The Starter Kit is a comprehensive generic set of Computer System Validation (CSV) documents for Agilent Software.

All computer systems - including hardware and software - must be fully validated to support the data generated for submission to regulatory agencies.

You can efficiently and cost-effectively validate your computer systems 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 for electronic records and signatures

We offer the following Software Validation products and services

- Generic Validation Documents (Starter Kit)
- Customization of Starter Kit based on Intended Use and Environment (Consulting Services)
- Execution of Customized Starter Kit (IQOQs)

Benefits

Validation Starter Kits will help to accelerate the Validation of Agilent Software by up to 50% or more to save both time and cost.
Validation Documents

Starter Kit includes all of the Validation documents required by GAMP5 (V Model/Risk Based Approach) for Data Integrity and Part/Annex 11 (Electronic Records & Signatures) Compliance.

GAMP5 V Model

Validation documents included in the Starter Kit are:

- Validation Plan (VP)
- Risk Assessment (RA)
- User Requirement Specification (URS)
- Functional Requirement Specification (FRS)
- 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/crosslab

This information is subject to change without notice.

© Agilent Technologies, Inc. 2018
Published in the USA, May 18, 2018
5991-9463EN