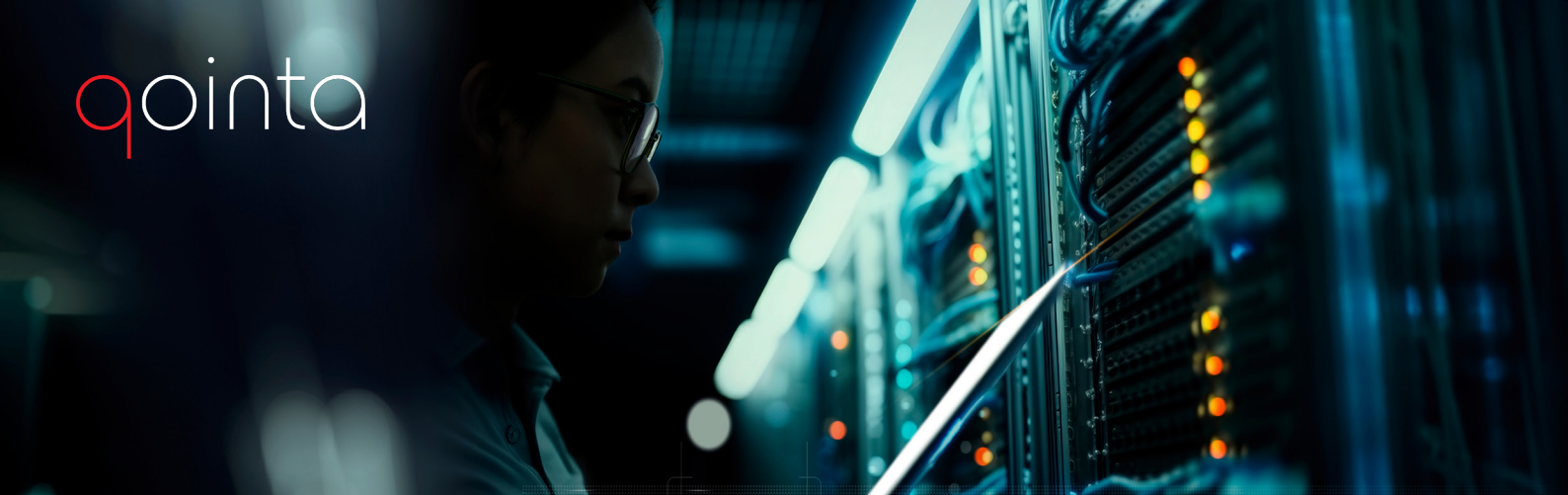




Ensuring Continuous Compliance in a Dynamic Regulatory Landscape

Introduction to IT Infrastructure Qualification

The early 21st century saw increased regulatory scrutiny on IT infrastructure supporting GxP significant applications in the Life Sciences sector. The challenge for many organizations lies in establishing an approach to manage their IT infrastructure that is both efficient and compliant with regulatory standards. qointa addresses this need by providing industry-leading IT infrastructure control and compliance services, building upon GAMP Good Practice Guide principles and extending them with best practices for comprehensive IS compliance.

IT Infrastructure: The Foundation of GxP Compliance

IT Infrastructure, encompassing computer systems, hardware, layered software (excluding business applications), network components, and the associated people and processes, is crucial for performing regulatory significant activities. Recognizing it as a utility, regulatory expectations mandate its fault-free operation and continuous availability, necessitating a planned qualification process and ongoing control to meet these standards effectively.

Our Comprehensive Services



Compliance Assessment

Conducting thorough IT infrastructure compliance assessments to align with industry best practices and regulatory expectations, utilizing internally developed tools for a comprehensive evaluation.



Process Development

Development of sustainable IT infrastructure qualification and control processes, combining qointa's risk-based approach with the client's existing practices for effective and sustainable compliance.



Infrastructure Qualification

A detailed process ensuring that both new and existing platforms are qualified effectively, adhering to regulatory standards while also being cost-effective.



Maintaining Control

Services designed to assist either end users or their service providers in maintaining a controlled IT environment, ensuring ongoing regulatory compliance.



IT Quality System Development

We aid organizations in establishing a robust IT Quality Management System (IT QMS) covering all aspects of qualification and control. This encompasses everything from the development of pragmatic processes to the creation of detailed procedures or work instructions, ensuring a holistic approach to IT infrastructure compliance.

Building Foundations of Trust with Premier Infrastructure Qualification Services

Is your data integrity strategy audit-ready and compliant?

“Is your IT infrastructure fully prepared to meet the rigorous demands of regulatory compliance, ensuring the seamless operation of GxP critical systems and applications?”

“How confident are you in the current qualification status of your IT infrastructure, and does it align with industry best practices and regulatory expectations for supporting life sciences operations?”

“Do you have a strategic approach to qualifying and maintaining your IT infrastructure that not only meets regulatory requirements but also drives operational excellence and cost efficiency? Discover how our Infrastructure Qualification Services can elevate your compliance strategy.”

Why Choose quinta?

01 Expertise in Regulatory Compliance

quinta's services are grounded in a deep understanding of regulatory requirements and industry best practices.

02 Cost-Effective Solutions

Our unique risk-based approach ensures that clients achieve compliance without unnecessary expenditure, offering significant cost savings.

03 Sustainable Compliance

We provide not just initial qualification support but also ongoing guidance to ensure your IT infrastructure remains compliant over time.

04 Customized Solutions

We tailor our services to your specific needs, ensuring a personalized and effective approach.

05 Holistic Approach

Our services cover every aspect of quality and regulatory support, offering a one-stop solution for your needs.



Let quinta guide your Life Science organization to not only achieve but sustain a state of compliance with our specialized IT infrastructure services. From initial assessments to the development of an IT QMS, we ensure your IT infrastructure meets regulatory expectations efficiently and effectively.

Elevate your quality and regulatory compliance with quinta.

Contact us today to explore how our services can empower your Life Science journey.



www.quinta.com
sales@quinta.com



+32 3 435 61 55
+1 646 661 29 72