

HOW COMPLIANCE IS HURTING QUALITY

Life Sciences Quality Teams Are Too Focused on Compliance And That Hurts Overall Quality

Strike a Balance that Gets it Right

There are **FIVE** Quality Imperatives



Quality



Safety



Efficacy



Continuity



Compliance

Yet, quality teams from Life Sciences companies **overemphasize compliance.**

66%

In a survey of 161 Life Sciences industry professionals, 66% of respondents named compliance as their top quality objective.¹

Focusing too heavily on compliance can have a negative impact on quality.

36%
of Companies

cite a lack of culture of quality as a top challenge to achieving quality objectives.³

There is a significant disconnect between perceived and real culture of quality within many organizations:

75%

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.²

42%

of Life Sciences executives report difficulty in creating a healthy culture in organizations involving multiple locations.³

KEY TAKEAWAY

Life Sciences companies must foster a culture of quality and build a framework that infuses quality into every aspect of their operations.

"The Agency realizes that in the past, the focus of the relationship between FDA and industry may have been on managing compliance rather than on a shared goal for continuously improving quality." - CDRH Director Jeff Shuren, M.D.

Compliance-focused quality teams are undervalued by their organizations because they are not aligned with the overall goal of improving quality.

Only 26% of quality professionals say that the quality function has a clear and compelling role in delivering corporate strategy.¹

Only 13% Only 13% of companies say quality is a priority for top management.¹



As a result, they become underfunded and cannot support continuous improvement objectives:

A vicious cycle ensues.

KEY TAKEAWAY

While compliance can be measured in isolated actions, quality permeates throughout an organization. Quality lapses anywhere in the product lifecycle can result in serious consequences.⁴

Balance Compliance and Quality with the Right KPIs

Measuring compliance and efficiency is important but manufacturers must establish KPIs that extend beyond checking a compliance box. For example:



DON'T ASK:

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

How quickly am I resolving complaints?



ASK THIS INSTEAD:

Were my CAPAs effective?

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

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

KEY TAKEAWAY

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

Download the **Balancing Compliance and Quality White Paper** for Deeper Insights

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Sources

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