



Ensuring Ongoing Compliance in a Dynamic Regulatory Environment

Ensuring Ongoing Compliance for Life Sciences Systems

Regulations in the Life Sciences industry are constantly evolving, and so are the interpretations of those regulations. As industry standards and best practices advance, maintaining product quality and patient safety remains a top priority. To ensure this, computerized systems must remain compliant throughout their operational lifecycle.

The Challenge of Ongoing Compliance

As Life Sciences organizations increasingly focus on their core business activities, there is a growing need to maintain the validated status of regulatory-critical systems in a cost-effective way. The GAMP Guide emphasizes the importance of this ongoing compliance.

Is Your IT-Infrastructure Compliance-ready?

“How confident are you in the ongoing compliance and maintenance of your validated computer systems amidst evolving regulations and operational demands? Discover how our Validation Maintenance Services can safeguard your compliance journey.”

“Facing challenges in keeping your computer systems validated, updated, and compliant without disrupting your core business operations? Learn how our tailored Maintenance Services can streamline your processes and enhance operational efficiency.”

What Does Ongoing Compliance Entail?

For computerized systems to remain compliant, they must:

- Stay properly qualified and validated.
- Receive appropriate maintenance and support.
- Support business processes in compliance with regulatory standards.

Given the evolving organizational and regulatory environment, periodic reviews are necessary to ensure continued compliance. However, for many Life Sciences organizations, dedicating full-time resources to this task or possessing the requisite specialist skills can be a challenge. Moreover, these activities are often considered non-core by many organizations.

While IT services are increasingly outsourced, Life Sciences companies can still maintain accountability for the compliant status of their systems by outsourcing day-to-day responsibilities to trusted partners.

“Do you have a strategic plan in place for the periodic review and maintenance of your computer system's validated status, ensuring it aligns with the latest regulatory standards? Find out how our Validation Maintenance Services can keep you ahead of the curve and inspection-ready.”

Your Partner in Sustaining Compliance and Enhancing Patient Safety

Our Comprehensive Services



Post-implementation Compliance Assessment:

We evaluate the current compliance status of IT infrastructure or systems, identifying and addressing any deficiencies to mitigate regulatory risks.



Development of Maintenance and Support Processes

Leveraging our unique Validation Accelerator Kit, we develop essential processes and procedures to uphold a compliant IT Quality Management System.



Revalidation Services

We offer efficient revalidation services, focusing on regulatory significant changes to speed up the process, minimize costs, and maximize investment returns.



Periodic Review:

qointa employs a risk-based approach to periodic review, ensuring that computerized systems remain compliant over time by Confirming adherence to the IS Quality System; Detecting any previously unnoticed incidents; Adapting to changes in the organizational or regulatory landscape; Maintaining readiness for regulatory inspections. This approach adjusts review frequency based on a thorough post-implementation risk assessment, ensuring that efforts are focused where they are most needed.



Third Party Oversight and SLA support:

Recognizing the challenge of overseeing outsourced IT services, qointa also provides oversight services. Whether for internal IT groups or external service providers, our oversight ensures compliance through periodic reviews, audits, and the day-to-day approval of documentation, all tailored within a client-specific Service Level Agreement (SLA).

Why Choose qointa?

01

Regulatory Mastery

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

04

Global Expertise

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

02

Quality Excellence

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

05

Holistic Approach

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

03

Customized Solutions

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

Partner with qointa to Ensure Ongoing Compliance

qointa provides the expertise and flexibility to help Life Sciences organizations maintain the compliance of their systems, ensuring continued product quality and patient safety. Let us handle the complexities of validation and compliance so you can focus on your core business.

Elevate your quality and regulatory compliance with qointa.

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



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