WHITE PAPER

Balancing Compliance and Quality

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EXECUTIVE SUMMARY

In a survey of 161 Life Sciences industry professionals, the majority (66%) of respondents named compliance as their top quality objective for 2019. A focus on compliance is natural and necessary for Life Sciences companies. Complying with regulations is a core part of their 'right to operate', making it possible for them to manufacture and sell their products.

But manufacturers that focus exclusively on compliance at the expense of other core quality objectives put themselves at significant risk. A compliance-only focus puts them at risk of failing in other quality areas such as product quality, safety, efficacy and continuity of supply. They may also lose sight of the ultimate goal, which is delivering safe, effective, high quality products to the market quickly and consistently.

On the other hand, manufacturers that balance compliance with a broader set of quality objectives, contributing the necessary resources to each area, are much more likely to achieve all key objectives at the same time.

In this paper, we examine:

- The difference between quality and compliance, including the reasons for imbalance across these in many Life Sciences organizations.
- The need for a balanced scorecard based on quality key performance indicators (KPIs) that measure both the efficiency and effectiveness of quality operations.
- How to foster a culture of quality within your organization, regardless of your company size or place on the maturity spectrum.

What you can learn in this paper from Life Sciences quality leaders.

There is a spectrum of Life Sciences manufacturers with diverse quality management capabilities. This includes emerging companies that are still struggling with foundational processes and data, to established, global industry leaders that have extensive quality management infrastructures and leverage advanced analytics to meet their quality objectives.

Based on conversations with Life Sciences manufacturers of all sizes, it is clear that balancing compliance and quality is a challenge faced across the board. The specific issues companies face may vary—e.g., a smaller company may be challenged with limited resources while a larger organization may struggle with extending quality best practices out to its acquisitions. Regardless, the end goal is the same—delivering safe and effective products to the market when and where they are needed.

No matter where you are on the quality management maturity spectrum (see Appendix A), we hope you will gain some valuable insights from this paper, which is based on our extensive experience in working with a broad range of Life Sciences manufacturers across the globe.

Quality Is Far More Than Compliance

Even when a company meets the standard of what is required by the U.S. Food and Drug Administration (FDA), the European Commission or other regulators, does meeting the minimum equate to quality products reaching the marketplace?

According to the FDA, the answer is "no." Under the Quality Metrics Program aimed at pharmaceutical manufacturers, the Case for Quality initiative aimed at medical device manufacturers, and other quality initiatives (e.g., eMDR, UDI), the FDA isn't asking a company to achieve compliance, but rather to prove a commitment to quality throughout all of its processes.

In today's "value versus volume" healthcare environment, where health systems and hospitals must deliver higher quality care at a lower cost, they are turning a more critical eye toward Life Sciences manufacturers and demanding evidence that their products are both safe and effective. Under pressure from payers, clinicians and patients, regulators including the FDA are, in turn, requiring manufacturers to go beyond "checking the compliance box," and demonstrate how they are leveraging quality across their operations to improve patient safety and outcomes.

It is commonly said: "Not all companies that are compliant have good quality, but companies with good quality are typically compliant." Compliance comes along with a larger focus on quality operations. The ultimate goal isn't to comply with a regulation, but to deliver safe, effective, high-quality products to the market quickly and consistently.

> "Life Sciences companies exist to help patients and save lives. Regulatory compliance provides guardrails to ensure all companies play by the same rules; however, the overall mission to serve the public and make the world a better place remains constant regardless of shifts in the regulatory landscape."
>
> *- Deloitte 2019 Life Sciences Regulatory Outlook 2019*[1]

Striking a Balance With the Right KPIs

When it comes to measuring performance, companies often strive for a "balanced scorecard"—where the internal functions of a business are achieving the desired external results.

However, in quality operations, if a manufacturer's scorecard is focused solely on compliance, then it is inherently out of balance. The measures do not sufficiently address the five quality objectives (product quality, product safety, continuity of supply, compliance).

In other cases a manufacturer may develop KPIs that measure the efficiency rather than effectiveness of its operations. Measuring how fast a task is completed is far easier than measuring whether an action had an impact on product quality and safety. Yes, it is important to measure compliance and efficiency. Whether small or large, a Life Sciences manufacturer needs to know how long it took to manage a complaint because it can't afford to waste resources.

But in order to strike a balance between quality and compliance, Life Sciences manufacturers must establish KPIs that go beyond checking a compliance box. These KPIs must get down to the root cause of quality issues and measure how effectively the company addressed them.

Given the increasingly outsourced Life Sciences supply chain, companies must also have KPIs focused on supplier quality performance. Too often manufacturers concentrate on the effectiveness and efficiency of internal operations without employing the same level of vigilance over their external business partners.

COMPLIANCE-BASED KPI

QUESTION: Did I complete my corrective and preventive actions (CAPA) on time?

This is a compliance metric that speaks to whether or not a company has complied with the results of a regulatory inspection.

QUESTION: How quickly am I resolving complaints?

This KPI is focused on complaint cycle time. It is about efficiency not effectiveness.

QUALITY-BASED KPI

QUESTION: Were my CAPAs effective?

This KPI, on the other hand, measures quality performance—did the company correct the issue and prevent it from happening again?

QUESTION: Did I resolve the complaints and are patients safer as a result of my actions?

This gets to the root of quality issues. It isn't how fast did I do it, but did I achieve the required results?

Performance-based quality teams generate a broad range of quality metrics to identify leading indicators of quality issues. This can uncover issues before they snowball into major events that require costly remediation. McKinsey & Company estimates that manufacturers can capture anywhere between $6 billion to $11 billion per year in recoverable costs by applying segment-leading quality practices[2].

Rather than simply tracking whether they completed a CAPA on time, or how quickly they resolved a complaint (referenced above), a performance-based quality team measures the effectiveness of its actions and whether they have improved quality as a result.

While compliance can be measured in isolated actions (e.g., CAPAs, complaint resolutions), quality permeates throughout an organization—from how a company manages internal change to how it manages its suppliers. A lapse in quality anywhere in the product lifecycle, from R&D through to post-market surveillance, can result in serious consequences. Therefore, Life Sciences quality teams require KPIs that enable them to measure quality as a system rather than a series of siloed steps.

Manufacturers with KPIs that balance compliance with quality have the insights necessary to address all five quality objectives. Furthermore, quality teams can show executive leadership that their role goes well beyond compliance scorekeeper and they can impact organization-wide performance.

63% of Life Sciences manufacturers anticipate using quality data to improve quality department performance, and nearly 40% named "economic performance" as a top quality goal for 2019.

- 2019 Life Sciences Quality Outlook

How to Foster a Culture of Quality

In order to balance compliance and quality, a manufacturer must build a culture of quality within its organization. This is more than the culture of the quality group itself—it is the culture of the entire organization, including third party suppliers and other external nodes of the supply chain. It means that every group and individual that plays a role in the product lifecycle understands the importance of quality and is committed to advancing it.

This is not an easy feat. A survey of manufacturers by Forbes Insights found there is a significant disconnect between perceived and real culture of quality within many organizations. Nearly 60 percent of respondents from across all levels said their organization exhibits "a comprehensive, group-wide culture of quality," but opinions vary widely when the results are broken down by role. While 75 percent of senior or C-suite titles believe their corporate cultures promote quality, less than half of those with quality job titles believe this to be the case.[3]

42% of Life Sciences executives report difficulty in creating a healthy culture across multiple locations/divisions

- Grant Thorton 2019 Return on Culture survey[4]

It is not enough for the C-suite to say, "We must focus on quality," or for the company to invest in advanced technologies for quality management without first investing in its policies, people, processes and data. Life Sciences manufacturers must build a framework that infuses quality into each and every aspect of their operations.

The table below shows key elements of that framework, as well as questions a company can ask to assess its current culture.

ORGANIZATIONAL COMPONENT	QUESTION(S) TO ASK
Policies and Decision Making: Start by establishing a global framework for policies and decision rights to support governance and risk management.	• Do I have the right level of governance in my quality systems? • Do I have enterprise-level oversight into quality processes that cover both internal and external parties (e.g., raw component suppliers, contract manufacturers)?
People/Talent: Communicate the importance of quality to all stakeholders. Explain how every role is responsible for delivering safe and effective products to the marketplace and emphasize the impact of quality throughout the complete continuum from the time the product is designed/developed through to the point of care and beyond.	• Do our employees put quality first in their decision-making and actions? • Do they understand how their roles impact the quality of products delivered to the marketplace? • Do our reporting structures support quality performance?
Process Optimization: Deliver effective and efficient processes in the right locations. Adopt an operating model that supports rapid growth and efficient integration.	• Are my quality team members located in areas where they will have the greatest impact? • Do we have quality professionals in each of our key locations globally, and do they have the skills necessary to drive quality performance (e.g., necessary language skills, understanding of local regulations)?
Integration: Take steps to integrate all quality systems and processes (e.g., CAPA, change control, document management, training management, etc.).	• Do we currently address quality in a siloes rather than a system impacting organization-wide performance? • Do we have a closed-loop quality management process in place that integrates CAPA, change control and complaint handling? • Are we able to determine how a lapse in quality in one area of the business impacts the other areas and take steps to proactively address it?
Data: Establish an accurate, complete and comprehensive single source of master quality data that can be leveraged to impact performance. Define consistent, global data standards.	• Where is our quality-related data housed and is it accessible, usable? • Can we rely on the integrity of the data or is it inaccurate, inconsistent and/or incomplete? • Are we confident basing decisions off the current data sources?
Actionable Business Insights: Establish the right compliance and quality KPIs to realize a balanced scorecard and achieve overall corporate goals related to quality.	• Does our scorecard lean too heavily on compliance metrics? • Are our KPIs focused on a rate of task completion rather than impact? • Do we have KPIs to measure all five quality objectives: product quality, safety, efficacy, continuity of supply and compliance? • Do we have KPIs that effectively measure supplier quality performance?

Conclusion

Healthcare today is all about quality. Regulators, clinicians, patients and advocacy groups recognize that the devices and drugs used in care delivery have a significant impact on patient care quality and outcomes. While regulatory compliance will always be a priority for Life Sciences manufacturers, an increasing number have recognized that compliance alone does not necessarily equate to delivering high quality products to patients. Rather than allocating resources exclusively to compliance activities, manufacturers large and small are striking a compliance/quality balance.

Still, it is not enough to throw money, labor and technology at quality initiatives. Manufacturers must have a comprehensive framework in place that establishes and maintains a culture of quality throughout their organizations and extends out to external business partners. A critical component of this framework is a balanced scorecard with KPIs that measure quality improvements, rather than compliance checklists.

Every company has the opportunity to improve its quality in some way. While the challenges may be different and the approaches may vary depending upon a company's capabilities, establishing a culture of quality through the framework provided in this paper can help mitigate risk and drive the development of more effective and safe products, while continuing to satisfy regulatory requirements.

As a next step, find out where your company is on the quality maturity spectrum. See Appendix A

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1 Deloitte Leading in times of change, Life Sciences regulatory outlook 2019, https://www2.deloitte.com/us/en/pages/regulatory/articles/life-sciences-regulatory-outlook.html

2 Capturing the value of good quality in medical devices, McKinsey & Company, February 2017, https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/capturingthe-value-of-good-quality-in- medical-devices

3 Culture of Quality, Forbes Insights, 2014, http://asq.org/culture-of-quality/files/Culture-of-Quality.pdf

4 Grant Thorton 2019 Return on Culture survey https://www.grantthornton.com/library/articles/advisory/2019/beyond-compliance-improvement.aspx

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Appendix A

Quality management maturity spectrum

	EARLY STAGE COMPANIES	MID-STAGE COMPANIES	ADVANCED COMPANIES
Policies and Decision Making	• Little governance in quality systems • Limited internal quality oversight • Very little external supplier oversight	• Limited governance in quality systems • Moderate internal quality oversight • Limited external supplier oversight	• Extensive governance in quality systems • Strong internal quality oversight • Strong external supplier oversight
People/ Talent	• Employees are task versus quality oriented	• Employees understand impact on quality but still primarily task oriented	• Leadership has established a true culture of quality that extends throughout its operations and out to external business partners • Employees not only understand their impact on overall quality but take steps to improve it
Process Optimization	• Quality functions in a silo outside of other departments	• Quality's reach extends into other departments but mainly reactive versus proactive • Quality team is primarily based in company's headquarters, limited quality representation in off-site/ remote locations and facilities	• Quality permeates throughout the organization, with quality professionals in the right places at the right times with the right knowledge and skills to drive improvements
Integration	• Very little integration – each department/ function acts independently with its own systems and processes • Difficult to determine how each component of the business impacts the other in terms of quality	• Some IT integration of quality with other departments/ functions, ability to share information but still largely manual • An understanding of how each component's quality impacts the others' but difficult to enact change that impacts quality across the board	• Quality is tightly integrated with all other departments/ functions throughout the enterprise • All stakeholders operate collaboratively within a common, electronic quality platform • This integration extends out to external business partners
Data	• With a reliance on manual, paper-based processes, quality data is scattered, difficult to access, likely inaccurate, incomplete	• Data is stored electronically in separate systems, no single, comprehensive source of quality data, still facing data quality challenges	• Company leverages an enterprise quality management system (EQMS) to establish a single source of accurate, complete and comprehensive quality data • Digitization of quality processes and data positions company to leverage Industry 4.0 technologies (e.g., AI, ML)
Actionable Business Insights	• Major challenge to gain insights from the data • KPIs are focused on compliance, task completion, and process efficiency	• Can perform analytics but can be manual and time/labor intensive • KPIs still weigh heavily on compliance	• Can easily perform advanced analytics • Balanced scorecard with KPIs focused on all quality elements: Product quality, safety, efficacy and continuity of supply, compliance • KPIs closely aligned to broader corporate objectives