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SQA Solution's experienced resources can integrate with your team to seamlessly enhance results and shorten project time.

COMPUTER SYSTEM VALIDATION SERVICE (CSV)

Can businesses really cut the cost of validation while remaining compliant and improving quality? SQA Solution can help Life Sciences organizations ensure compliance and reduce costs. Our Validation team provides a suite of validation services for GMP, GCP, and GLP applications used in pharmaceutical, bio-pharmaceutical, and medical device industries. Our background in technology and compliance puts us in an advantageous position to meet our pharm-aceutical clients' computer validation needs.

CREATING SOLUTIONS

SQA Solution delivers leading Compliance and Computer System Validation services that are designed to help reduce the overall cost of compliance for Life Sciences organizations. We offer our clients comprehensive services, including leadership and a range of strategic solutions and tactical services that provide cost-effective and comprehensive compliance and validation.

If you are looking for strategic and sustainable changes in your approach to Compliance and Computer System Validation, our team of highly-qualified testing consultants can deliver a broad suite of solutions in the areas of computer systems validation, infrastructure qualification, IT Quality Management, and process improvement. This will allow your organization to address Compliance and CSV issues, reduce costs without risking regulatory non-compliance, and leverage leading-edge beneficial technologies. We offer a full suite of tactical and strategic solutions. Depending on your specific needs, we can support your project with any or all of the services.

How SQA Solution Can Help You

Want to learn more about how SQA Solution can help you to create and implement your organization's Compliance and CSV strategy?

Contact Us to get detailed information about what's included in our services.

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CSV Documentation

- Project Plans
- Validation Master Plans and Risk-based Strategies
- Migration Plans
- URS
- FRS
- System Development/Configuration
- Implementation/Retirement Plans
- Change Control
- Standard Operating Procedures (SOPs)
- Traceability Matrix
- Installation Qualifications
- Operational Qualifications
- Performance Qualifications
- Quality Manual and Quality System Procedures Writing
- Quality Management Program

Computer-Related System Validation

- Laboratory Information Management Systems (LIMS)
- ERP Validation
- Quality Documentation Systems
- SFA/CRM systems
- Life Sciences support systems and applications, order & warehouse management systems
- Clinical and medical device support systems
- Data Transfers
- SAS Testing

Protocol Execution

- Execution of IQ/OQ
- Documentation of Test Results
- Incident Remediation and Retesting

Audits

- Gap Analysis and Quality Audits
- Internal & Vendor Audits
- Quality Control Audit Services
- FDA Audit Services
- System Audit (GLP/GMP)

Clinical/R&D Systems

- Documentum
- ClinTrace, ClinTrial
- Oracle Clinical
- Aris-G, eDE, eDM
- PhOSCo (IBM Clinware), PharmaTrace

SQA SOLUTION

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