Agilent CrossLab
From Insight to Outcome

Agilent Computer System Validation Services

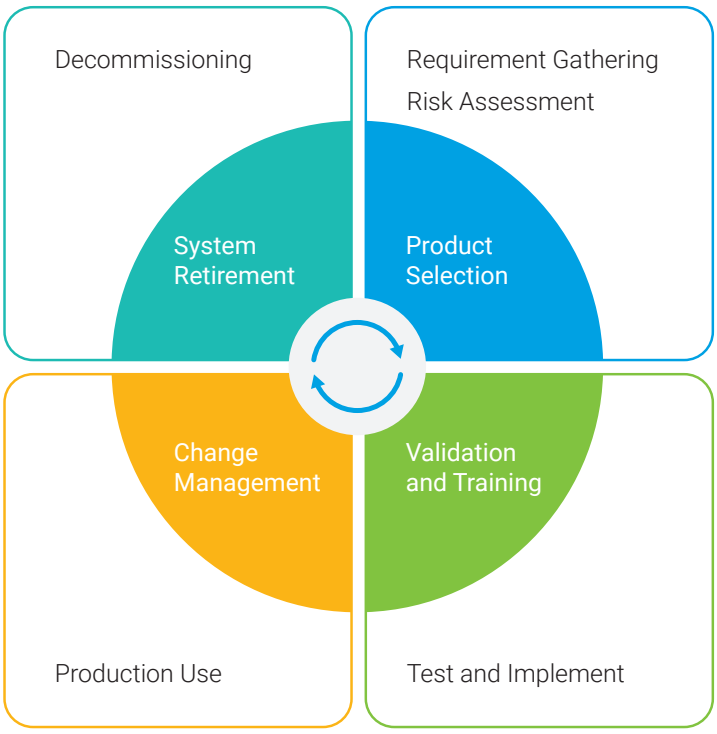
Agilent

Ensure Compliance and Data Integrity with Agilent Computer System Validation Services

Agilent CrossLab
Ranked #1 Compliance Services
Per independent survey conducted 2019

Computer System Validation (CSV) is a regulatory requirement for all computerized systems used in regulated environments in the Pharmaceutical, Biotech, Nutraceutical, and Medical Device industries. CSV ensures that computerized systems are performing properly according to customer intended uses and regulatory requirements, such as:

- FDA 21 CFR Part 11
- FDA 21 CFR Part 210/211
- Eudralex and PIC/S Annex 11

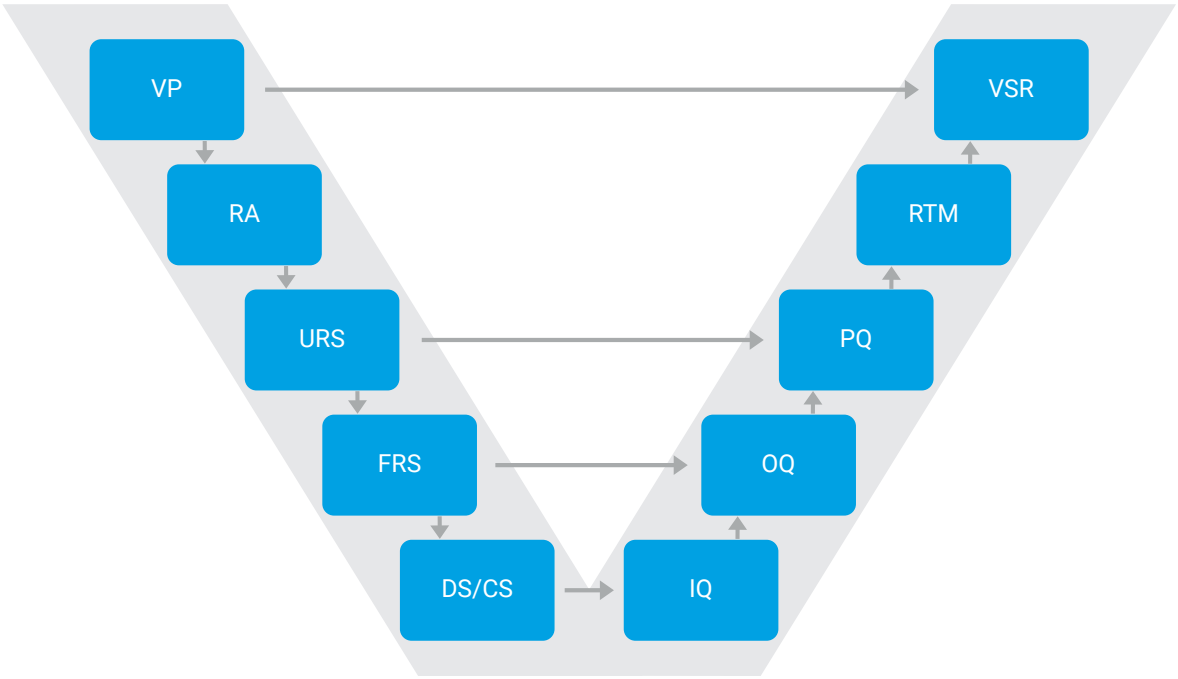


Life cycle of Computer System Validation

The validation process is a life cycle that begins with product/vendor selection and system implementation through production use and into the decommissioning/retirement phase. Agilent Technologies can assist our customers through all phases of the validation life cycle: Requirements Gathering, Risk Assessment, Validation and Training, Change Management consulting, and System Retirement.

Agilent's CSV program based on GAMP® 5 "V" model

Agilent's CSV program provides customers with a customizable consultative service that is based on the GAMP® 5 paradigm for a risk-based approach to Computer System Validation. Our compliance consulting team can evaluate customer requirements, environments, and system architecture to provide a comprehensive CSV package.



Validation Plan (VP) – Provides the basis for the entire validation process and the objectives that will be met during the validation.

Risk Assessments (RA) – Regulatory RA helps the customer determine if the system is GMP, GLP, GxP (or other regulations) applicable, and the level of risk to the applicable regulations. **Functional RA** helps determine the level of testing for the functional requirements.

User Requirements Specification (URS) – Documents how and what the customers need the system to do to meet their intended purpose.

Functional Requirements Specification (FRS) – Describes how the system will functionally meet the User Requirements.

Design/Configuration Specification (DS/CS) – Contains all of the hardware and software specifications to properly build the system as well as the access and security configurations for Part 11 compliance.

Installation Qualification (IQ) – Provides documented evidence that the system has been installed and configured correctly as per the Configuration Specification document.

Operational Qualification (OQ) – Provides documented evidence that the system operates according to the functional requirements.

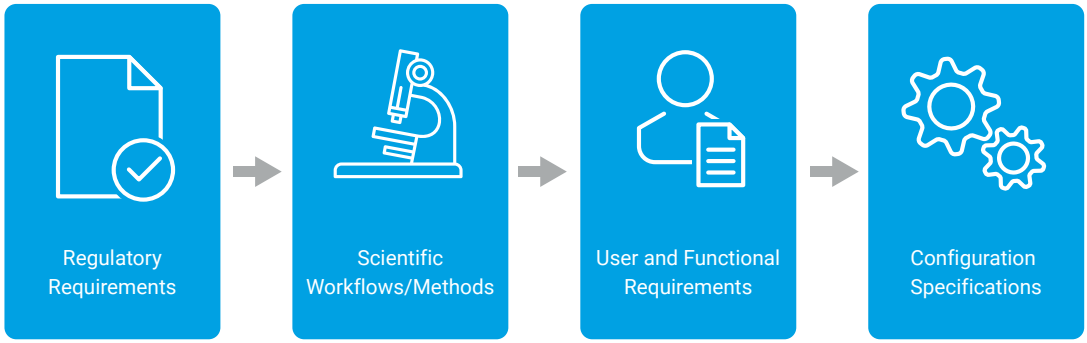
Performance Qualification (PQ) – Provides documented evidence that the system holistically performs according to the user requirements (Intended Use).

Requirements Traceability Matrix (RTM) – Documents the relationship between requirements and tests/procedures by cross-referencing the tests performed to the user requirements, functional requirements, and configuration specifications.

Validation Summary Report (VSR) – Summarizes the results of the installation, operational, and performance qualification testing activities. Forms the basis for the release of the system into the Production Environment.

Requirements Gathering Process

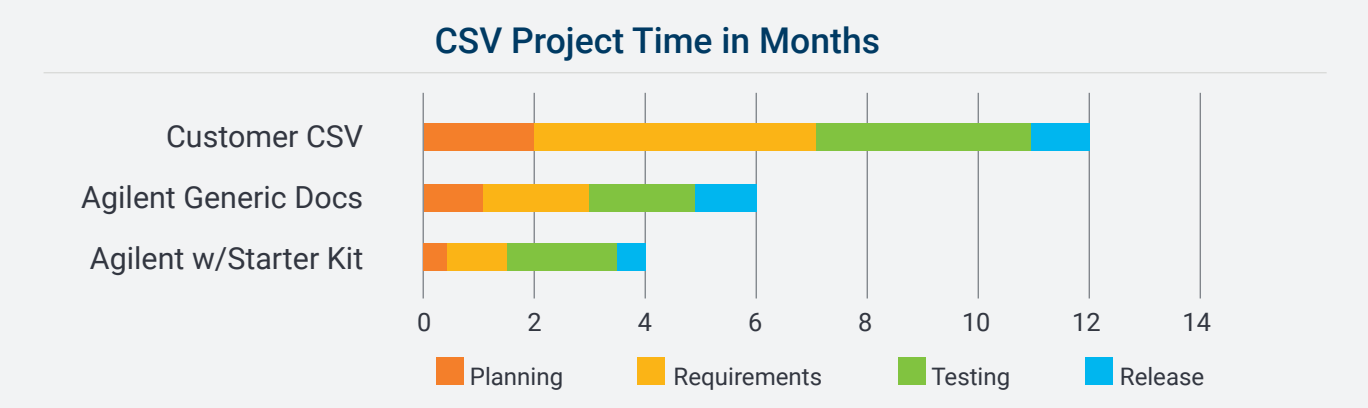
The CSV process forms the foundation of regulatory compliance and data integrity by ensuring that the system is configured and operating correctly to meet regulatory requirements. The CSV process is also responsible for ensuring that the customer's applications and workflows (Intended Use) can be successfully executed within the system's capable boundaries. These customer-specific requirements are commonly referred to as User Requirements, and they form the basis for the CSV process.



Agilent's Validation Starter Kits - Helping customers achieve faster ROI

Agilent utilizes our extensive experience and starter kits that we have created for some of our most popular laboratory computerized systems. These documents allow Agilent to reduce the overall CSV project time, which helps our customers get their computerized systems into production faster without compromising compliance or quality. While Agilent's CSV program can provide all the necessary templates to meet rigorous CSV standards, we are also flexible in using customer templates as long as all regulatory and Intended Use requirements are sufficiently documented and met by testing or procedure.

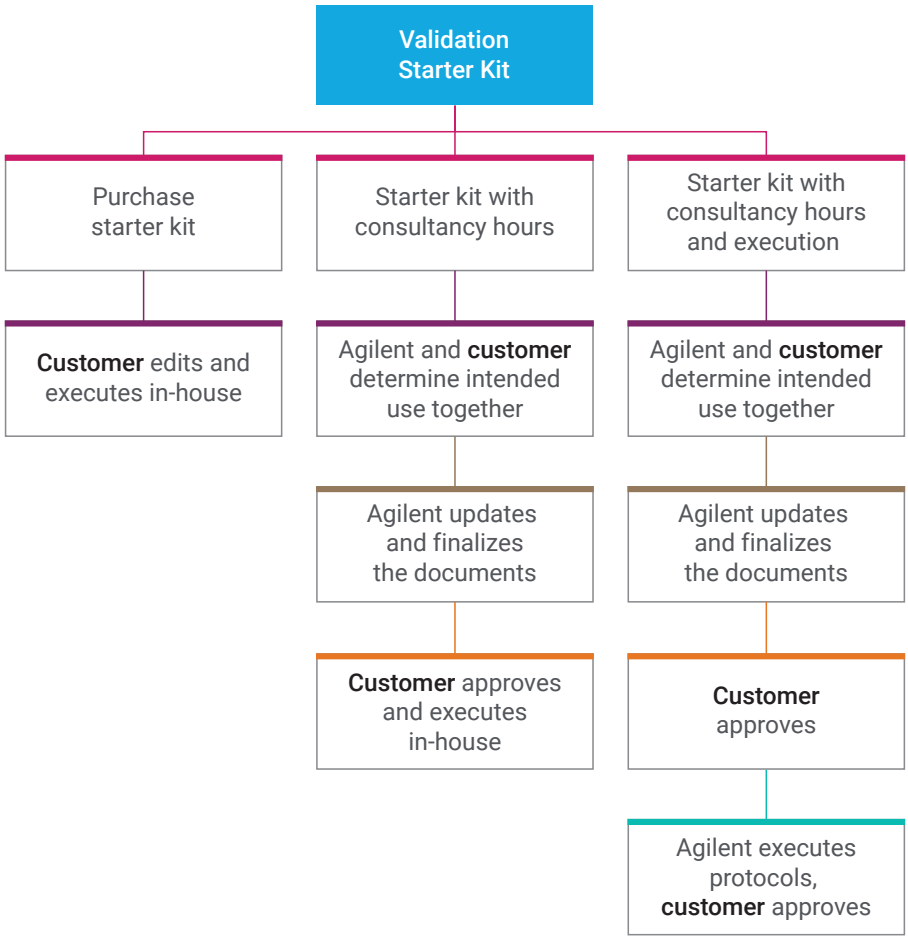
Delivery Time Customer	Delivery Time Agilent (Generic Documents)	Delivery Time Agilent (Starter Kits)
1 Year	5–7 months 50% time savings	3–4 months 75% time savings



Our Validation Starter Kits provide efficiency, compliance, and flexibility to allow our customers to decide how they want to utilize our services. Our Validation Starter Kits contain templates for all of the GAMP® 5 documents discussed above but tailored specifically for Agilent's Laboratory Informatic products (as applicable).

We offer Validation Starter Kits with flexibility and additional consulting services:

- Customer configures Starter Kit for their Intended Use and execute themselves.
- Agilent configures Starter Kit based on Intended Use (Consulting Services), execution performed by customer.
- Agilent configures Starter Kit based on Intended Use and executes testing (Consulting Services), PQ execution performed by customer.



In summary, Agilent Starter Kits provide many benefits:

- Generic—Foundation for validations
- Include all standard documents (GAMP® 5 model)
- Accelerate validation for Agilent software
- Customizable documentation
- Execution service for IQ/OQ (optional for additional price)

Compliance Consulting Services—Going Further

Agilent can provide auditing, consultation, document writing, test execution, and training services to ensure that our customer's compliance requirements are met in an efficient, cost-effective manner.

Audits/Assessments

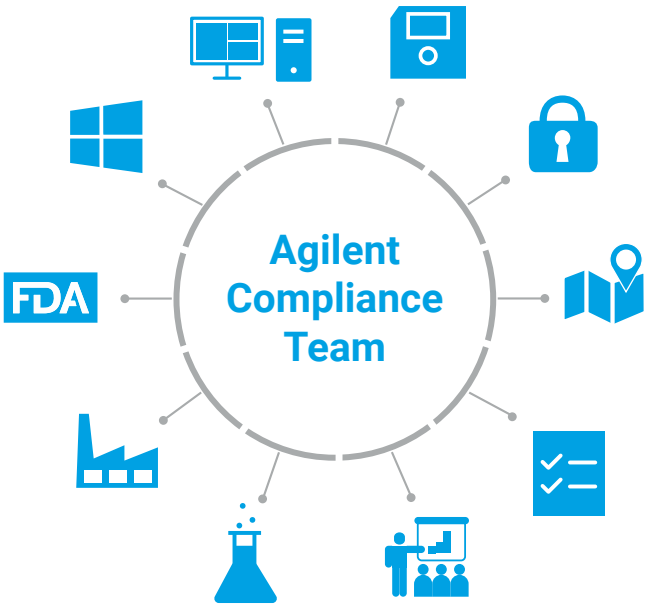
Agilent Technologies can offer an auditing service for data integrity based on Laboratory and IT best practices, regulations, and recently released data integrity guidance.

Custom Procedure Writing

Agilent Technologies can offer a procedure writing service to help our customers maintain the validated state of their systems once placed in the production environment.

Compliance Training and Education

Agilent Technologies can offer training courses to give your employees the knowledge they need to understand and be compliant to regulations applicable to your business.



Where can Agilent Help?

Agilent is able to partner with you to address many of the changes facing your lab. Please contact for assistance with:

- **Windows upgrades**
  Completing and supporting CSV activities
- **OpenLab installation or upgrade**
  Provide starter kit, completing and supporting CSV activities
- **Installation of any Agilent software or third-party software**
  Completing and supporting CSV activities
- **Data Integrity Risk Assessments and DI Remediations**
  Complete assessments and help you find solutions to close gaps
- **Audit Preparation**
  Perform pre-audits, identify risks, prepare analysts
- **Training**
  Classroom or eTraining
- **New Laboratory Build**
  Purchasing, project management, completing and supporting CSV and/or USP <1058> activities
- **Becoming a Regulated Laboratory**
  Review and creation of procedures and processes

References

- 21 CFR Part 11, Electronic Records; Electronic Signatures, current revision
- 21 CFR Part 211, Current Good Manufacturing Practice for Finished Pharmaceuticals, current revision
- GAMP 5: A Risk-Based Approach to Compliant GxP Computerized Systems, February 2008
- Eudralex, Volume 4, Annex 11: Computerised Systems
- Data Integrity and Compliance with Drug CGMP: Questions and Answers, December 2018
- USP Chapter <1058> Analytical Instrument Qualification, First Supplement to USP 40-NF35, August 2017

Agilent CrossLab
From Insight to Outcome

All systems (software + hardware) must be fully validated to support data generated for submission to regulatory agencies.

Validation establishes that a system can consistently and accurately produce results that meet a pre-determined specification.

Systems must be validated for their Intended Use and environment.

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Have confidence in your data integrity program with Agilent CrossLab, the industry leader in instrument and software qualification and computer system validation services.

To know more, visit:

www.agilent.com/chem/computer-system-validation

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Trusted Answers