



Upholding Data Integrity in the Regulated Healthcare Industry

Unlocking Data Integrity Excellence

In today's data-driven world, ensuring the integrity, reliability, and security of your data is paramount. At qointa, we specialize in providing comprehensive Data Integrity Services tailored to meet the evolving needs of your organization. With our expertise and commitment to excellence, we help you maintain compliance, mitigate risks, and optimize your data management processes.

What is Data Integrity?

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 21 CFR 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.

Our Comprehensive Services

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|  <p>Validation Services</p> <p>Ensure the accuracy and reliability of computer systems and software.</p> |  <p>Quality System Audits</p> <p>Conduct audits to identify areas for improvement and ensure adherence to regulatory standards.</p> |
|  <p>Risk-Based Approach</p> <p>Utilize the GAMP5 framework to identify and mitigate potential risks effectively.</p> |  <p>Tailored Quality Management Systems</p> <p>Based on GAMP5 and FDA QSR standards, providing a solid foundation for compliance.</p> |
|  <p>CSV Planning and Support</p> <p>From planning to implementation, receive comprehensive support for computerized system validation.</p> |  <p>Scalable Approach</p> <p>Services are scalable to accommodate evolving needs, ensuring flexibility and cost-effectiveness.</p> |
|  <p>Technology and Vendor Evaluation</p> <p>Evaluate technology solutions and vendors to ensure compatibility and reliability.</p> |  <p>Integration with Existing Systems</p> <p>Seamlessly integrate services with current quality systems to minimize disruption.</p> |
|  <p>Periodic Review Services</p> <p>Maintain the validated state of systems to ensure ongoing compliance.</p> |  <p>Gap Analysis and Remediation</p> <p>Identify areas of non-compliance and implement remediation strategies effectively.</p> |

Is your data integrity strategy audit-ready and compliant?

Are you fully confident in the integrity of your data across its lifecycle, from creation to retirement, in compliance with global regulatory standards like FDA 21 CFR Part 11 and EU Annex 11?"

"How equipped is your organization to address the challenges of maintaining impeccable data integrity in an era where data is increasingly digital and audits are more rigorous than ever?"

"Does your current strategy for data integrity safeguard against the risks of data breaches and ensure the reliability and trustworthiness of your critical data? Explore how our Data Integrity Services can fortify your defenses and enhance your compliance posture."

Why Choose quinta?

01 Expertise

Leverage quinta's proven leadership in data integrity to navigate the complexities of compliance and validation, enhancing product quality, patient safety, and operational efficiency.

02 Risk-Based Approach

Benefit from a strategic, risk-based approach to validation and compliance, ensuring cost-effective solutions that withstand regulatory scrutiny.

03 Regulatory Readiness

With quinta's services, prepare for and excel in regulatory inspections, ensuring your data integrity practices are robust and defensible.

**"Safeguarding Your Data,
Elevating Integrity to
Excellence."**



Trust quinta to guide your organization through the complexities of data integrity and compliance, ensuring your computerized systems and data management practices are both effective and audit-ready. Our scalable solutions are designed to meet your specific needs, providing the assurance needed to focus on your core mission.

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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