TriRadial
SOLUTIONS

Architecting a Scalable and Proactive Quality Infrastructure

Industry Challenge

In an environment of continued industry consolidation and ever-increasing forms of collaboration, creating and maintaining a robust Quality System can be a daunting task, but is absolutely essential to ensure your company's strategic goals are on track and remain in compliance. Quality has always been a critical element to a company's success but was typically seen only as a cost driver and, more often, a hindrance to speed and innovation. Today, Quality is rightly seen as a strategic driver and can be a competitive advantage. Companies who fail to learn from their mistakes or remain reactive to problems are increasingly out of step with those who can anticipate problems and put actions in place to mitigate likelihood of failures early in the development lifecycle.

The TriRadial Solution

At TriRadial, we believe strongly that quality should not be a bolted on, added cost at the end of a process. Compliance should be an enabler to the business, rather than a tax on the organization. *Companies can achieve greater levels of compliance through optimized business processes that are specifically designed around global regulations and industry leading practices.* Operational risk is minimized by aligning the quality system to operational performance, tightening the symbiotic relationship between procedures and business activities. Depending on the scope and goals of the effort, increased value can also be achieved through

A scalable Quality infrastructure can improve productivity, create a competitive advantage and help shift a company's culture to one of proactive compliance

the addition of technology to enable configurable workflows and leverage data throughout the product lifecycle. *Our approach supports clients in producing predictable results, while increasing productivity & quality.*

Quality Maturity Assessment:

It is important to determine where a company is on the Proactive Quality maturity curve. A rapid assessment against industry standards and regulatory expectations helps determine not only where an organization stands currently, but also where it should be within a target time horizon. Key aspects, such as organization structure, quality system elements and documentation, recent audit/inspection results and technology enablers, paint a picture of the current state and help form the basis for prioritization of future Quality System development needs. We then work with clients to architect the future state Quality System and develop a roadmap for building and implementing the necessary components.

Quality System Design and Build:

Building out a Quality System (QS) requires a well-orchestrated program of people, process and technology transformations to develop a sustainable QS framework. Design activities involve determining the right organization structure, not only for the QS function but also implications for the broader company organization. Teams and roles should be aligned to suit the size and relative need for the organization. Key activities also include creating the right core procedures, right-sized to fit with the structure. TriRadial employs Quality by Design principles to build quality into the process early and to ensure that lessons from past experience are leveraged early in the development lifecycle. TriRadial also helps companies build specific skills needed to maintain the Quality infrastructure, such as scalable risk-based audit programs, CAPA workshops and process redesign to ensure Quality considerations are integrated early in development. Implementing a new Quality System can also involve significant cultural changes, so we also facilitate change management programs for clients to help ensure successful adoption of the new QS capabilities.

Quality Measures:

Quality Systems should measure the health of the organization. Key quality indicators, specific to the organization, therefore need to be identified and are invaluable to identify problem areas while providing comprehensive quality oversight. Depending on the target maturity level of the organization, various technology enablers can be designed and implemented to provide increased visibility and control. TriRadial has experience defining process-aligned metrics presented in management dashboard visualizations. Through our accelerators (e.g., quality metrics and dashboard examples), and leading practices and lessons learned, we help advance the development of core QS capabilities.

Quality Maturity
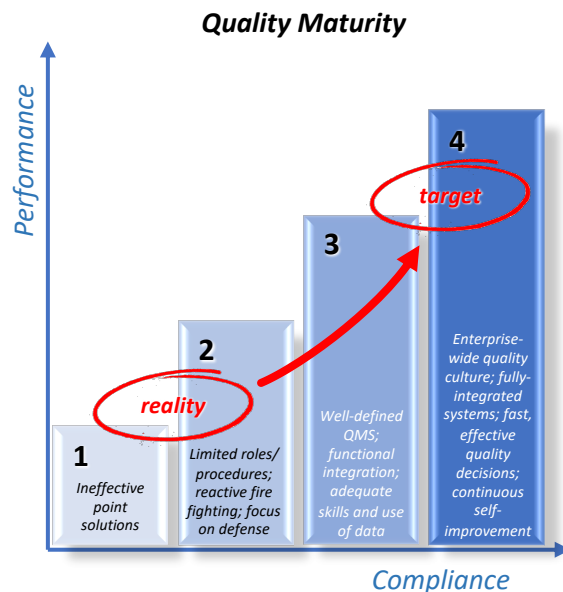
The Results

The outcome of building out a scalable QS is no less than a culture shift across the organization. Teams have increased visibility into potential risks and understand where and how to intervene to mitigate them before they manifest into problems. The new Quality System creates an empowered organization that takes ownership of quality at the source and has the tools to effectively monitor quality throughout a product's lifecycle. Quality is viewed as a competitive advantage and a true enabler to creating successful outcomes.

Contact Us:

Phone: 1-866-TRI-RADL (874-7235)
On the web: www.triradial.com
Email: info@TriRadial.com