



Achieving Sustainable Compliance in the Life Sciences Industry

Empowering Life Sciences through IS Compliance

In the rapidly evolving Life Sciences sector, organizations are increasingly dependent on specialized and general business applications for GxP critical tasks. With regulatory expectations becoming more pragmatic, as evidenced by the latest GAMP Guide (GAMP 5), there's a clear path to achieving IS compliance while improving efficiency.

qointa leverages GAMP 5's risk-based approach to offer a Lean IS Compliance Program, designed to assist organizations in achieving cost-effective and sustainable compliance. This approach is validated by input and review from US and European regulatory agencies, highlighting the critical role of the regulated company's QA organization and the support of suppliers.

Our Comprehensive Services

Tailored for each client, our program consists of defined stages using predefined models, tools, and templates to accelerate activities, minimize costs, and ensure ROI assessment at each stage.

Assessment



A one-day health check confirms program scope, providing a high-level view of current IS compliance, identifying gaps, inefficiencies, and cost-saving opportunities across IS Quality Management System, computer systems validation, maintenance and support processes, IT infrastructure qualification, and training.



Education and Knowledge Transfer

qointa consultants ensure staff are educated to fulfill responsibilities, enabling cost-effective, consistent risk-based IS compliance across the organization.

Sustain and Improve

After program completion, clients sustain and improve IS Compliance using knowledge transferred in the Education and Knowledge Transfer stage, with qointa providing ongoing strategic or tactical support as needed.



Strategy and Roadmap Definition



Based on assessment outputs, this stage offers an IS Compliance Strategy and transition model with realistic goals to measure progress towards cost-effective compliance. Leveraging IS/IT standards, the roadmap streamlines operations, facilitates organizational change management, and ensures compliance.

**Pioneering Cost-Effective
Compliance Solutions for the Life
Sciences Industry**

Are your Information Systems audit-ready and compliant?

“Are you navigating the complex landscape of IS compliance with confidence, ensuring your systems align with current and future regulatory standards while optimizing operational efficiency?”

“How does your organization approach the challenge of maintaining IS compliance in a rapidly evolving regulatory environment, without compromising on innovation and business growth?”

“Is your strategy for IS compliance robust enough to withstand the scrutiny of regulatory inspections and audits, while also being flexible to adapt to technological advancements? Explore how our IS Compliance Services can support your journey towards sustainable compliance excellence.”

Why Choose quinta?

01 Regulatory Mastery

We excel in understanding and navigating complex regulatory requirements, ensuring compliance and product approval.

02 Quality Excellence

qinta is committed to helping you maintain the highest standards of quality throughout your operations.

03 Customized Solutions

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

04 Global Expertise

Our team has extensive experience in dealing with regulatory standards and compliance across the globe.

05 Holistic Approach

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



qinta is dedicated to helping Life Sciences organizations navigate the complexities of IS compliance with our expertly designed programs and services. By partnering with us, you gain access to unparalleled expertise and a proven approach to achieving sustainable compliance.

Elevate your quality and regulatory compliance with quinta.

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



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