

Infrastructure Qualification Services

After initial detailed regulatory inspections at the start of the 21st century, review of IT infrastructure supporting GxP significant applications has become an established part of many regulatory inspections. However, many Life Sciences organizations struggle to establish a cost effective, efficient and regulatory compliant approach to managing their enterprise-wide IT Infrastructure.

While the principles for accomplishing this are becoming more widely understood, pragmatic guidance and support is lacking for those organizations wishing to develop a risk- based, pragmatic and sustainable approach based upon accepted best practice.

01 IT Infrastructure Qualification, Control & Compliance.


IT Infrastructure is the collection of computer systems, including hardware, layered software (excluding business applications) and network components used to support an organization.

From a regulatory perspective, IT Infrastructure also includes people, and established processes and procedures, and in order to be considered compliant these are usually brought together as part of an IT Quality Management System (IT QMS).

IT Infrastructure is generally accepted as a commodity that allows users of business applications to perform regulatory significant activities and can be thought of as a utility. It is required to be fault free and continuously available.

It is for these reasons that regulatory expectations for the initial qualification and ongoing control of IT Infrastructure exist.

Life Sciences organizations must ensure that Infrastructure meets such expectations. This is best achieved by implementing and executing a planned qualification process, reinforced by a set of



procedures that will ensure ongoing control following completion of the qualification exercise. However, different infrastructure components may require different levels of qualification and control, depending upon the potential risk to product quality or patient safety.

02 Infrastructure Services from quinta.

quinta provides a number of IT Infrastructure control and compliance services to assist clients to qualify their own IT Infrastructure, establish and then maintain a documented state of control.

Building upon the GAMP Good Practice Guide for IT Infrastructure Control and Compliance, quinta has extended these concepts to develop a set of industry leading best practices. As part of an overall approach to IS Compliance, our services combine current regulatory expectations with IT industry standards to deliver cost effective and sustainable IT Infrastructure control and compliance.

□ Compliance Assessments

As part of a range of IS compliance assessments, we conduct IT infrastructure compliance assessments, using internally developed tools, against current industry best practices and regulatory expectations.

Based upon the outcome of an initial health check, such assessments can be extended to review representative infrastructure platforms and components, and in some cases will include a complete review of the entire IT infrastructure landscape. Focusing on the key areas of the IT infrastructure, each compliance assessment is conducted using a checklist, grouped into specific topics (e.g. qualification life cycle, risk management, training and education, document management, etc).

Assessments are all based on current regulations, regulatory guidance and industry standards, with the documented responses tailored to the applicable regulations

□ Process Development

Based upon the recommendations of the Compliance Assessment Report, we then work with our clients to develop a set of sustainable IT infrastructure qualification and control processes.

Based upon the concepts outlined in the GAMP Good Practice Guide for IT Infrastructure Control and Compliance, this combines the best of the client's existing processes with our own risk-based approach to IT Infrastructure control and compliance.

Depending upon the outcome of the compliance assessment, this will include the prospective qualification of new infrastructure, the formalization or development of ongoing processes and procedures, and may include the retrospective qualification of existing infrastructure.

□ Infrastructure Qualification

We have developed a unique, risk-based approach to IT Infrastructure qualification, which allows existing or new platforms and components to be appropriately and cost effectively qualified.

This extends established concepts to newer technologies such as virtual machines and middleware, allowing clients to benefit from resulting cost savings in a compliant manner.

We will either provide on-going guidance and support or provide consulting resources to supervise qualification activities on an on-going basis. Where necessary, this will include the retrospective qualification of existing IT infrastructure and the establishment of an appropriate control baseline

□ **Maintaining Control**

Once qualified, the IT infrastructure must be maintained and supported in a controlled manner. While some life sciences companies retain this responsibility in-house, other organizations are looking to outsource non-core IT and IS services. We have developed a complementary service to support end users or their service providers in maintaining a state of control, thereby meeting regulatory expectations for on-going control and compliance.

□ **IT Quality System**

Where necessary, we assist clients to establish an appropriate IT QMS covering all qualification and control activities. This starts with the development of pragmatic processes and extends to the development of appropriate procedures or work instructions.

Whatever your current qualified status, qointa can help achieve and sustain a cost effective state of control.

