

6 Tips for Effective Quality Systems

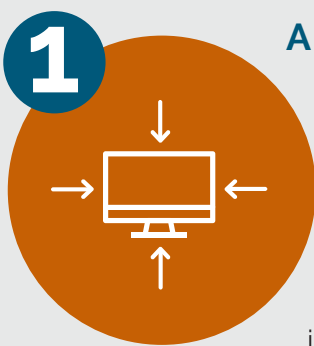
How to Shift From a Culture of Compliance to a Culture of Quality

The global life sciences industry is rapidly focusing beyond a culture of compliance to a culture of quality.

Fundamental to this shift is a manufacturer's ability to provide regulators and executives with greater visibility into its operations and quality processes. Many of the new regulations and guidelines require that manufacturers make substantial changes to their quality systems, data management and submission processes.

Here are six quality management success factors that are necessary to meet the evolving regulatory landscape.

1



A single electronic source of truth

A quality management system must serve as the single source of truth for a manufacturer's enterprise-wide quality operations. It must have the ability to track and store quality data related to the entire product lifecycle from design through to post market surveillance. The solution must serve as a central, electronic repository for all quality data, enabling the manufacturer to quickly access the information they need, when they need it.

2



Communication and collaboration

Achieving enterprise-wide quality requires all parties to the process to effectively and openly communicate at every step in the process. This includes individuals across different business sites, and even external collaborators and business partners. A quality management solution must facilitate this broad level of collaboration—serving as a single communication platform for all quality-related processes and information.

3



Robust, yet not cumbersome

Faced with more complex and stringent regulations, mid-sized and emerging manufacturers need a quality management solution that is robust enough to meet their complex needs, but at the same time is easy to use. The solution must feature user-friendly interfaces tailored to the various collaborators who will use it throughout the enterprise. The system must leverage best practice processes that align with regulatory standards and industry guidelines. Automated and standard workflows are another critical component, guiding users through the various steps necessary to achieve high quality outcomes.

4



Access to meaningful business insights

As regulatory requirements related to quality become more stringent and the risk for noncompliance increases, manufacturers must be able to quickly uncover and address potential issues. A quality management solution should feature data segmentation, dashboards and reporting that allows users at all levels of the organization to gain meaningful insights into their operations for data-driven decision making.

5



Track and trace abilities

An extended focus beyond compliance to quality requires a manufacturer to demonstrate to regulators how it is achieving quality throughout its operations. This includes the ability to track the full cycle of corrective and preventative actions (CAPAs)—from the identification of root cause, to actions to address it, and through to verification that the actions were effective. A quality management solution must provide a full audit trail of critical actions, and enable users to store supporting documentation.

6



Flexibility and scalability

Global regulations are constantly changing, as are a manufacturer's operations. A manufacturer that invests in its quality management capabilities today does not want to have to reinvent the wheel in the future. A quality management system must be both flexible to adapt to changing demands, and scalable to meet growing needs.

Next steps

To learn more download our white paper "[How Evolving Regulatory Pressure Will Impact Emerging Life Science Companies.](#)" or contact us at: info@spartasystems.com.