SPK and Associates

Connecting Computer System Validation to Daily Operations

6 Tips For Validation Improvement

Today's Presenter

Carlos Almeida
Vice President, Software Engineering

SPK and Associates

Agenda

01 – Who is SPK and Associates?

02 – Computer System Validation

03 – Computer System Assurance

Who is SPK and Associates?

SPK and Associates is a leading woman-owned Engineering & IT Services Company that serves product development teams. For 25 years, we have helped our customers harness technology to optimize engineering and attain their business goals. We understand the systems, processes, data and applications critical to successful product development, and dedicate ourselves to helping you build, test, and release your products faster and better.

Our core expertise covers four functional areas: Product Lifecycle Management (MCAD, PLM, PDM); Software Lifecycle Management (ALM, DevOps); Cloud for Engineering (Infrastructure, Compliance, Validation and Security); Data Engineering and Analytics. Medical Device/Life Sciences Deep Knowledge and Experience.

HQ in Scotts Valley, California.

greenlight guru

Greenlight Guru Implementation Partner

stryker

Johnson & Johnson

Medtronic

B BRAUN

COVIDIEN

positive results for life

SPK and Associates

Why Do We Validate?

- Drive Patient Safety, Product Quality and Ensure Data Integrity
- To Comply With FDA Regulations

- *If you don't* -> Observations (483's), Warning Letters, Financial Penalties or Worse.

*Any software used to automate any part of the device production process, or any part of the quality system must be validated for its intended use, as required by **21 CFR §820.70(i).** This requirement applies to any software used to automate device design, testing, component acceptance, manufacturing, labeling, packaging, distribution, complaint handling, or to automate any other aspect of the quality system.*

*In addition, computer systems used to create, modify, and maintain electronic records and to manage electronic signatures are also subject to the validation requirements. **(See 21 CFR §11.10(a).)** Such computer systems must be validated to ensure accuracy, reliability, consistent intended performance, and the ability to discern invalid or altered records.*

All production and/or quality system software, even if purchased off-the-shelf, should have documented requirements that fully define its intended use, and information against which testing results and other evidence can be compared, to show that the software is validated for its intended use.

How Do We Validate?

Computer System Validation (CSV) - Traditional

Computer System Assurance (CSA)- Newer Approach

Need To Accommodate Both Methodologies

SPK and Associates

Computer Systems Validation (CSV)

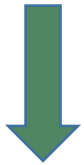
Most of our Customers Still ask for this approach – but that is changing – Many On Prem

Validation Plan

#	Item /Task	Owner	DONE
1	Validation Plan Authoring (With Customer Approval)	SPK	
2	Roles Established	SPK/Customer	
3	Templates Established (Optional)	SPK/Customer	
4	Vendor Training Completed (As Needed)	SPK/Customer	
5	Document Signing/Routing methodology established	SPK/Customer	
6	Validation Plan Sign Off	SPK/Customer	

Computer Systems Validation (CSV)

User/System Requirements
Part CFR 11
Risk Assessment

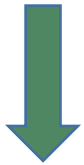


#	Item /Task	Owner	DONE
7	User Requirements Authoring (Intended Use) – Leverage/Build SOPs	Customer/SPK	
8	System Requirements Authoring	Customer/SPK	
9	Part CFR 11 Document Authoring	SPK/Customer	
10	Risk Assessment Authoring (FMEA)	SPK/Customer	
11	Risk Assessment Sign-off (With Mitigations)	Customer	
12	User Requirements Sign-Off	Customer	
13	System Requirements Sign-Off	Customer	
14	Part CFR 11 Document Sign-off	Customer	

SPK and Associates

Computer Systems Validation (CSV)

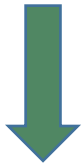
IQ



#	Item /Task	Owner	DONE
15	Installation Qualification Requirements Authoring	SPK	
16	Installation Qualification Requirements Sign-off	SPK/Customer	
17	Installation Qualification Protocol Authoring	SPK	
18	Installation Qualification Protocol Sign-off	SPK/Customer	
19	Installation Qualification Protocol Execution	SPK	
20	Installation Qualification Protocol Execution Sign-Off (Objective Evidence)	SPK/Customer	

Computer Systems Validation (CSV)

OQ / PQ



#	Item /Task	Owner	DONE
21	Operational/Performance Qualification Requirements Authoring	SPK	
22	Operational/Performance Qualification Requirements Sign-off	SPK/Customer	
23	Operational/Performance Qualification Protocol Authoring	SPK	
24	Operational/Performance Qualification Protocol Sign-off	SPK/Customer	
25	Operational/Performance Qualification Protocol Execution	SPK	
26	Operational/Performance Qualification Protocol Execution Sign-Off (Objective Evidence)	SPK/Customer	

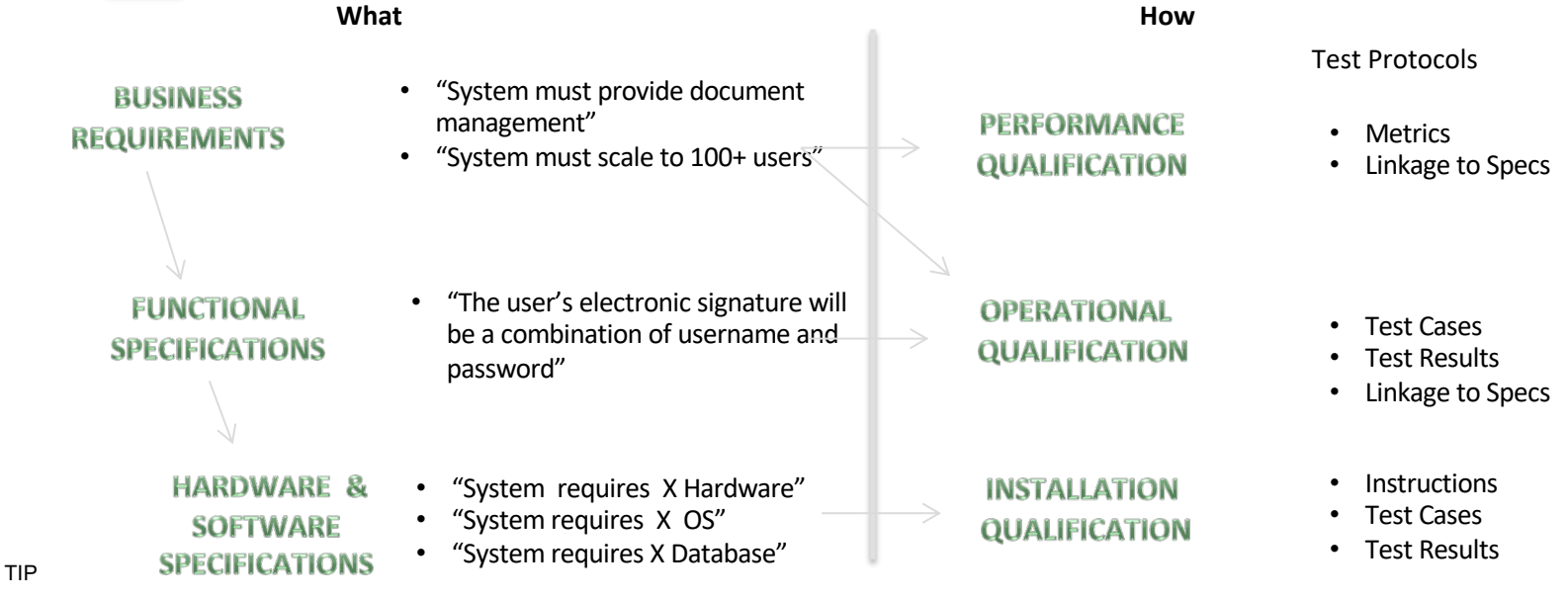
Computer Systems Validation (CSV)

Deviations
Mitigations
Traceability Matrix
Final Validation Report
Change Control

#	Item /Task	Owner	DONE
27	Report Deviations	SPK	
28	Mitigate Deviations (New Requirements/Tests/Design)	SPK/Customer	
29	Update Validation	SPK	
30	Traceability Matrix	SPK	
31	Final Validation Report	SPK	
32	Ongoing Change Control Process	SPK/Customer	

SPK and Associates

Computer Systems Validation (CSV)



TIP

Typically Takes Months - If Customer Does On Their Own

1. Much Less Time - If Skilled Partner Assists (Engineering SME + Compliance)

TIP

SPK and Associates

Computer Systems Validation (CSV) – On Cloud

2. Leverage Vendors (Supplier Documentation) to get credit for their work – reduce redundant efforts.

IQ is replaced by Vendor Assessment/Qualification

A strong supplier assessment program will ensure that the user is satisfied as to the quality of the software / computer system being used on the cloud.

A thorough supplier audit may provide justification to allow the user to leverage some supplier testing, i.e., do not repeat testing already performed by the vendor (get value for your money),

e.g. for Software as a Service (SaaS) if the vendor has a strong QMS in place and has already validated the system, then there may be no requirement for the user to re-validate the out-of-the-box features.

Computer Systems Validation (CSV) – On Cloud

Manage Your Cloud Risk Leveraging Vendors

1. Data security and controls: As with other third-party custodians, providers must assess the strength of a cloud vendor's internal controls.
2. Data transmission: Data may be transmitted over the Internet or wireless networks. Identify where the data is transmitted and stored.
3. Multitenancy: This requires healthcare organizations to consider the possible commingling of data on shared hardware.
4. Location: Moving data to the cloud means moving assets to a remote location that the healthcare provider doesn't control. Additionally, data may be stored outside of the U.S.
5. Reliability: When relying on a shared resource such as the cloud, healthcare organizations face the risk that resources may not be available when needed.
6. Sustainability: Determine the adequacy of a cloud provider's disaster recovery, and business continuity plans to understand how operations will continue if the cloud is out of service

Computer Systems Validation (CSV) – On Cloud

Manage Your Cloud Risk continued (Leverage Certifications)

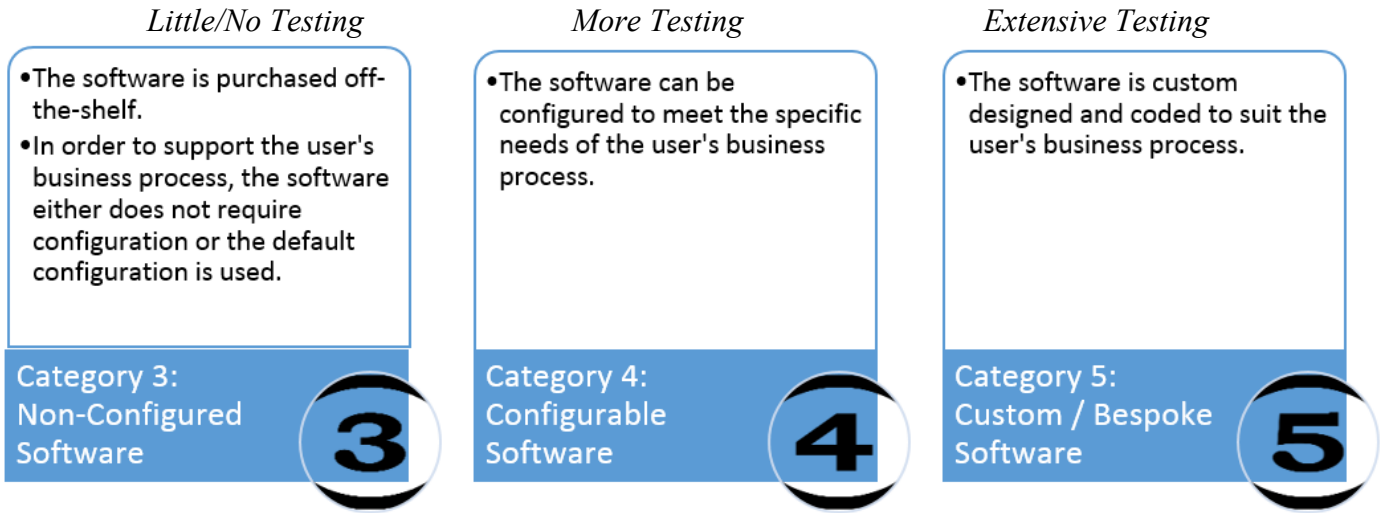
Data security and controls: As with other third-party custodians, providers must assess the strength of a cloud vendor's internal controls.

- **SO/IEC 27001** - ISO 27001 is specification for an information security management system (ISMS), which is a framework for an organization's information risk management processes.
- **SOC 2 - SOC 2** (System and Organization Controls) is a regularly refreshed report that focuses on non-financial reporting controls as they relate to security, availability, and confidentiality of a cloud service.
- **SOC 3 - SOC 3** (System and Organization Controls) is a regularly refreshed report that focuses on internal controls as they relate to security, availability, and confidentiality of a cloud service.
- **FedRAMP** - The Federal Risk and Authorization Management Program (FedRAMP) is a U.S. Federal government-wide program that provides a standardized approach to security assessment, authorization, and continuous monitoring for cloud products and services.
- **STAR** - The Security, Trust, Assurance, and Risk (STAR) Registry is a publicly accessible registry that documents the security and privacy controls.

If your Cloud Solution is leveraging AWS, you get these and more.

Computer Systems Validation (CSV) – On Cloud

3. Risk Approach to Cloud Solution Vendor Updates (Intended Use)



TIP

Select your Cloud Based Solution based on leveraging as much out-of-the-box Intended Use as possible. **Greenlight Guru** is the world's first MedTech Lifecycle Excellence Platform (MLE) & only QMS Software designed specifically for the medical device industry.

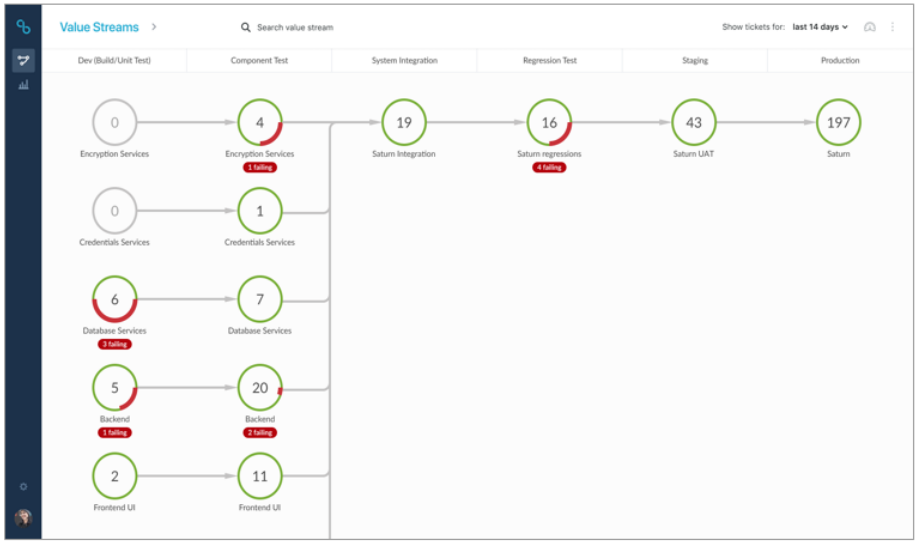
Computer Systems Validation (CSV) – On Cloud

4. Utilize Automated Testing to run your Validation tests – Leverage pipeline DevOps ALM methodology.

TIP

The FDA supports and encourages the use of automation, information technology, and data solutions throughout the product lifecycle in the design, manufacturing, service, and support of medical devices. - Think ALM and Test Harness - Think DevOps Pipelines created to rerun your test cases as needed – as determined by risk.

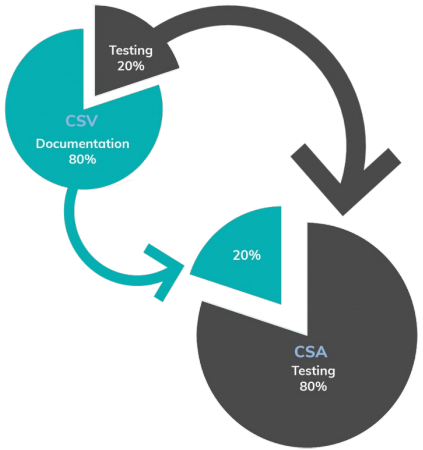
Automated systems provide manufacturers advantages for reducing or eliminating errors, increasing business value, optimizing resources, and reducing patient risk. These capabilities provide significant benefits in enhancing product quality and safety.



SPK and Associates

Computer Systems Assurance (CSA)

CSV	CSA
Focus on creating documentation records for compliance	Focus on testing for higher confidence in system performance
"Validate" everything (and potentially miss higher risk areas)	Risked-Based "Assurance, applying the right amount of rigor for a given level of risk to patient safety and/or product quality
Ignoring previous assurance activity or related risk controls	"Take Credit" for prior assurance activity and upstream/downstream risk controls.



New FDA Guidance expected to be released this year.

Leverages GAMP 5 2nd Edition - Discussion of current FDA activity on Computer Software Assurance (CSA) approaches and clear links to ISPE/GAMP guidance on Data Integrity (DI) have been added.

Computer Systems Assurance (CSA)

5. Use a Risk-Based (Direct vs Indirect) model to reduce the amount testing. Focus on direct impact to Patient Safety, Product Quality and Data Integrity

TIP

- **Direct system software'** (e.g. inspects or dispositions product, labeling systems) will require testing based on risk, and expected deliverables are similar to current expectations, i.e. the riskier the application, the more testing and documentation is required.
- **'Indirect system'** is software that does not directly impact the product or patient safety but does impact the quality system (e.g. Document Control, Complaint Management, Lifecycle Management tools). The same rigor is not needed for the assurance of these types of systems, and they require less documentation.

Computer Systems Assurance (CSA)

6. Upgrade your Validation team to enable higher level testing paradigm (Scripted/Unscripted).

TIP

Allow for Scripted and Unscripted Testing

- **'Scripted Testing'** is what we would know as traditional testing. Scripted tests as we know usually contain at a minimum a test Objective for the test script, a step-by-step test procedure, Expected Results and a Pass/Fail. Scripted Testing is to be used to test to higher risk (Direct) systems or features as the software does directly impact the product or patient safety. *Still want to automate these!
- **'Unscripted testing'** is testing that is carried out without the use of detailed test scripts. Unscripted Testing is to be used to test lower risk (Indirect) systems or features as the software does not directly impact the product or patient safety but does impact the quality system. There should be a Test Objective and a Pass/Fail, but no step-by-step test procedure. Upgrade your Testers to be SMEs – less step by step – more strategic.

6 Tips For Validation Improvement

1. Leverage Vendors (Supplier Documentation) to get credit for their work – reduce redundant efforts.
2. Use a Risk-Based (Direct vs Indirect) model to reduce the amount testing. Focus on direct impact to Patient Safety, Product Quality and Data Integrity
3. Utilize Automated Testing to run your Validation tests – Leverage pipeline DevOps ALM thinking.
4. Select your Cloud Based Solution based on leveraging as much out-of-the-box Intended Use as possible. Greenlight Guru is the world's first MedTech Lifecycle Excellence Platform (MLE) & only QMS Software designed specifically for the medical device industry.
5. Upgrade your Validation team to enable higher level testing paradigm (Scripted/Unscripted).
6. Work with an experienced SME/Partner to expedite your overall validation (Weeks instead of Months)

SPK and Associates

Thank You! "I have more questions!"

Send any specific questions to…

info@spkaa.com