Quality 2030: *quality inside*

Forward-thinking Life Sciences CXOs will transform Quality from a cost center to a value creator

Thriving on disruption series

By 2030, Quality in Life Sciences will transform into a catalyst for amplifying value. By infusing quality throughout the enterprise, organizations can create offerings that align with customer needs, lower compliance risk, and fuel continuous improvement. There are so many opportunities for quality to become a competitive advantage that Quality transformation should be on the boardroom agenda for years to come. How can CXOs take their organizations there? By bringing *quality inside*.

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A new way of Quality

The journey to *quality inside*.

Imagine if the Quality function could be transformed from a cost center to a value-adding force in the Life Sciences organization. Quality insights could, for example:

- Accelerate the development of new products and services that meet customer needs.
- Prevent compliance issues, potential fines, and reputation damage before they occur.
- Reduce the burden and reliance on internal audit by proactively identifying quality risks.
- Leverage technology that can automate and monitor quality real-time, resulting in a continuous improvement loop.[1]

This *new way of quality* would amplify value in the form of improved partnerships with the business, new talent models for career growth, and better, simpler processes – not to mention significant financial benefits. Imagine the impact these changes would have on drug effectiveness, affordability, innovation, and, ultimately, the organization's brand.

The current Quality function, however, grapples with a number of limitations and requires structural change to become future-ready. Therefore, industry frontrunners will leverage learnings from previous attempts to transform, insights from other industries, and innovative partnerships to enable strategic quality goals and objectives.

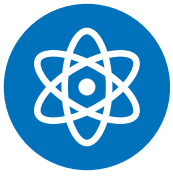
There are so many opportunities for quality to become a competitive advantage for Life Sciences companies that Quality transformation should be a key boardroom topic over the coming years. Ultimately, CXOs should focus on achieving a state we call *quality inside* by 2030.

In this paper, we seek to highlight how CXOs can help their organizations achieve *quality inside* by 2030. In so doing, they can realize improved customer experience, avoid noncompliance penalties and potentially irreparable damage to their brands, and, ultimately, drive competitive advantage.

Life sciences quality has the potential to surpass all other industries

While the formal Quality function has long been at the heart of this aim, the future requires infusing quality throughout the company. Many industry leaders have been advocating for this more holistic view of quality for some time. Yet, most employees still view compliance as Quality's primary, if not sole, purview. As we look toward 2030 and consider changes in the external and internal environments, it is clear that Life Sciences companies must kick their transformation journeys into high gear, and begin the evolution toward a state of *quality inside*.

By 2030, *quality inside* will be enabled by three key pillars:



1. Technology and innovation:

CXOs are already focused on integrating innovative technologies across a variety of internal functions. Looking forward, technologies from artificial intelligence (AI) to predictive analytics will play a key role in enabling the shift to *quality inside*. The potential for technology to be a game changer for quality is evidenced by the fact that 80% of Life Sciences CEOs expect to see a return on investment for AI, robotic process automation (RPA), and digital technologies in the next 1-3 years, according to KPMG's 2019 Global CEO Outlook survey.[2]

2. Operating model:

To transform Quality, CXOs should consider how the entire Life Sciences operating model needs to shift, such that quality is infused across the organization. This will mean transformation of regulatory efforts to encompass stringent risk assessment processes, handling of complex quality issues using innovative approaches, and an increase in partnerships with suppliers and contract manufacturing organizations. CXOs are particularly focused on third-party partnerships to achieve organizational agility, as indicated by 68% of Life Sciences respondents to KPMG's 2019 Global CEO Outlook survey.[3]

3. Talent and culture:

Forward-thinking Life Sciences organizations will address the need for short- and long-term talent to support the shift to a quality culture. Leadership will need to advance a quality mindset throughout the enterprise, empower teams to manage the change, and ensure that quality efforts are aligned with the value chain. Once again, this outlook is already reflected in the CXO agenda – 44% of CEOs intend to upskill more than half of their current workforce over the next three years.[4]

Keeping pace with the speed of change

Why Quality must adapt to trends from consumerism to eroding margins.

The Quality function has already undertaken massive transformation efforts in the last few years, in response to a more stringent regulatory environment, new delivery mechanisms, and increased supply chain complexity. The need for further change will only be amplified by emerging trends, such as digitalization, new business models, and disruptive competitors. Of particular importance is the technological progression that is allowing personalized medicine, e.g., new modalities like gene therapy and drugs for rare diseases, which will require organizations to adapt their approach to quality and support a decentralized supply chain.

Below are a number of significant changes occurring in the industry ecosystem that will make it necessary to adapt current Quality functions to become *fit for purpose*:

New patient-centric business models

Life Sciences organizations are instituting a wide variety of new business models, e.g., *beyond the pill* services and solutions that are driven by new technologies and patient-centricity; outcomes-based care models in response to payer scrutiny of prices and value; and a greater focus on niche patient pools through the provision of specialty and rare disease drugs, as well as personalized medicine and combination therapies. By 2030, leading Life Sciences organizations are likely to explore and introduce many additional innovative business models. As companies define their roles in this new paradigm, the Quality function will need to expand its scope to ensure the quality of consumer-focused products and solutions across an increasingly stratified patient and end-user landscape.

Fragmented supply chains

As most Life Sciences organizations operate on a global scale, they are subject to the unique geopolitical developments and legal parameters of different regions. In recent years, supply chain complexity has increased through the growing use of contract manufacturing organizations (CMOs), as well as centralized and outsourced back-office processes. As manufacturing continues to expand into a variety of locations throughout the world, supply chains will be further fragmented, thus expanding the scope that Quality must oversee. This will be challenging without localized quality expertise and practices, including a focus on ensuring that local third parties abide by the same quality standards as the organization. Finally, the shift from batch manufacturing to continuous manufacturing is likely to further accelerate with biologics and personalized medicine – creating an impetus for quality to keep pace.

Disruptive technologies

Disruptive digital technologies have game-changing potential for Life Sciences companies. For example, AI can be used in real-time release testing to dramatically reduce lead times and costs. Advanced data & analytics (D&A) will have the same impact on research & development (R&D) timelines and costs. Technologies with significant untapped potential, like blockchain, are likely to have a major impact on assurance functions. In order to take advantage of the efficiency, accuracy, and customer-centricity promised by these innovative technologies, associated quality will need to undergo strict assurance and control.

Continuously evolving regulatory requirements

The regulatory landscape is moving away from the three dominant bodies – the Food and Drug Administration (FDA), the European Medicines Agency (EMA), and the Pharmaceutical and Food Safety Bureau (PFSB) in Japan – toward an increasingly country-specific approach. This shift is creating a fragmented regulatory landscape, even while directives like the European Medical Device Regulation (EUMDR) seek to harmonize global regulations. Ultimately, companies will need to balance local and global approaches to quality.

Eroding margins

There is more pricing scrutiny in Life Sciences than ever before, due to patent expiry of blockbuster drugs, greater focus on specialty drugs, new entrants in the Asia-Pacific region, and increased adoption of generics and biosimilars. As companies adjust their pricing strategies to reflect a lower return on investment (ROI) (in some cases as low as 1-2 percent[5]), they must also evaluate the cost of Quality. To achieve this, they must evolve Quality from a cost center to a value-adding entity and distribute ownership of quality across all functions.

Trend	Description	Impact on quality
Patient-centric business models	*Beyond the pill*, outcomes-based care, and increased focus on specialty/rare disease drugs	• Develop new quality model to allow super-local (i.e., hospital-level) quality assurance & control
Fragmented supply chains	Global operations introduce greater number of geopolitical and legal considerations	• Manage proliferation of quality systems • Streamline hand-overs
Disruptive technologies	Adoption of disruptive digital technologies, e.g., RPA, advanced D&A, and AI	• Align technology and quality capabilities • Develop strict data assurance policies and processes
Evolving regulatory environment	Fragmented environment as industry moves away from three dominant regulatory bodies (FDA, EMA and PFSB)	• Transform role of Quality • Develop framework to align with local regulations • Cooperate on future-proofed compliance model
Eroding margins	Decreased return on investment from drug discovery and new modalities	• Unlock value creation potential of quality

A saturated function

Why traditional Quality has reached its limit.

While Quality functions within Life Sciences organizations have made significant progress in recent years, the reality is that emerging industry trends will shed more of a spotlight on some of the function's limitations, for example:

Reactive nature: Based on KPMG member firms' work with clients, it has become clear that ~40 percent of Quality resources are spent on reactive activities, such as non-conformity resolution, corrective actions, and complaint handling.[6] Even Quality Control (QC) activities can be regarded as reactive, as they only detect issues after they have occurred. By contrast, more proactive and predictive quality practices, such as inline quality monitoring, would provide operators with insights that allow intervention and prevention of non-compliances in the first place.

Need to focus on more than compliance: While the industry is committed to applying Good Manufacturing Practices (GMP) standards, there is still a disproportionate focus on passing audits. In turn, audit observations typically result in additional regulatory scrutiny, thus further increasing compliance complexity.

The focus on potential risks, while critical, limits the Quality function's purview to regulatory compliance, instead of root-cause analyses that would help ensure greater productivity and throughput.

Potential misalignment of costs and business value: KPMG professionals' experience with Life Sciences clients has revealed that, while direct Quality function costs have historically amounted to 1-2 percent of total revenue,[7] the actual total cost of Quality is significantly higher. We have seen that hidden costs – driven by complicated policies, unclear corrective and preventive action (CAPA) processes, unnecessary escalations, and excessive internal auditing – often raise the total to as much as 5-6 percent of total revenue.

The effectiveness of Quality: A wake-up call

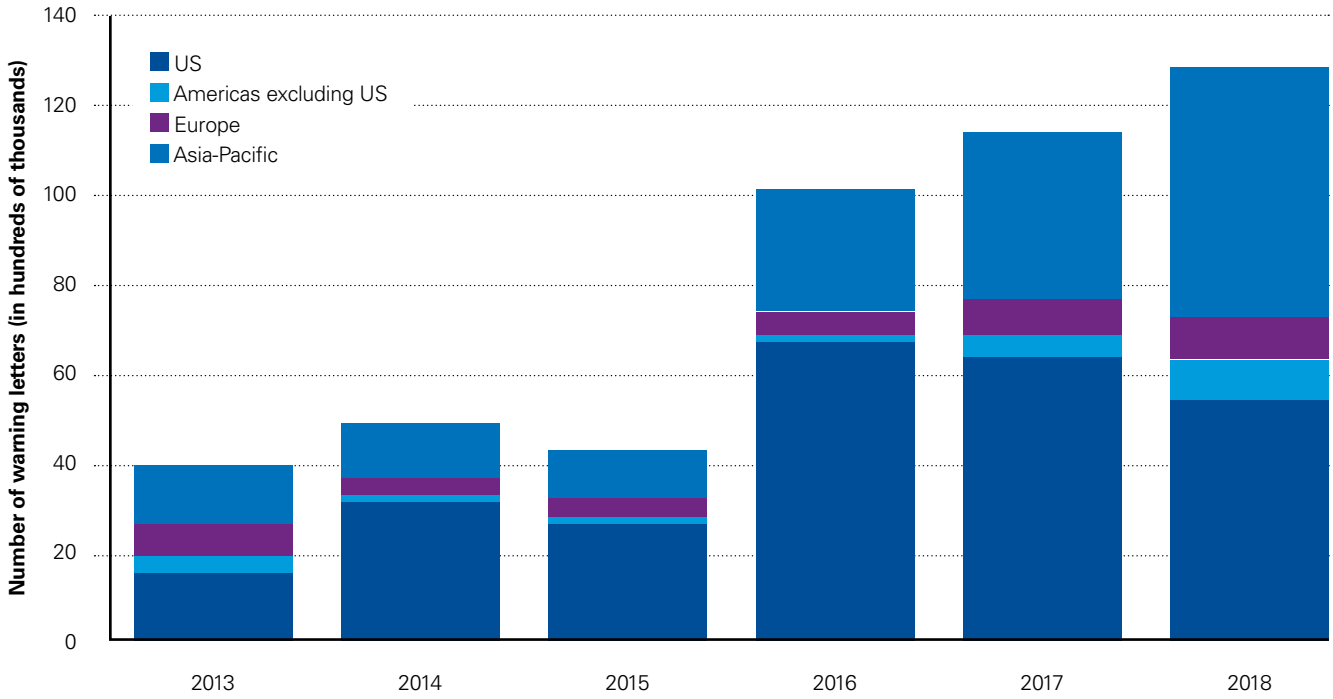
In the past, many Life Sciences organizations assumed that simply advancing the formal Quality function from a reactive, compliance-driven approach to a more proactive one would increase effectiveness and overcome limitations. While deploying new technologies, methods, and systems may have been beneficial in some instances, it doesn't seem that these efforts have increased the effectiveness of Quality overall.

While there is limited data to support or negate the value of such improvements, we used two proxies to evaluate Quality effectiveness – FDA warning letters issued to GMP manufacturers and Adverse Drug Events (ADEs) reported.

FDA reports indicate there has been a distinctive upward trend in warning letters over the past few years, particularly in Asia. From 2006 to 2014, FDA-reported ADEs increased two-fold to a total of 902,323 serious outcomes -- 244,408 deaths, 72,141 disabilities, and 585,774 other serious outcomes.[8]

Some of these outcomes are to be expected given macro trends, such as the increased volume of contract manufacturing, the shift of some facilities from the U.S. to Asia, and the complexity of personalized medicine and rare disease drug development. However, the reality is that these trends are likely to continue, and perhaps intensify, thus requiring a more proactive approach to quality.

FDA warning letters for GMP drug product manufacturing sites



Source: GMP warning letters posted by the FDA, 1 Jan 2013 to 31 Dec 2018

The cost of Quality:
Three lenses of transparency

To analyze and address the cost of Quality, organizations can use one of three lenses that provide more transparency:

Visible vs. hidden costs

The first lens addresses hidden quality costs, which, in our experience with clients, can be 3 to 6 times higher than visible Quality function costs. Examples of hidden costs include unnecessary validation activities due to misinterpreted R&D regulatory requirements, longer lead times stemming from extended quarantine in the supply chain, and lost opportunity and resolution costs resulting from product recalls.

Proactive vs. reactive cost contributors

The second lens involves differentiating between proactive and reactive cost allocation. Proactive cost contributors to Quality include training, internal audits, risk assessments, batch releases, and control & testing, while reactive contributors include field actions, non-conformities, and escalations. Typically, KPMG's client work shows that the ratio of proactive to reactive cost contributors is approximately 60:40 percent. While this is a step in the right direction, it is critical to delve a bit deeper and differentiate between types of activities when analyzing overall Quality costs.

Insights vs. transactions

Through the third lens, organizations can determine whether Quality expenditures result in real insights or if they are only transactional. For example, with a proactive cost activity like batch record release, there is value in preventing issues from occurring; however, a detailed analysis usually reveals that the majority of activity was merely transactional. In our experience, close to 50 percent of all Quality activities are transactional in nature, and the remaining half are insight-driven.

Uncovering the degree to which cost drivers contribute to overall Quality costs could provide a clearer view of how the Quality function is performing, as well as insights that could inform transformation efforts.

Visible costs	Hidden costs
1-2%	5-6%

Proactive	Reactive
60%	40%

Insight-driven	Transactional
50%	50%

Source: KPMG proprietary analysis

The *quality inside* vision

What will a Life Sciences organization with *quality inside* look like in 2030?

In 2030, we envision that Quality in Life Sciences will be radically different from its current state: a quality mindset and culture will infuse the entire organization – supported by technology and data, enabled by shifts in the organizational structure, and realized by employees with appropriate skill sets.

The state of *quality inside* will involve oversight by a small team of quality experts, transparency into quality outcomes by individuals responsible for execution (e.g., production line operators), elevation of mission-critical activities (e.g., R&D, manufacturing) through the use of disruptive technologies and advanced D&A, and fully automated transactional activities.

While the three main Quality domains of assurance, control, and regulatory compliance will still exist, there will likely be significant changes in where they reside and how they are executed:

Quality Assurance (QA) will be highly automated, using new auditing, training, and validation techniques enabled by secure technologies like blockchain. A total quality mindset will be evident across the organization as the newest behavioral science techniques are used to integrate human resources, value chain management, and quality. Errors will be reduced to an absolute minimum using a Human Error predictive tool developed with industry partners. The most difficult quality questions will be resolved through a *dilemma reconciliation*[9] approach, adopted across multiple levels of the organization. There will be total trust in data and algorithms applied in auditing and assurance. The whole assurance organization will shift from monitoring compliance to proactive detection of potential issues, all at a fraction of the current cost.

Quality Control (QC) will be completely integrated into the business at the point of decision-making – with the R&D project team, in the manufacturing environment, or in close proximity to patients (and other end users). At the same time, a small central QC unit staffed with specialized experts will still deal with exceptions and issues.

Regulatory compliance will center around a regulatory interface based on an *open window* philosophy, i.e., complete transparency into the organization's quality performance. Already, industry groups are collaborating on enhancing global quality standards based on the latest insights from organizations in other industries, e.g., aerospace companies, AI specialists, internet platforms, and marketing agencies.

Ultimately, quality will be embedded in the organization to the point that individuals are able to use quality to add value while undertaking a wide variety of transactional activities, e.g., discovering a new molecule in Tel Aviv, facilitating method transfer from an R&D center in Basel to one in Moscow, manufacturing syringes in Tokyo, coding a piece of software for new diagnostic tooling in Cork, or performing the last personalization before a product reaches a patient in Nairobi. *Quality inside* will be a major differentiator for the organization's brand, allowing companies to accelerate growth and improve performance across global markets, and facilitate personalization of medicine down to individual patients, no matter where they reside.

As Life Sciences organizations look forward, they can gain insights from leading quality practices in other industries, for example:

In the automotive industry, Toyota used quality as the basis for their *Toyota Way 2001* based on the concepts that the right processes lead to the right results, talent development drives value in the organization, and solving root problems results in organizational learning. Today, many global car manufacturers have raised quality standards by applying Industry 4.0, using technologies such as the Internet of Things (IoT), AI and Digital Twin. This approach allows companies to embed quality in their cultures and throughout the product lifecycle – from concept and design to production and after-market services. Leading automotive companies already use remote monitoring and maintenance to improve quality continually, while the data collected from products and production machines provides valuable insights that influence business planning and product development.

Across the banking industry, many companies employ proactive, and even predictive, quality controls. For example, most credit card companies manage potential fraud incidents before customers become aware of the event or experience any anxiety. Almost all financial institutions apply social media data mining and psychometric testing to predict the credit-worthiness of customers lacking established credit histories.

In the technology industry, leaders like Microsoft are using AI to predict potential coding errors during software development, which enables reduced time to market. This often involves a response loop through which customer feedback is incorporated into AI coding, thus helping organizations predict development issues and monitor development processes.

As Life Sciences CXOs look toward 2030, they will be confronted with multiple strategic questions. For example: How will quality be measured when innovative therapies are adopted in global markets across a variety of care settings? How are quality standards for Software as a Medical Device (SaMD) expected to evolve? How can quality be guaranteed in the future if the majority of our products are manufactured in China? How can Africa secure a place in the future of quality, so that the region has access to leading medicines? Clearly, it is critical to invest the time required to navigate such complex issues. The starting point is to define a clear vision for what *quality inside* means for your organization.

Quality in Asia-Pacific:
Using technology to leapfrog Western approaches

The Asia-Pacific region continues to present significant opportunities for Life Sciences CXOs to improve quality and, thereby, expand revenues, broaden global footprints, and gain market share. Although not without challenges, such as numerous FDA warning letters in the last year alone,[10] this region demonstrates strong long-term potential, which may even be accelerated by ongoing regulatory reforms. Local governments in the region recognize the need to align quality standards with international guidelines, and are, therefore, instituting more stringent requirements for the manufacture and distribution of medicines. For example:

- China's drug and medical device regulatory agency has adopted requirements that align with other large global compliance agencies.[11] The country has tightened controls over generic drug manufacturing through several stages of upgraded GMP requirements. Over the last three years, the agency has eliminated nearly half of the country's generic drug manufacturers, due to their inability to make the process investments and improvements required to remain compliant. Similarly, increasingly stringent Good Supply Practices (GSP) requirements are resulting in a decrease in local distributors.
- In October 2018, the Indian Ministry of Health and Family Welfare proposed amendments to the 1945 Drugs & Cosmetics Rules, aiming to expand their focus from finished product testing to testing at all stages of the manufacturing process.[12] This move was designed to align India's local GMP requirements with World Health Organization GMPs.

As these markets evolve and cement their position in global manufacturing footprints, there is an opportunity for Life Sciences companies to use technology-enabled quality as a source of competitive advantage. They can build modernized, future-ready production facilities that support projected volume growth in the Asia-Pacific region in a cost-effective, high-quality manner.

As organizations develop these facilities with the latest technology advancements, they have a real opportunity to leapfrog quality standards and processes in the US and Europe, and create global hubs (i.e., Centers of Excellence) for a wide spectrum of quality activities. Some leading Life Sciences organizations have already set up best-in-class manufacturing centers in China, many using advanced quality systems that set new pharmaceutical manufacturing standards not only for China, but also for the rest of the world. Going forward, as CXOs think about the strategic priority of emerging markets, and in particular countries in the Asia-Pacific region, quality can be a key differentiator for their organizations.

The gray area:
Using *dilemma reconciliation* to solve complex quality issues

Although some quality issues are relatively straightforward, others, such as product quarantines and recalls, require analyses from multiple angles. Struggling to reconcile seemingly contradictory dilemmas can leave organizations in a state of inertia. Typical dilemmas often relate to organizational agility, risk management, and technology and innovation – such as:

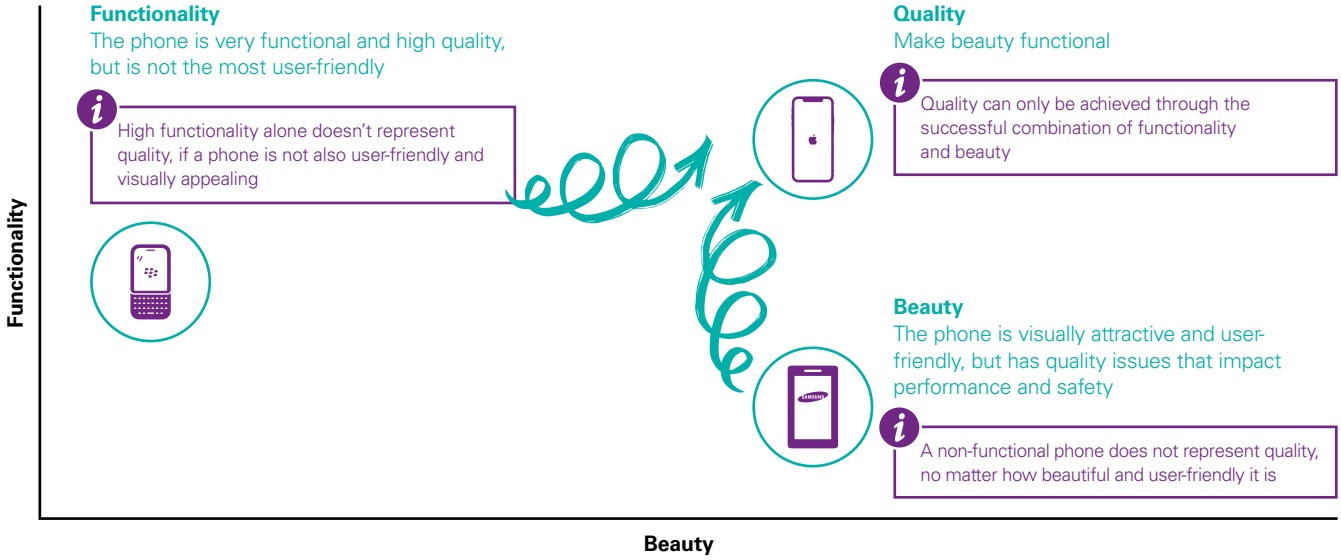
- How can the organization standardize Quality management, while still being adaptable and flexible?
- How can Quality contribute to accelerated product development, while ensuring zero defects?
- How can the organization leverage the latest technology advancements, while managing expectations and budgets in a cost-constrained environment?
- How can the organization balance the need for centralized Quality systems with the need to make country- and region-specific IT investments?
- How can Quality create trusted relationships with customers, if full transparency isn't possible due to evolving regulations related to pricing?

Unfortunately, such issues are usually resolved in silos, with Quality representing the regulatory compliance point of view and value chain partners representing the business side, resulting in an either-or resolution. In actuality, challenges that appear irreconcilable can be better addressed through a *dilemma reconciliation* approach to quality.* Through this method of decision-making, organizations can find ways to standardize quality management while remaining agile, accelerate product development while ensuring zero defects, and increase customer-centricity while maintaining compliance with external regulations.

To illustrate, it is useful to take a look at other industries once more. If we consider the mobile phone sector, there is an ongoing struggle to balance functionality with aesthetics and form. The Blackberry was a highly functional handset with exemplary quality, but it was not considered to be user-friendly, which ultimately contributed to the company's demise.[13] Samsung achieved market share leadership in the smartphone market through multiple well-designed and user-friendly devices – and yet, they still took a heavy hit to their bottom line with the exploding battery issue in the Note 7.[14] Apple's iPhone successfully balances functionality and beauty, creating a high quality smart device.

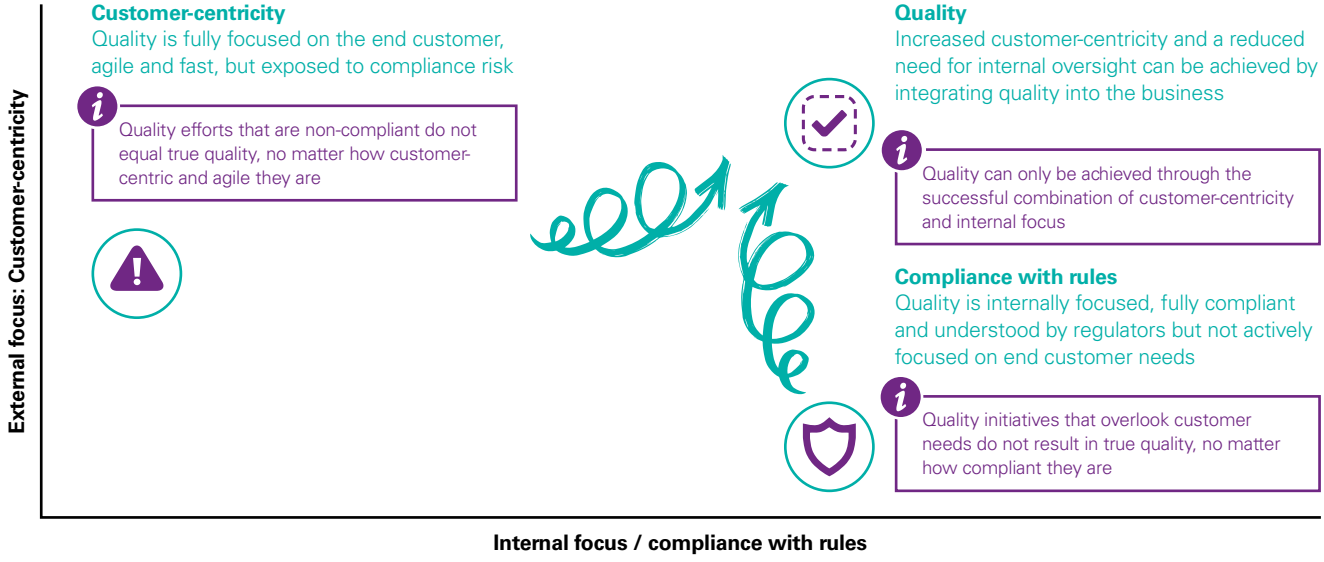
* The Dilemma Reconciliation approach was developed by a team led by Fons Trompenaars and Charles Hampden-Turner, and continues to be used in KPMG client work today.

Dilemma reconciliation example in the mobile phone industry



In the same vein as some leading smartphone models, Life Sciences organizations can adopt a *dilemma reconciliation* approach to quality, sharpening their quality vision and balancing benefits and challenges that outwardly appear irreconcilable. As an example, companies can increase customer-centricity while also checking the compliance box, by transferring quality responsibilities and oversight into the business, thereby reducing the need for centralized oversight.

Resolving a dilemma requires combining values to achieve quality



Bringing the *quality inside* vision to life

Although a full Quality transformation will likely take several years, it is critical to note that significant value can be captured from the start.

By charting the journey to 2030, CXOs can balance short-term wins (e.g., efficiency gains) with longer-term initiatives (e.g., adoption of technology drivers) – and thus create a self-funding transformation. Therefore, CXOs require a multi-year roadmap that provides a systematic approach to organizational change through a customized journey that allows for strategic flexibility.

Based on the results of KPMG's 2019 Global CEO Outlook survey, Life Sciences leaders are already leaning in this direction: (1) 80% of Life Sciences CEOs expect to see ROI for AI, RPA and other digital technologies in the next 1-3 years,[15] (2) 68% believe that third-party partnerships are critical to achieve organizational agility,[16] and (3) 44% intend to upskill more than half of their current workforce with new capabilities over the next three years.[17]

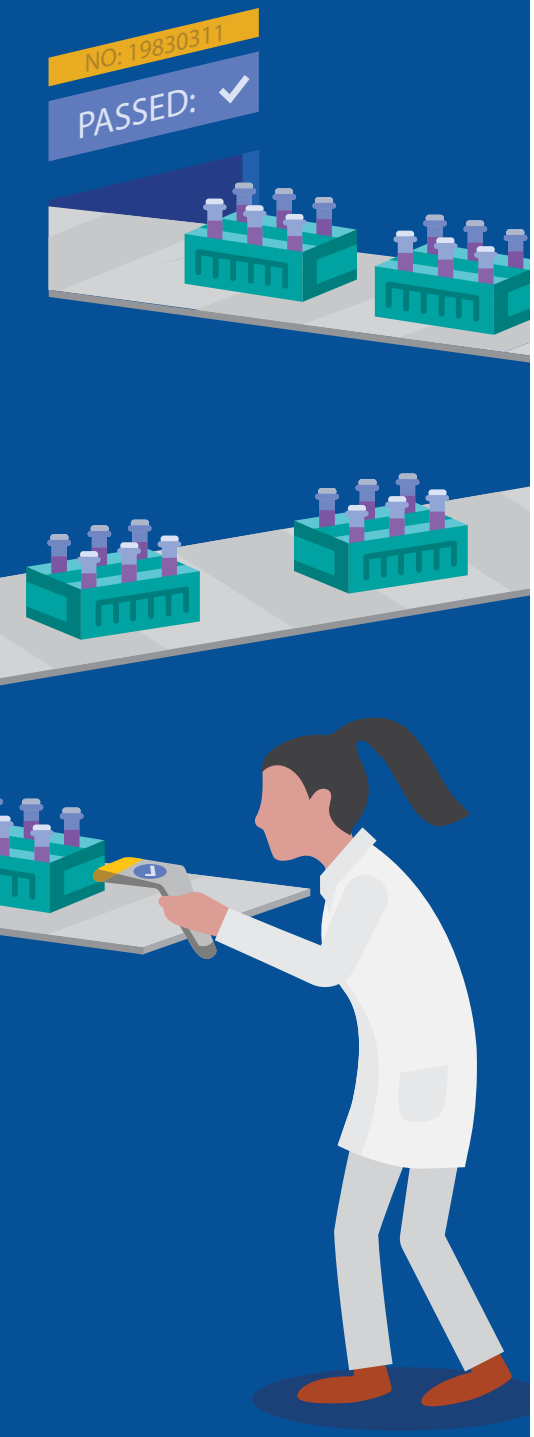
In our view, successful Life Sciences Quality transformations will be grounded in three key pillars:

1. Technology and innovation

Although Life Sciences CXOs take quality into account as they embrace emerging technologies, it is critical that technologies adopted for quality align with the value chain. This is imperative whether the technologies are used for sampling, method approval, or quality control. For example, intelligent automation will allow process simplification to improve the speed, agility, and reliability of quality. At the same time, AI and process analytical technology (PAT) will help organizations derive predictive and actionable insights, and achieve better business performance.

Ultimately, the entire organization will benefit from noncompliance reduction, human error prevention, shorter lead times, and support for strategic goals like personalized medicine. It is important to remember that, to the extent that quality can increase internal efficiency by automating transactional activities, those funds can be re-invested in innovation.

Disruptive technologies are anchored around a number of value pockets, as illustrated below:



2. Operating model

To accommodate *quality inside*, there are a number of operating building blocks that need to shift. CXOs will foster an increased focus on strategic partnerships and alliances between quality and digital innovators that can provide access to the latest technologies. Partnering and two-way communication with both CMOs and peers will help align quality systems across the industry and allow seamless sharing of quality data.

In order to find common ground on complex quality issues, the *dilemma reconciliation* approach will be adopted on multiple levels of the organization. Quality performance will be fully managed by the business; or, if it still resides within its own department, the function will provide a balanced view across the organization, including the impact of quality measures on costs, lead times, and, ultimately, patients.

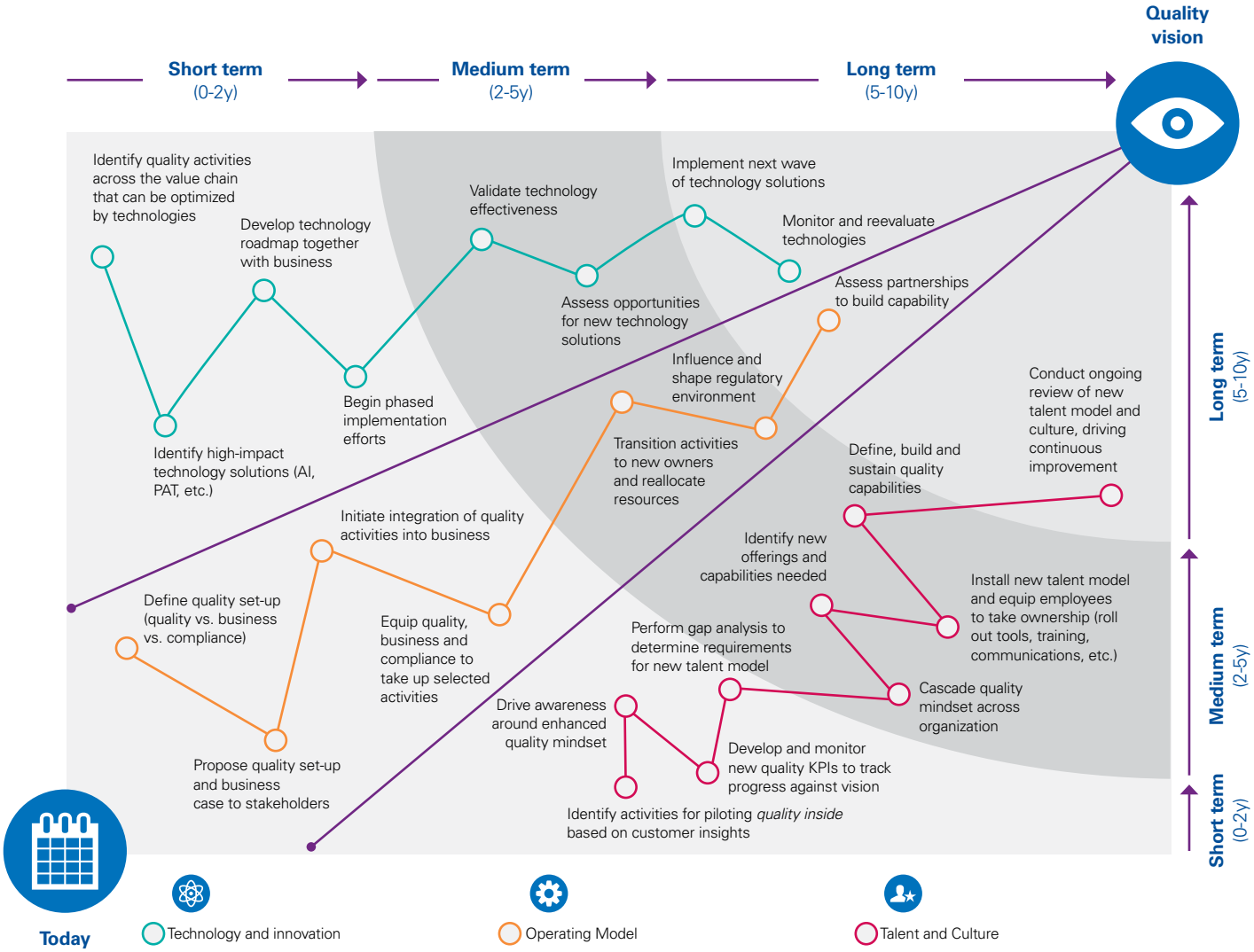
Finally, as D&A will play a prominent role in this new operating model, enhanced assurance processes will be required to ensure that data can be trusted. Although the D&A assurance team is likely to remain centralized during the *quality inside* journey, strict assurance of data and algorithms will be maintained. Finally, most administrative work and QC activities will be reduced to a minimum as they are woven throughout the organization.

3. Talent and culture

Quality will become a strategic business partner that supports other parts of the value chain, providing both insight and foresight. A Life Sciences organization with a culture of quality will embrace proactive decision-making, shift focus from compliance to resolution of root causes, and engage in constructive dialogue with regulators.

Specifically, CXOs will need to create a new talent model, acquiring and training personnel that can support more collaborative interactions and joint solutioning with regulators and other industry players. There will be more of a need for an insight-oriented workforce that is well-versed in strategic and analytical thinking, able to master advanced digital and technology skills, open to partnering, and amenable to working within a new operating model. Technology investments will be planned in close coordination with talent and hiring plans, given the need to align skill sets. Finally, CXOs must lead the charge when it comes to adopting a quality mindset so that teams feel supported and empowered in making this systemic change.

Roadmap to *quality inside* by 2030 (illustrative)



First steps toward *quality inside*

Transforming the Quality organization to a state of *quality inside* requires a balance among short-term successes, medium-term capability-building, and generation of maximum value over the coming decade.

Specifically, this will involve a stepwise transition from the status quo reactive state, to a more proactive approach to quality initiatives, to quality as a fully predictive force. CXOs need to initiate the first steps toward *quality inside*, now:

Define a quality vision for your organization

Create a bold, provocative *quality inside* vision, including a definition of success for the future-ready quality function. This vision will be the cornerstone for creating change and infusing quality throughout the organization by 2030.

Leverage technology as a key enabler

Move beyond pilots and proofs-of-concept by building a technology-based strategy for *quality inside*. This will enable quality to remain in lockstep with the fast pace of R&D, while also enabling incremental changes in supply chain and commercial organization quality.

Collaborate and co-create

Forge partnerships with other Life Sciences companies and work proactively with regulatory bodies to shape future policies and quality standards that are aligned with evolving business and operating models across the globe.

Explore performance improvement opportunities

Work toward full cost transparency and identify initiatives that will help drive toward future-readiness – leveraging learnings from other companies and sectors, and realigning the organization accordingly.

Establish new ways of working

To support a quality-focused culture, organizations should take a systematic approach to workforce planning, training, and even job rotation. Leadership should have visible involvement in the transformation journey, instilling a culture of quality ownership across the enterprise, while driving and managing the change.

When it comes to the future of quality, industry trends and success stories from other sectors speak to the necessity of change. Forward-thinking Life Sciences CXOs realize that there is a world to gain in transforming Quality from a compliance-driven function to a value-adding force. By bringing *quality inside*, Life Sciences organizations can achieve significant value and realize competitive advantage by 2030.

Sourcing & notes

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KPMG's Global Strategy Group works with private, public and not-for-profit organizations to develop and implement strategy from 'Innovation to Results' helping clients achieve their goals and objectives. KPMG Global Strategy professionals develop insights and ideas to address organizational challenges such as growth, operating strategy, cost, deals, digital strategy and transformation.

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Designed by CREATE. | CRT117390 September 2019