ENSURE DATA INTEGRITY AND REGULATORY COMPLIANCE

Agilent CrossLab
From Insight to Outcome

Agilent CrossLab Computer System Validation (CSV) Services

Produce consistent results that meet established specifications

All computer systems—including hardware and software—must be fully validated to support the data generated for submission to regulatory agencies. Specifically, systems need to be validated for their "intended use," application/method, and environment 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 computer systems—regardless of make or model—by partnering with Agilent. Our experts can help assess your overall risk, streamline validation by focusing on high-risk areas, and comply with regulatory guidelines and regulations:

- GAMP5, 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

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

Reduce your CSV time by up to 50%: The Agilent CrossLab team can take the stress out of meeting these documentation requirements:

System validation based on GAMP5

- Validation plan (VP)
- Risk assessment (RA)
- User requirements specification (URS)
- Functional requirement specification (FRS)
- Configuration specification/design specification (CS/DS)
- Installation qualification (IQ)
- Operational qualification (OQ)
- Performance qualification (PQ)/user acceptance testing (UAT)
- Trace matrix (TM)
- Validation summary report (VSR)
- SOPs (Training, use, maintenance, administration, etc.)

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

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A CSV partner you can trust

Validation is a lifecycle 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
- Generic validation documents
- Custom validation development
- Validation execution (IQOQ)

"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.

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

Be confident that your computer systems are fully validated and audit ready
Contact your Agilent representative to learn more

Published in USA, May 18, 2017
5991-8153EN

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