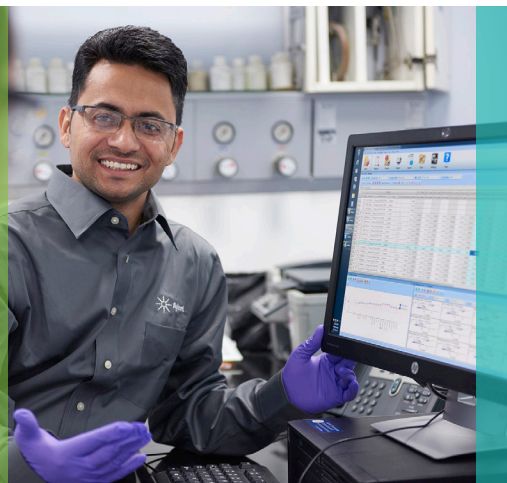


# Reducing Time to Achieve a Compliant Validation

## 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](http://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

1  
Again

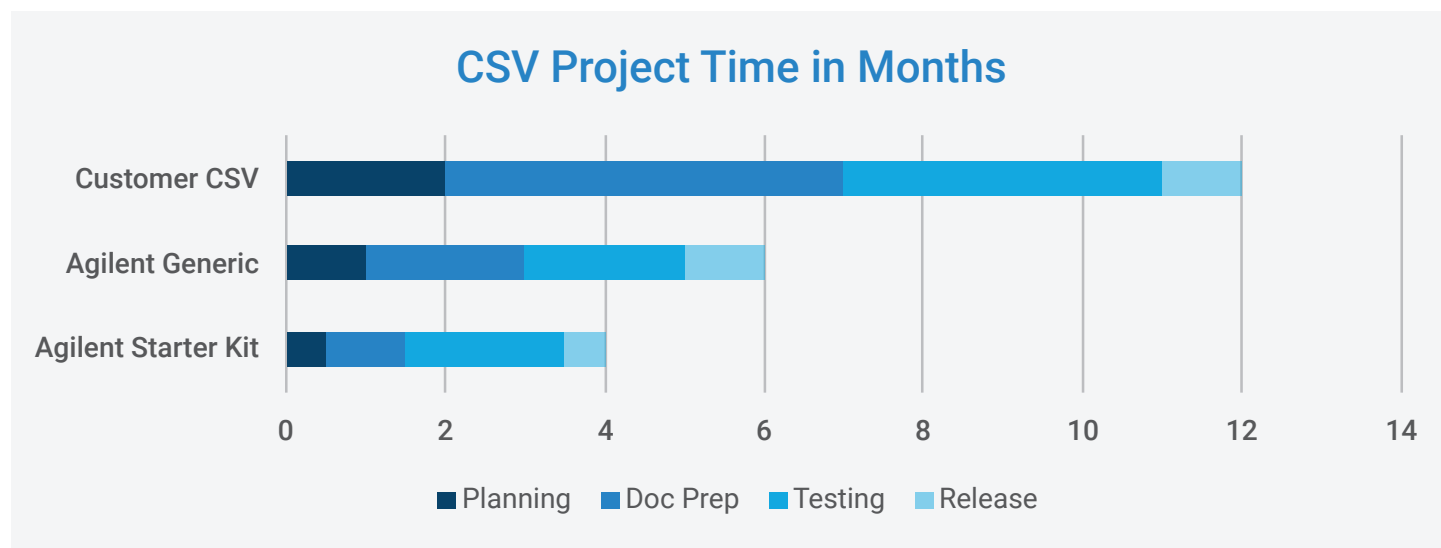
Agilent  
**CrossLab**

Ranked #1 in  
Compliance  
Services

Per independent surveys

## 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/computer-system-validation](http://www.agilent.com/chem/computer-system-validation)

DE44246.3710300926

This information is subject to change without notice.

© Agilent Technologies, Inc. 2022  
Published in the USA, September 27, 2022  
5991-9463EN