The Importance of Implementing a Right-Sized Quality Framework

Mitigate Risk by Ensuring Document Compliance

VERISTA

Your Quality Framework Is an Essential Building Block for Computer System Validation

Deploying a Quality Framework is an essential step in ensuring intended use and purpose of software and systems. It also facilitates that in the end, whatever you are producing or the services you are providing are 'fit for intended purpose and use.'

The framework is created to safeguard:

- Patient safety
- Product quality
- System and data integrity

WHAT IS THE RIGHT-SIZED MODEL FOR YOUR COMPANY?

How do you know what size and complexity Quality Framework your company should introduce? Defining the business needs and understanding the company's direction is a start. Oftentimes, companies hire quality team members based on previous perceptions and notions of what a Quality Framework should look like. They revert back to past experiences, resource availability, departmental ownership and other factors which can cloud what's needed to right-size the best Quality Framework for today. Starting with the end in mind is critical in defining the right-sized model that's needed to support your business needs.

START BY THINKING ABOUT THE QUALITY FRAMEWORK WITH YOUR END OBJECTIVES IN MIND

1. Is this the first implementation or starting point for the Quality Framework?
2. Are you implementing the Quality Framework to validate new software or infrastructure?
3. Is this implementation in support of a first product launch, or launch of a new product?
4. Are you looking to create a 'lean' framework to optimize time and resource requirements?

A GOOD FRAMEWORK IS FLEXIBLE AND ALLOWS FOR GROWTH AND DECLINE

Technology is moving fast and a Quality Framework should be scalable and flexible to meet changing needs. Its function is to follow a lifecycle approach and should be adaptable to include risk, complexity, and computerized system use. Implementing a right-sized framework can streamline processes, provide clear direction to supporting teams, optimize resource time, save on re-work and safeguard the business during audits.

Figure 1: Components of a Quality Framework

CLOUD-BASED SOLUTIONS

Are you engaging with suppliers and vendors for your system applications, data management storage, etc? Most companies are employing cloud-based systems through suppliers and vendors. While vendors employ validation efforts, the manufacturer must have their own that are maintained and controlled. Below are our recommended DOs and DONTs.

Do NOT blindly trust suppliers for validation activities.

DO your research and choose wisely. Your cloud-based solution supplier can make your validation easy or put you at risk.

DO implement a Quality Framework that accounts for clear validation expectations.

YOU, as the client, are responsible for the lifecycle activities and safeguarding patient safety.

CONSIDER ALL REGULATORY IMPACT

Interpreting and understanding regulations can be confusing and time-consuming for a business. Deployment of a proper Quality Framework requires a complete understanding of the varied regulations in all of the markets the company operates in, in order to properly determine the right-sized framework.

A compete framework must consider:
- GAMP5
- GDPR
- CFR Part 11
- CSR Part 820
- Eudralex Volume 4 Annex 11
- Pharmaceutical Inspection Cooperation Scheme (PIC/S)

The aspects of lifecycle development can be easily managed when the right-sized Quality Framework is implemented and based on the business needs. It's important to note that all elements must be in place to ensure compliance. The supporting departments need to work collaboratively to ensure success! Understanding the end objective will allow you to make an informed decision on the size of the Quality Framework that will work for your business.

A Quality Framework ensures that you are inspection-ready, helps the business growth while mitigating risk, and enhances business processes and efficiencies. Finally, it should be flexible and scale to meet your technology and business growth – all while ensuring patient safety, product quality and data integrity.

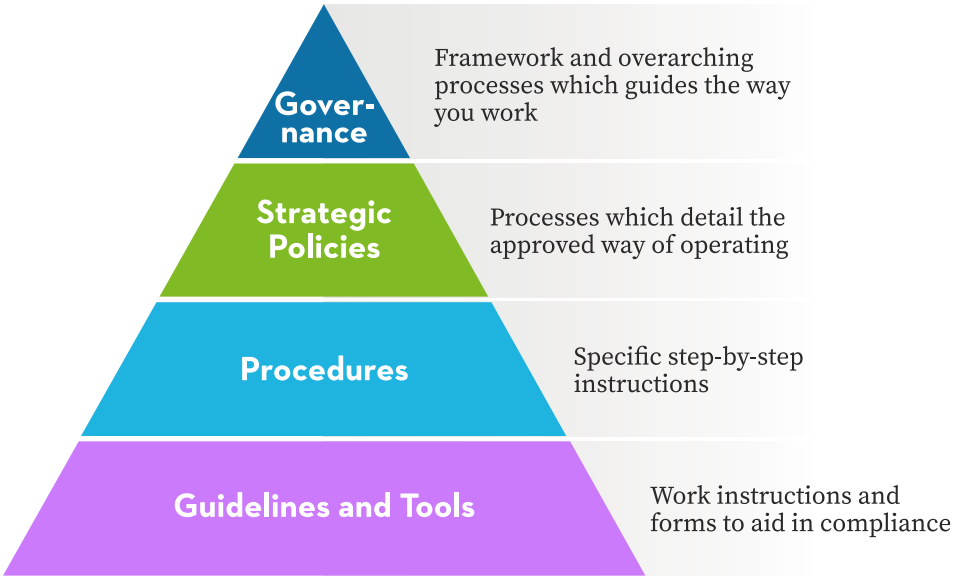

Figure 2: Overarching Governance Strategy and Tools to Support a Right-Sized Quality Framework

TAKEAWAY

At Verista, we deliver a 'right-sized' IT Quality Framework approach for CSV/CSA that mitigates compliance risk and ensures IT systems, data, and documents are maintained in accordance with industry guidelines and best practices.

Verista is a leading business, technology and compliance company that enables clients to improve health and improve lives.

We help clients solve their most critical and complex challenges across the GxP lifecycle, from preclinical and clinical to commercialization, manufacturing and distribution - bringing together decades of knowledge, the most advanced engagement platforms and transformative technologies. This allows clients to benefit from the ease, efficiency, and trust that results from working with one partner who excels across specialties.

Verista's clients trust the company's 650+ experts to deliver consistent, safe, and high-quality results across the product development lifecycle in the areas of quality and compliance, manufacturing solutions and life sciences consulting.

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