FACT SHEET

Good Manufacturing Practice

Data integrity problems are on the rise

What is data integrity?

The FDA defines data integrity as “the completeness, consistency, and accuracy of data. Complete, consistent, and accurate data should be attributable, legible, contemporaneously recorded, original or a true copy, and accurate.”

Maintaining and assuring the accuracy and consistency of product data over its entire lifecycle is critically important in the pharmaceutical industry. Ensuring data integrity requires that there are mechanisms in place to prevent accidental and/or intentional unauthorized modification of the data.

Increasing breaches in data integrity are reflected in FDA Warning Letters, which cite violations such as “multiple incidents of performing ‘trial testing,’” “disregarding test results,” “no assurance that you maintain complete electronic raw data,” and “your firm did not have proper controls in place to prevent the unauthorized manipulation of your laboratory’s raw electronic data.” Other highlighted factors include a lack of computer systems control, audit trail features not being turned on, a lack of systems for data backup and recovery, unclear access rights in terms of ability to add/delete data, and sharing of passwords to access computer systems.

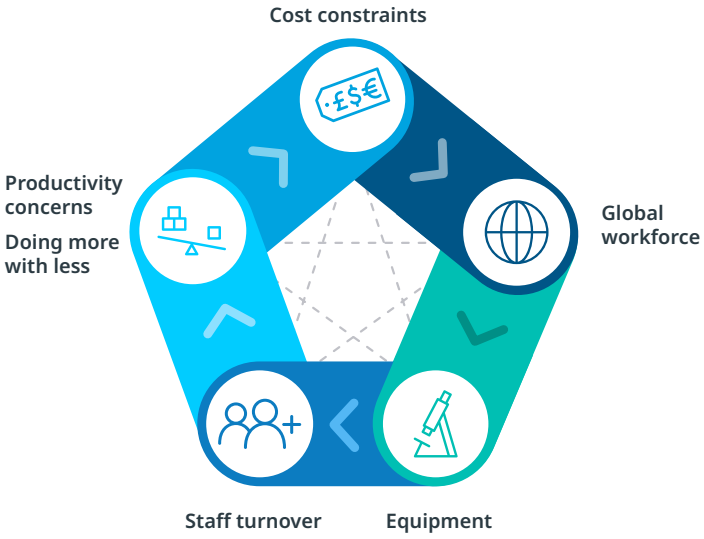
Incorrect or false data related to product identity, quality, purity or potency has serious implications, which include patient injury, drug shortages, damage to corporate reputation, lost profits, and both civil and criminal liability. More challenging to quantify is the impact of lost credibility with customers, employees and regulatory bodies.

Problems with data integrity may arise from various market-related issues, and may involve both external and internal factors. For example, multiple mergers and acquisitions have resulted in disparate, non-leveraged and ultimately non-integrated quality systems. Industry contraction has forced many companies to do the same (or sometimes more) work with fewer resources, resulting in reduced focus on important quality elements. There is a trend for biopharma companies to focus on core businesses, forming outsourcing

> The cost of non-compliance is seldom calculated but it significantly outweighs the cost of proactively implementing the processes, technology and organizational culture to ensure compliance.

partnerships to handle non-core elements. These partnerships mean that companies must place greater reliance on their partners' quality systems. While quality process optimization can serve as a business enabler and differentiator, such opportunities are often missed. In addition, data from key business indicators – such as results from audits, complaint trends, non-conformances, corrective and preventive action (CAPAs), and investigations – may not be used to address overall business enhancement opportunities.

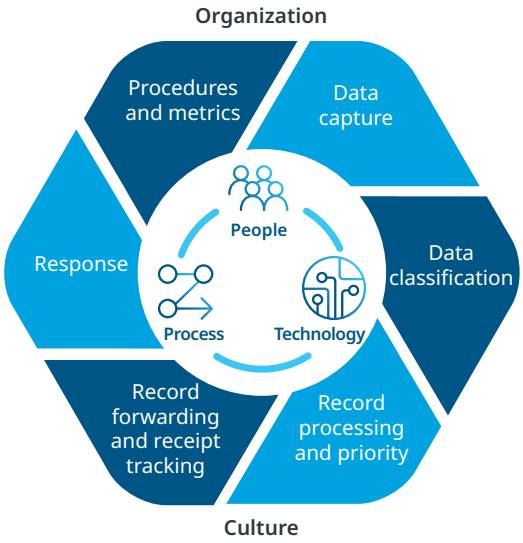
FIGURE 1: EXTERNAL FACTORS IMPEDING EXECUTION



External factors impeding the execution of quality-related initiatives (Figure 1) include cost constraints, leading to reduced resources (people and facilities), global workforce (with reliance on external suppliers and remote workers), equipment (which may be dated or not properly maintained or implemented), staff turnover, and productivity concerns (doing more with less).

Internal factors impeding execution (Figure 2) center around organizational culture, which is under corporate control and strongly influences all elements of the business. These internal factors include people, process and technology, all of which interact with organizational and cultural characteristics.

FIGURE 2: INTERNAL FACTORS IMPEDING EXECUTION



Factors that enable data integrity breaches

Factors enabling data integrity breaches represent flaws in the corporate environment. Quality systems are critical, but corporate culture is the leading risk factor for compromising integrity and compliance.

- Leadership may be lax in holding teams accountable to ethical and quality standards, with a lack of appropriate principles, systems, controls, and oversight.
- Financial success may be prioritized over product quality.
- Autocracy, leading to a culture of "please the boss" rather than focusing on doing the right thing.
- A focus on innovation at the expense of compliance and product quality.
- A lack of organizational communications and integrated teamwork.
- A culture of complacency and fear.
- Personal integrity problems, with corporate culture as a contributing factor.

Other root causes of data integrity problems include:

- Layers of risk are added by market trends for growth in generics and globalization.
- Many manufacturers lack the oversight, financial strength or expertise and infrastructure to design and implement quality systems effectively.
- Quality system deficiencies within companies, their suppliers and outsourcing partners.
- Poor procedures and/or lack of awareness of rules or requirements.
- Training gaps and unintentional errors, resulting in procedures not being followed, or mistakes being made.

To meet increasing and ongoing changes to regulatory requirements, pharmaceutical companies must:

- Establish a quality management system (QMS) with management controls that define the organizational values and expectations with regard to data integrity.
- Continuously improve to create a culture of quality that fosters the detection, reporting and management of data integrity issues.

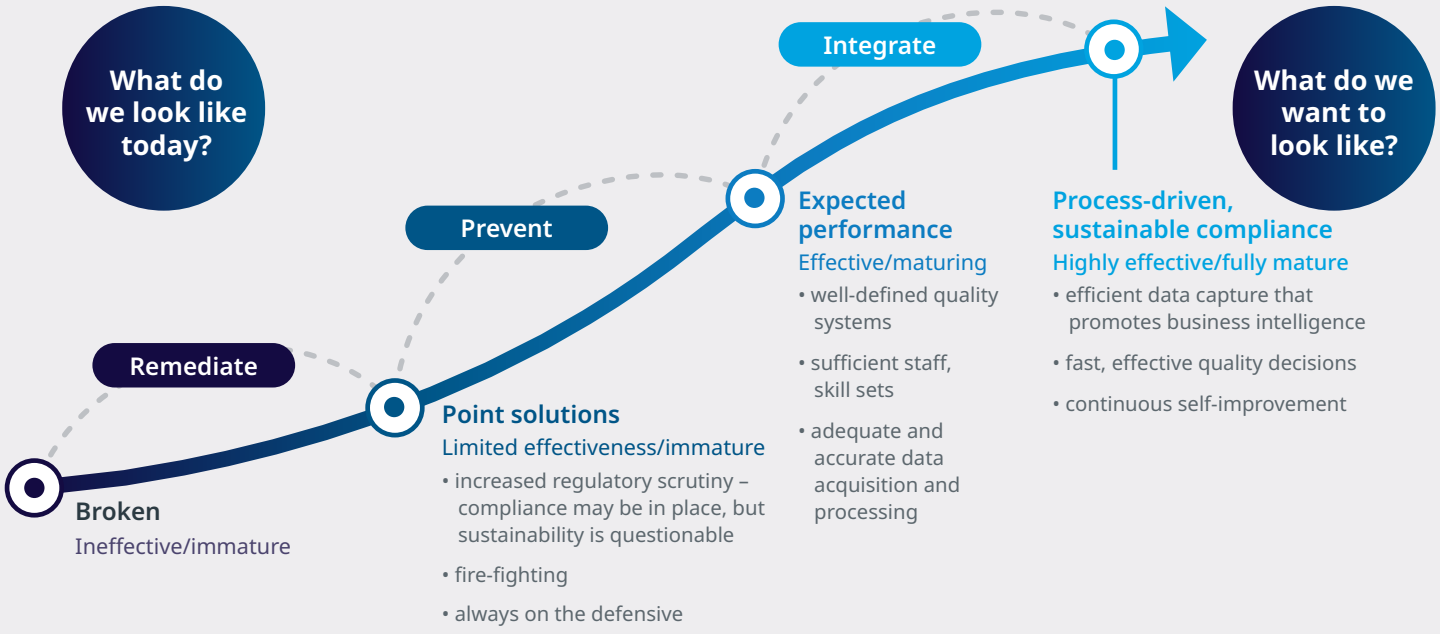
IQVIA APPROACH TO SUSTAINABLE COMPLIANCE

Understanding individual quality systems is essential in evaluating the overall corporate approach to quality. The true test of a quality management system is how it works when things go wrong. A risk-based approach is appropriate for uncovering data integrity issues and the approach should be based on the perceived urgency, leadership's commitment to quality, and the role and remit of the individual making the assessment.

Unless there is a specific cause for a focused inquiry, data integrity issues should be detected, triaged and remediated as part of regularly scheduled internal and external audits, and through routine controls and operations. Gaining a broad perspective across quality system elements will help in identifying trends and prioritizing specific areas to probe based on risk. It is important to remember that data integrity issues may be a harbinger of larger problems.

The compliance maturity curve represents a structured approach for characterizing and optimizing quality systems. Placement of an organization/site on the compliance maturity curve is based on a structured assessment of current organizational, process, and technology dimensions across quality systems. Depending on the urgency of any issues identified, this

FIGURE 3: COMPLIANCE MATURITY CURVE



can drive a business case and timelines to support the design of prioritized work plans across sites to meet future requirements and enhance operational efficiency, compliance and quality.

WE EMPLOY A STRUCTURED APPROACH FOR REMEDIATING AND PREVENTING ISSUES

Based on this structured approach for characterizing and optimizing quality systems, there are five leading solutions for remediating and preventing data integrity problems:

- Investigating and remediating data integrity issues.
- Creating a culture of quality.
- Developing visible, engaged leadership with commitment to continuous improvement.
- Recruitment and retention strategies that support sound good manufacturing practice (GMP) and good documentation practices (GDPs)
- Practical, balanced performance management.

Pharmaceutical company leaders should embrace and exemplify an organizational culture of quality and continuous improvement, giving staff the necessary resources, time and training to succeed in their work.

Conclusion

Rather than waiting for a Warning Letter or consent decree to trigger organizational change, taking proactive approaches to quality is imperative. Pharmaceutical company leaders should embrace and exemplify an organizational culture of quality and continuous improvement, giving staff the necessary resources, time and training to succeed in their work.

There should be zero tolerance for intentional falsification of records, and staff who voluntarily report infractions should be protected from any form of retaliation. Companies should use rigorous selection and oversight processes for their suppliers and contractors. Finally, top-quality internal/external audit programs are vital investments, as is the retention of external legal and technical experts at the earliest possible point when a further perspective is needed.

Waiting too long can cause problems to become more serious, risky and expensive, threatening the entire supply chain.

CONTACT US

4820 Emperor Boulevard | Durham | NC 27703 | United States

regulatory_quality_compliance@iqvia.com

iqvia.com/smartsolve

IQVIA TECHNOLOGIES