the new era.

✘ **Operate in a risk averse culture.** They avoid risk-taking decisions with innovative strategies.

✘ **Lack understanding of technology and specific digital expertise.**

✘ Use paper-based legacy systems that need to be maintained during the lifecycle of the product and are difficult to migrate.

✘ Face compliance and regulation challenges.

✘ Are hindered by resource constraints.

6. The big pitfalls

What are the risks?

The health sciences market shows a strong competitive landscape. The increasingly rapid pace of transformative innovation is forcing companies to adapt to changing circumstances.

Organizations are living in a new environment where the purpose of data accessibility is to derive insights regarding trends and patterns, so as to uncover bottlenecks and inefficiencies.

Data is power. Data is an increasingly valuable asset. Intelligent exploitation of data is critical for enterprises to compete effectively in the health science's market.

QA departments can not only rely on interpreting a small amount of data. They need to view the whole picture to survive.

Organizations that remain in the outdated traditional quality framework must be re-designed to be robust and flexible in quality terms to survive. If they do not adapt, they will waste time and resources and will lose competitive advantage.

6. The big pitfalls

What are the opportunities?

Smart Quality transformation brings opportunities for improving several aspects:

Streamlined processes

- A 50 percent improvement in quality metrics (Makarova et al., 2022)
- Boost productivity by between 50 to 100 percent (Carra et al., 2021)
- Reduce lead times for quality control labs by 60 to 70 percent (Carra et al., 2021)
- Increase productivity and speed in quality control by 50-100% (Carpintero et al., 2021)
- Increase productivity and speed in quality assurance processes by 25-40% (Carpintero et al., 2021)

+50%

**Improvement
in quality metrics**

+50-100%

**Increase productivity
and speed in quality control**

6. The big pitfalls

What are the opportunities?

Smart Quality transformation brings opportunities for improving several aspects:

Assure compliance with cost reduction

- Enable organizations to reduce their total cost of quality assurance by up to 50 percent (Carpintero et al., 2021)

Process reliability

- Significant increase in manufacturing and supply chain reliability (Foster et al., 2021)
- Increase the capacity and responsiveness of manufacturing and supply chain by 20 to 30 percent (Carpintero et al., 2021)

Competitive advantage

- Generate a 30 percent improvement in time to market (Foster et al., 2021)



+30%

**Time to market
improvement**



+50%

**Total cost of quality assurance
reduction**

What are the opportunities?

Smart Quality transformation brings opportunities for improving several aspects:

Better product quality due to better preventive tools

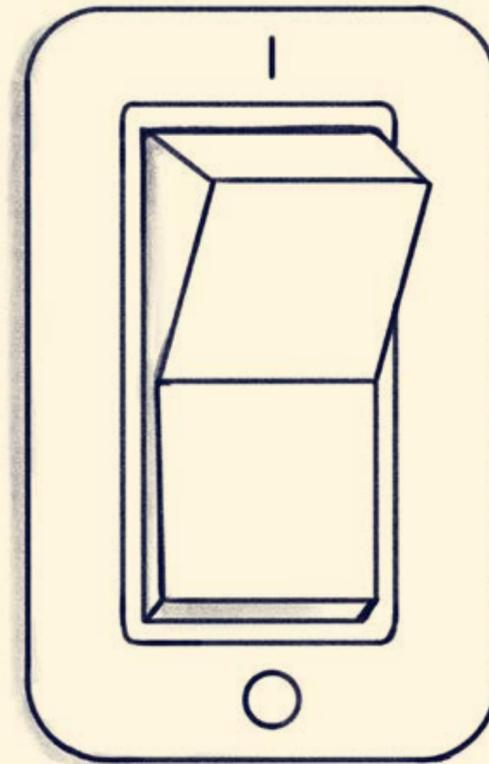
- Reduce the overall volume of deviations and nonconformances by 80% percent (Carpintero et al., 2021)
- Reduce the investigation cycle time for deviations and nonconformances by 90 percent (Foster et al., 2021)
- Through this transformation, you could achieve a 70 percent reduction in deviations, and a 20 percent improvement in on-time in-full delivery (Makarova et al., 2022)

-80%
Deviations and nonconformances reduction

-90%
Investigation cycle time for deviations and nonconformances reduction

Step 7

The transformation to Smart Quality



6. The transformation to Smart Quality

The transformation to Smart Quality is key to successfully standardizing across sites and ensuring a controlled adoption of new technologies.

The goal of Smart Quality is to implement a closed-loop control to meet regulatory guidance following a new digital transformation strategy towards autonomous processes and increased speed to market.

Here, we can identify 5 different Smart Quality maturity levels in organizations, from simple paper-based processes to fully automated and integrated processes of the future.

How Smart Quality level ups

But what differentiates leading Smart Quality organizations? What do they do that is fundamentally different from others? And what are its distinctive traits?

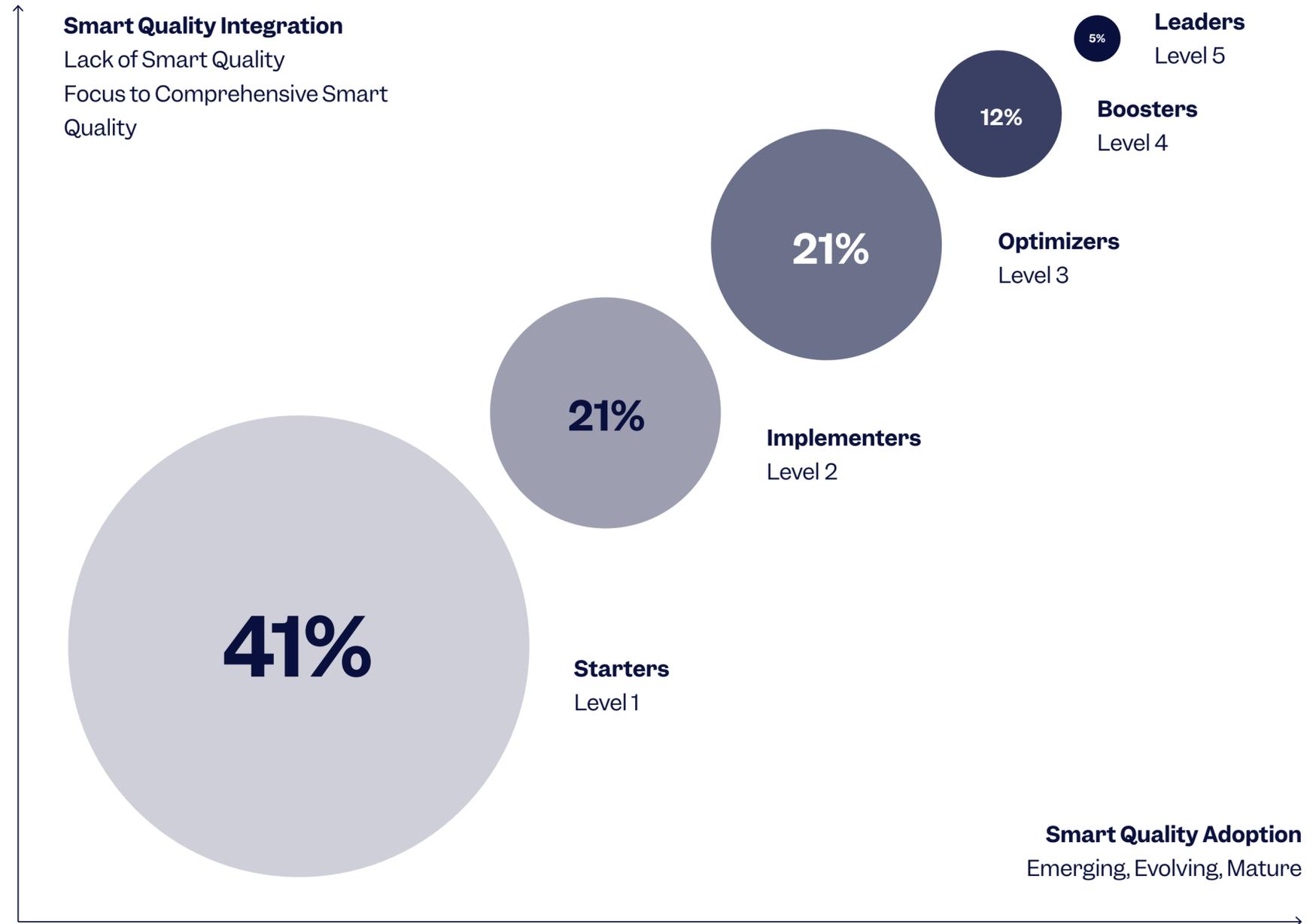
Answering these questions is key to knowing how your company can take advantage of arising opportunities, evolve as an organization, and build a better bottom line. Today, most Life Sciences companies are only scratching the surface of what's possible.



It's time to explore the levels of the new Smart Quality Maturity Model.

6. The transformation to Smart Quality

The Smart Quality Maturity Model



Starters

*Quality is seen as a necessary evil,
a cost-heavy burden of doing business*

41%

These companies are focused on the most visible aspects of compliance.

Quality operates focused on compliance as the baseline with cost reductions as the variable objective.

- Immature quality culture
- Inadequate quality ownership
- Some digital siloes

Key Traits

- Quality is mainly the responsibility of the Quality Unit
- The organization is pre-digital with manual paper-based processes and some digital siloes
- The focus of current digital technology is on costs to reduce quality defects and variation in operations departments: production, quality assurance, quality control, supply chain, etc.
- Management is skeptical of the value of advanced digital technologies
- Immature quality culture

Implementers

Quality brings new clarity to teams

21%

These companies have started the transition from a linear-based approach to a forward-looking quality approach. Quality teams at these organizations have developed more collaborative processes with a limited but growing level of automation.

- Fragmented resources
- Passive compliance function
- Misalignment quality and business objectives

Key Traits

- Still some manual paper-based processes
- Smart Quality initiatives are being planned or implemented in pilot projects
- Medium level of automation, integration and systems standardization remains in silos
- Digital culture may exist, but only in silos
- Adoption of new technologies to reduce nonconformities
- Quality and business objectives are not yet fully aligned



Optimizers

Turning quality into a bright asset within departments

21%

These companies have moved beyond the traditional quality approach and have shared quality ownership, role clarity, joint accountability with key stakeholders, and more documentation of their now more sustainable continuous improvement practices within departments. There is purpose and strategy behind quality efforts but only in some, not all, areas of business.

- Quality ownership within departments
- Adoption of data analytical tools (stand-alone/client-servers)
- Digital initiatives generate improvement

Key Traits

- Quality Culture is established in some separated departments
- High level of automation, integration and systems standardization in silos
- Integrated digital network in silos
- Real-time process monitoring is being implemented
- Adoption of data analytical tools with stand-alone or client server applications to assist departmental new requirements
- Many digital initiatives generating improvements
- Strong digital and quality culture in silos

Boosters

Spreading the light of quality across multiple areas of business supported by leadership boards

12%

Organizations at this Booster level are masters of data-driven processes with sophisticated practices for analytics, non-conformities research, and monitoring and measuring the success of specific efforts. They are successfully integrating smart quality strategies across multiple areas of business in a streamlined fashion with buy-in from leadership.

- Company-wide commitment with quality
- Strong digital culture
- Real-time process monitoring objectives

Key Traits

- Quality is mainly seen as everyone’s responsibility
- Quality Culture is established across the organization
- Smart Quality initiatives are implemented all around the organization
- Clear company-wide digital transformation roadmap Integrated digital network with real-time predictive analysis
- Represent the highest level of automation and integration achievable with current technology
- Real-time process monitoring
- Adoption of data analytical tools and

- cloud-based applications to assist Quality Assurance and Regulatory Affairs in meeting new requirements for data integrity, compliance monitoring, and deviation avoidance
- Many digital initiatives generating business value in measurable ways
- Strong knowledge management process to access information in an easy and robust way
- Adoption of a digital transformation roadmap for technology to standardize systems across sites
- Strong digital and quality culture

Leaders

Smart Quality enlightens the entire organization!

5%

As Leaders of Smart Quality, these companies are robust in all dimensions of maturity. But what really separates them from others is how quality is seen as a key catalyst for value creation and dominates the mindset of the entire organization. Quality is a competitive advantage —with a tangible, real impact on business profit.

These companies harness a plethora of integrated people, processes, and technological elements to drive successful value-creating outcomes. They are fully integrated into digital transformation, making it a part of their company culture. This empowers them to react quickly to market shifts and industry trends. They easily navigate the ever-changing regulatory environment.

- Quality is at the forefront of all business decisions
- Autonomous, self-optimizing, plug-and-play processes
- Adaption of new technologies leading to more efficiencies

Key Traits

- The future state. The highest maturity level is aspirational to inspire development of new technology
- Autonomous, self-optimizing, plug-and-play processes.
- Artificial Intelligence (AI) assistance in investigations and reporting
- Machine Learning (ML) implementation
- Real-time data access to enable faster and better-informed decision-making, leading to more efficiencies on-site.

Final ideas

**Smart Quality
is a never-ending
journey!**

The Era of Smart Quality

For decades, Life Sciences organizations have viewed quality as a behind-the-scenes cost of doing business. As a result, many organizations have been focused on reactive solutions, defensive compliance, and analyzing transactional data in search of what went wrong/non-conformities.

However, the quality function is now at an inflection point. In order to thrive and take the lead, Life Sciences must embrace the new quality paradigm —crossing the threshold beyond the “compliance-only” perspective.

Life Sciences need to assure Quality —but they will need Smart Quality to remain competitive in the future and build resilience into their operating model

But, how can Life Sciences break through structural barriers, and engage everyone in this new paradigm while optimizing quality processes, reducing compliance risk, and seizing the emergent opportunities for innovation?

Shifting from quality cost to embracing a new state-of-the-(Sm)art Quality, Life Sciences companies now have the unique opportunity to integrate compliance into their regular operations, embedding quality into every aspect of the organization, and using it to fundamentally create more value, boosting science and ultimately improve patients’ lives.

What does the future look like?

Smart Quality will drive changes across organizations to adapt to the turbulent waters of the globalized world.

The strong foundations of Smart Quality will uphold a brilliant future with strong digital cultures, digital visions and excellent governance of data.

Smart Quality-ready organizations will integrate compliance and quality in all company operations, showing better operational excellence, overall performance, and innovation. Quality management will be visible and present in each and every step of processes. The ingredients of awareness, involvement, and ownership of quality will deliver true quality products and services.

Design-thinking methodology, digitization, advanced analytics, artificial intelligence and automation will redesign quality processes to be more streamlined and us-

er-friendly. Smart Quality will potentially eliminate some manual manufacturing steps and manual data collection steps, improving accuracy, saving effort, and reducing costs.

Data will generate business value in measurable ways. Data analytical tools and cloud-based applications will assist in meeting new requirements for data integrity, compliance monitoring, and deviation avoidance. The information obtained by technology will provide insights to improve processes and performance. It will even reduce Corrective and Preventive Actions (CAPAs) and ultimately simplify change management.

Last but not least, organizations will have higher employee satisfaction when using user-friendly, attractive and effective digital tools. Employees will follow their own learning path to adapt their skills and performance to the evolving needs and be future-ready.

Final ideas

Reach Smart Quality with Scilife

**Ready to become frontrunners of Smart Quality,
reach peak performance and empower all your
organization to take ownership of Quality?**

We're here, ready to help you switch on the Smart
Quality light and engage all your teams to overcome
this mind-shift.

Count on us and light the way!

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What is Quality Culture?

The quality culture of a company is a mixture of quality-oriented thoughts, beliefs, behaviors, mindsets, practices, actions and processes that provide value to your products or service requirements, your customers and other stakeholders.

The Smart Quality framework builds a culture of trust, accountability and transparency between employees. The participation of employees in quality processes is a key element in the whole organization.

All employees are encouraged to participate actively in quality initiatives to focus on continuous improvement and anticipating customer needs, even before the customers themselves are aware of them.

It is vital to promote the participation of all employees to have greater cross-collaboration across the entire organization to integrate quality into day-to-day activities. This guarantees that quality becomes embedded in the culture of your organization and becomes the core value proposition.

Human resources are a key asset in the quality culture of an organization because they can contribute to product quality actively. The greater the quality foundations in the organization the greater performance you will attain.

Quality improvements succeed when employees are recognized and empowered for their quality achievements after changes are followed and implemented.

Acknowledgement of employees suggestions to improve quality is free and an opportunity to involve and empower the team in quality issues.

Motivating employees using recognition and personal training plans is a key asset to increase awareness of quality improvement in processes, be more efficient, and reduce costs. Bear in mind that a happy employee embeds quality in the organization.

What is Design Thinking?

Design thinking is a systematic approach for creatively and effectively identifying and solving human problems in a collaborative way. It focuses on developing an understanding of the people's needs and problems to design products or services. This process involves brainstorming, prototyping, and experimentation to end up with a solution that solves the problem. Design Thinking can be applied in quality initiatives alongside other problem solv-

ing/ continuous improvement methodologies (PDCA, DMAIC), in order to solve quality challenges.

What is Continuous improvement?

Continuous improvement is an effort to improve a given process, ad Infinitum Continuous improvement has no observable or measurable plateaus, it is improvement for improvement' sake (Baker, 2019).

What is Continual improvement?

Continual improvement is the ability to find a leverage point in the system, where one could invest resources somewhere in the system to achieve a far greater gain somewhere else. There is a measurable or observable change of state and the transformed state exists until the next change of state (Baker, 2019).

Sources

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Scilife