



Comprehensive Validation Services for the Life Sciences Industry

The Continuous Evolution of Computer Systems Validation

For over twenty years, the landscape of computer systems validation (CSV) has seen substantial changes—from the initial focus on Good Manufacturing Practice (GMP) and Good Laboratory Practice (GLP) to the current risk-based approach. As business processes become increasingly supported by complex software applications critical to product quality and patient safety, the need for thorough validation has never been more significant.

Why Validation Matters

Data integrity is a prerequisite for the regulated healthcare industry due to a direct impact on product quality and patient safety. Electronic data and computerized systems have introduced new challenges to maintaining data integrity, as it is much easier to change electronic data and records than it is to change a paper or other physical record.

FDA mandates the electronic data integrity through 21CFR Part 11 and 21 CFR Part 820 regulations. Health Canada has adopted Pharmaceutical Inspection Cooperation Scheme's (PIC/S) good guidance for computerized systems in regulated GXP environments, while the European Commission details electronic data integrity requirements in EU EudraLex Annex 11.

The integrity of regulated data relies upon the compliance of the computer systems responsible for managing regulated data. Due to increasing complexity of computerized systems landscape and lack of a balance between cost, schedule and appropriate level of compliance, the regulated organizations and its vendors often struggle to implement the most effective and defensible compliance standards, and, as a result, are at a disadvantage when it comes to data integrity.

qointa: Your Partner in Risk-Based Validation

qointa specializes in risk-based computer systems validation, offering tailored services that ensure your systems meet regulatory requirements efficiently. Our services are flexible, scalable, and can be provided as one-off engagements or as part of a long-term services agreement.

“Is your organization equipped to ensure that every computer system validation is not only compliant but also optimized for efficiency, minimizing risk and maximizing return on investment?”

“Have you experienced challenges in maintaining the validated status of your critical systems in a landscape of ever-changing regulatory requirements? Learn how our Computer System Validation Services can offer peace of mind and strategic advantage.”

“Do you seek a partner who can transform the complexity of computer system validation into a streamlined, cost-effective process, ensuring your operations are audit-ready and future-proof? Let's explore how our tailored solutions can meet your unique needs.”

Leading the Way in Risk-Based Computer System Validation

Our Comprehensive Services



Validation Framework Development

We assist Life Sciences organizations in developing flexible and scalable validation models, tailored to the size and complexity of their systems. Our risk-based approach ensures intelligent validation, covering everything from simple spreadsheets to enterprise-level systems, always cost-effectively.



Computer System Validation

Our expert consultants specialize in validating critical computerized and business systems across various domains, including laboratory data systems, clinical trial management, manufacturing process control, and more. Whether strategic or tactical, we integrate validation seamlessly into project planning, ensuring regulatory compliance without compromising on-time delivery and budget.

qointa is a trusted partner in validating mission-critical systems, including:

- Laboratory Data Systems
- Clinical Trial and Data Management Systems
- Manufacturing Control Systems
- ERP Systems
- Electronic Quality Management Systems
- Regulatory Information Management Systems
- Cloud Computing & SaaS Platforms
- Medical Device Software
- Custom-developed Software
- IT Infrastructure



Project Leadership

Maintaining the delicate balance between validation requirements and project constraints requires specialized expertise. qointa's consultants, with a strong track record in the Life Sciences industry, provide invaluable input to complex projects. We help navigate regulatory complexities, facilitate decision-making, and ensure alignment with program priorities.



Strategic and Tactical Support

Whether integrating validation activities into project planning or developing key validation documentation, our consultants ensure that validation does not become an overhead but a seamlessly integrated component of project execution.



AI & Cloud-Based Integration

With the rise of AI and cloud technologies, we specialize in validating these systems to meet regulatory requirements. Whether it's AI in clinical trials or cloud-based data management, we ensure these modern systems are validated and compliant.



Document Accelerator Kit

Our constantly updated Document Kit provides the latest regulatory guidance and best practices, ensuring that your validation process is both efficient and compliant.

Why Choose qointa?

01

Depth of Experience

Our consultants bring unparalleled expertise in CSV, combined with a thorough understanding of regulatory requirements and critical business processes.

02

Risk-Based Approach

Our methodologies prioritize risks, ensuring validation efforts are proportional to the potential impact on product quality and patient safety.

03

Regulatory Insight

Stay ahead of evolving regulations with our expertise.

04

Strategic Validation Planning

Ensure your validation activities are aligned with business priorities and regulatory expectations.

05

Cost-Effective Compliance

Achieve compliance without unnecessary expenditure, leveraging our risk-based validation approach.

With years of experience in Life Sciences, qointa is committed to providing cost-effective, risk-based validation solutions that are flexible, scalable, and compliant. Whether you're validating cloud-based systems, AI integrations, lab automation / process automation software, or critical enterprise software, our team helps ensure your systems meet regulatory standards – on time and within budget.

Discover how our comprehensive CSV services can support your objectives, ensuring that your systems are validated effectively and efficiently.



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