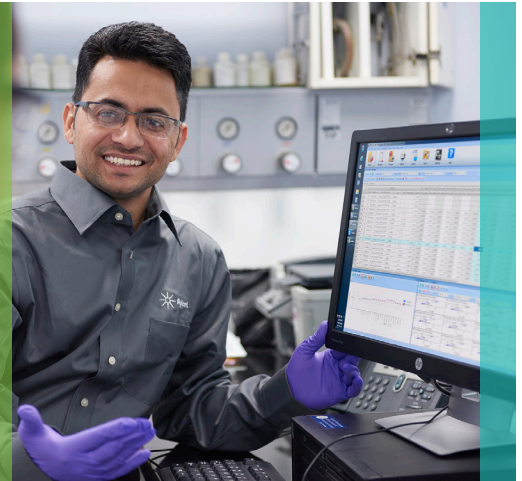


Reducing Time to Achieve a Compliant Validation

Agilent's Software Validation Starter Kits



The Starter Kit is a comprehensive suite of Computer System Validation (CSV) templates for Agilent Software.

Agilent
CrossLab
From Insight to Outcome

All computerized systems - including hardware and software - must be fully validated to meet intended use and regulatory requirements. By partnering with Agilent, you can efficiently and cost-effectively validate your computerized systems. Our experts can help assess your overall risk, streamline the validation process by focusing on high-risk areas, and comply with industry 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

Real stories from the lab

See an example of Agilent CrossLab insight at work at

www.agilent.com/en/video/story51

We offer the following Software Validation products and services

- CSV Consultancy and Validation Services
- [Validation Starter Kits](#)
- Customization of Starter kit (based on intended Use and Environment)
- Execution of Customized Starter Kit Test Protocols (IQOQs)
- SOP Writing

Benefits

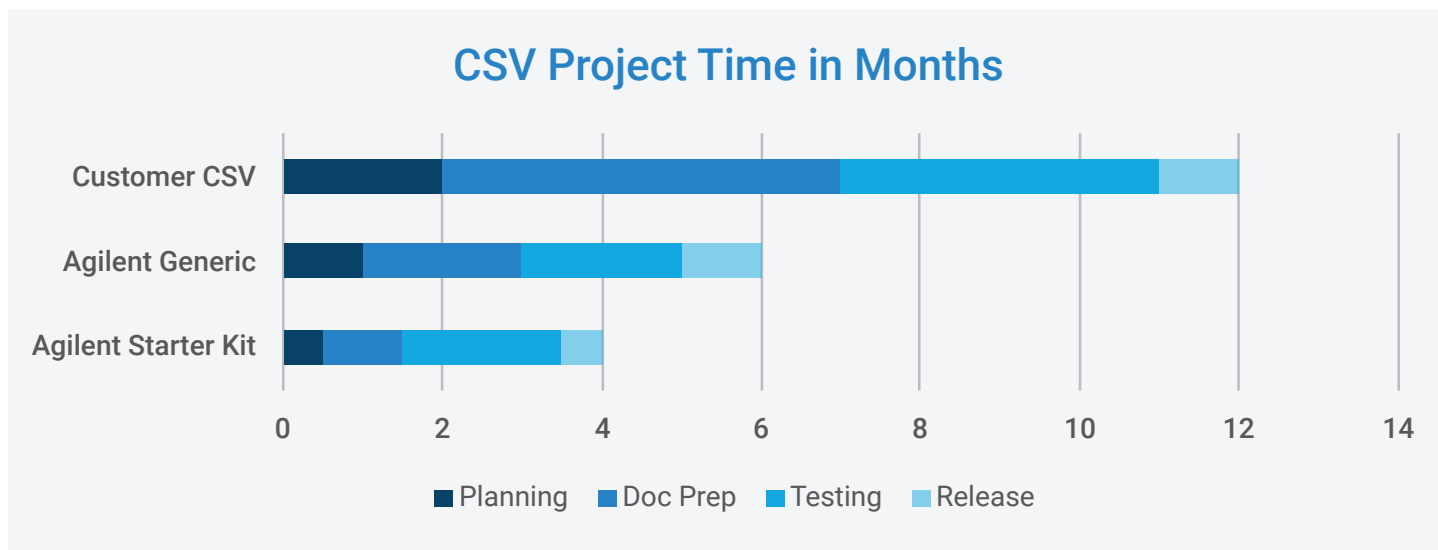
Validation Starter Kits will help to accelerate the Validation of Agilent Software to save both time and cost. Benefits of up to 50% are often achieved.

- Save time and cost (up to 50%)
- Faster ROI on technology investments
- Utilize industry accepted GAMP® 5 process
- Starter kits can be executed by customer or with experienced Agilent Compliance Consultants



Validation Documents

Starter Kit includes all of the Validation documents required by GAMP® 5 (V Model/Risk-Based Approach) for Data Integrity and Part/Annex 11 (Electronic Records and Signatures) Compliance.



Validation documents included in the Starter Kit are:

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)

For more information on Software Validation Kits, please visit

www.agilent.com/chem/validation-starter-kits

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This information is subject to change without notice.

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Published in the USA, August 20, 2021
5991-9463EN