Ensure Data Integrity And Regulatory Compliance

Agilent CrossLab Computer System Validation (CSV) Services

Produce consistent results that meet established specifications

All computerized systems-including hardware and software-must be fully validated to meet intended use and regulatory requirements. Specifically, computerized systems need to be validated for their "intended use"; architecture, environment, and scientific application/method workflows to be considered compliant. In addition, data integrity compliance is the main focus of regulatory audits and warning letters issued by the FDA.

You can efficiently and cost-effectively validate your computerized systems by using Agilent's Computer System Validation (CSV) Services. By partnering with Agilent, our compliance experts can help assess your overall risk and streamline your validation. Focusing our expert resources on your high-risk areas, ensures compliance with regulatory guidelines and regulations:

- GAMP® 5, including the risk-based approach and V model documentation
- US Food and Drug Administration (FDA) 21 CFR Part 11 and EU Annex 11 for electronic records and signatures

Reduce your CSV time by taking the stress out of meeting these documentation requirements:

System validation based on GAMP® 5

- Validation Plan (VP)
- Risk Assessment (RA)
- User Requirement Specification (URS)
- Functional Requirement Specification (FRS)
- Functional Risk Assessment (FRA)
- Design/Configuration Specification (DS/CS)
- Installation Qualification (IQ)
- Operational Qualification (OQ)
- Performance Qualification (PQ)
- Requirements Trace Matrix (RTM)
- Validation Summary Report (VSR)

System validation based on US FDA 21 CFR Part 11 and EU Annex 11

- Login/password Security
- Electronic Records Security
- Electronic Signatures
- Audit Trails
- Backup
- Disaster Recovery
- Data Integrity

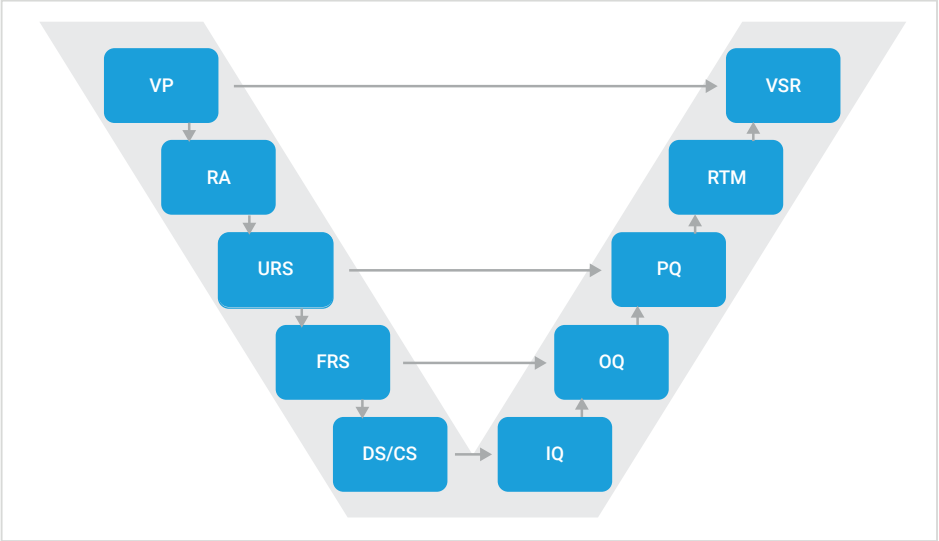
Agilent CrossLab
From Insight to Outcome

The Agilent CrossLab team can help to reduce your CSV time by up to

Contact your Agilent representative today, and let our knowledgeable validation experts help you with your CSV efforts

www.agilent.com/en/service/laboratory-services/compliance-services/validation-starter-kits

Agilent
Trusted Answers



A CSV partner you can trust

Validation is a life-cycle process that includes new system commissioning, change control for system upgrades/relocations, and decommissioning systems for archival. Agilent supports your lab every step of the way with these CSV services:

- Audits/assessments
- Validation starter kit documents
- Custom validation development
- Validation test execution (IQOQ)
- SOP writing
- Project management

How we help stories from the lab

Story No. **85**

Extra Compliance Rigor

Keeping instruments current helps reduce risk

Get the full story at
www.agilent.com/chem/story85

Story No. **87**

Creative Collaboration

A service visit results in better compliance protocols

Get the full story at
www.agilent.com/chem/story87

"From insight to outcome" isn't just our motto… it's our mission

Imagine how productive you would be if you could access a global team of experts who strive to deliver insight every time they interact with your lab. That's just what you get with Agilent CrossLab-the world leader in innovative laboratory services, software, and consumables.

1 Again

Agilent CrossLab

Ranked #1 in Compliance Services

Per independent surveys

Be confident that your computer systems are fully validated and audit-ready. Contact your Agilent representative to learn more.
www.agilent.com/chem/computer-system-validation

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