

Process-driven compliance, right-sized for your organization



Industry Challenge

As businesses grow, needs evolve and processes change. As new partners enter the picture, there can be dramatic shifts in responsibilities, often causing confusion and leading to non-compliance.

Productivity efforts aimed at leaning out processes can sometimes inadvertently remove essential quality and compliance elements. The constant push to do more with less and leverage external partners wherever possible makes it difficult for people to understand and explain key processes, let alone demonstrate effective compliance.

In 2017, 3 of the top 5 reasons the FDA issued 483s were the absence of appropriate procedures, or not following the ones that existed. This is not because organizations do not understand the importance of following approved procedures; this is most often because procedures are poorly written, have not been modified to support company growth or do not align with regulations. Compliance should not be a bolted-on, added cost to the organization; it should be embedded within the day-to-day processes that drive the business.

The TriRadial Solution

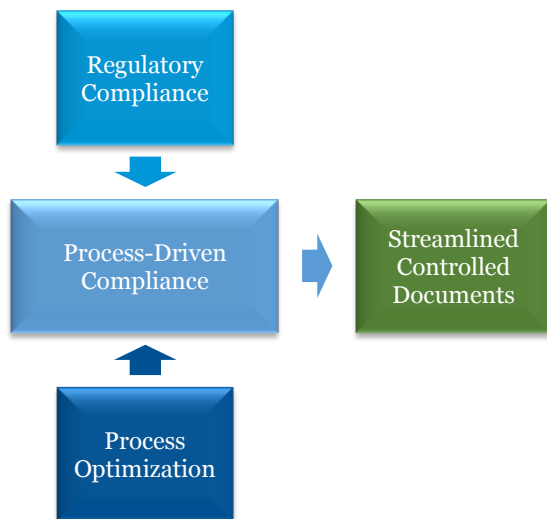
Most companies, at one point or another, want to optimize business processes, reduce non-value-added activities and document policies and procedures. At TriRadial, we believe in going beyond basic process reengineering to achieve what we call **process-driven compliance**. Compliance should be an enabler to the business, rather than a tax on the organization. Companies can achieve greater levels

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of compliance through optimized business processes that are specifically designed around global regulations and industry leading practices. Procedures should align seamlessly with processes and ensure consistent and repeatable execution.

At TriRadial, we take a 3-step approach to process and procedure development: 1) design the process with global **regulations and leading practices** as the starting point, 2) align processes to **organizational realities** and gain buy-in from key stakeholders and 3) adopt a **simple, streamlined format** for controlled documents (Policies, SOPs, Work Instructions). Our approach minimizes operational risk by aligning the quality system to operational performance, tightening the symbiotic relationship between SOPs and business activities.

We also recommend implementing technology enablers to help ensure compliance and drive consistent outputs. BPM software, for example, can enable configurable workflows and improve reuse of structured data for downstream processes.



Root it in the Regs:

Our process experts are focused on efficiencies but start with the *regulations*. We use regulations from leading health authorities to map out and define the minimum requirements for each process. We then augment that starting point by calling on our own experience implementing and managing leading practice process from across the industry to ensure the process is best in class. We will also look at regional differences in regulations and local business needs when harmonizing processes globally.

Align with Organizational Realities:

A streamlined, compliant process is only useful if the organization is able to implement it. The TriRadial team works closely with your teams to ensure that it can be implemented as intended given the size and structure and roles of a given team. Especially in small team environments, fitting a process to the team is critical to success. Organizational alignment and role definition are often key elements in any process design effort.

People also need to understand *why* the need for change before *what* and *how* they will be doing things differently. Our team works closely with all stakeholders to take them through proposed processes, from the regs to the actions, so that all can agree before decisions are made to codify the process in the procedure and have it approved and rolled out to the organization.

Adopt a Simple, Streamlined Format:

The goal is to develop a streamlined set of complimentary templates in a well-defined documentation hierarchy to organize SOPs, Work Instructions (WIs), and other essential controlled documents. SOPs and WIs should be authored as a package, as the two are interrelated. The structure provides consistency in SOP governance, while allowing a fair degree of specificity within the WI to account for variance in location, capabilities, or focus. The result is improved clarity in purpose and scope, standardized content, reduced administrative burden, and increased accountability and compliance. The modular design also serves to improve training by standardizing content delivery in sections that align well with process optimization activities.

The Results

Grounding processes in the regulations and infusing them with leading practices, right-sized for the organization and supported by the right technology enablers, puts the organization in a strong position to execute with confidence. A solid, integrated framework also helps the organization demonstrate to stakeholders, both internal and external, that it is in control of its process. Teams operate efficiently and everyone understands their roles. As new partners enter the picture, the clearly defined steps and roles make it easier to determine where and how they will participate. Overall, our approach supports clients in producing predictable results, while increasing productivity & quality.

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