Arcondis

Computer System Assurance

Abstract: This paper gives a short introduction to the new FDA guideline on Computer Software Assurance (CSA), the differences to Computer System Validation, the benefits of CSA, and how Arcondis can support you with introducing CSA in your company.

Content

What is CSA?

In a GMP environment, patient safety, data integrity and product quality are of utmost importance. Computerised operations are under highest regulatory scrutiny: both FDA and EU GMP guidelines stipulate the need to validate processes, systems and software which replaces manual operations

Since the introduction of the CSV Guideline in 2011, the regulatory bodies require validation of computerised systems (CSV) to assure patient safety and product quality, and they require full documentation, audit trails and scripted testing as proof.

It is expected that in 2021 a new FDA guidance will be released on this subject, concerning Computer Software Assurance (CSA), where the focus is more on the electronic systems and the software used. This new FDA guidance aims to minimize misinterpretation of regulations, to clarify existing approaches, to increase the possibility of technology innovation and to introduce a risk-based approach to software testing & computer systems.

CSA

Computer Software Assurance is a risk-based approach to computer systems and the software used, that is product quality-focused and patient-centric. CSA follows a critical thinking approach, still focusing on patient safety, product quality, and data integrity, but with more concise, risk-based testing and less documentation.

However, Computer System Assurance is not a replacement for, nor a contradiction of, current Computer System Validation approaches as defined in GAMP 5. Rather, CSA is a reinforcement, or restatement, of the GAMP 5 key principles of product and process understanding, quality risk management, and leveraging supplier activities. CSA combines risk-based testing with risk-based documentation

1 CSA and CSV
What are the differences?

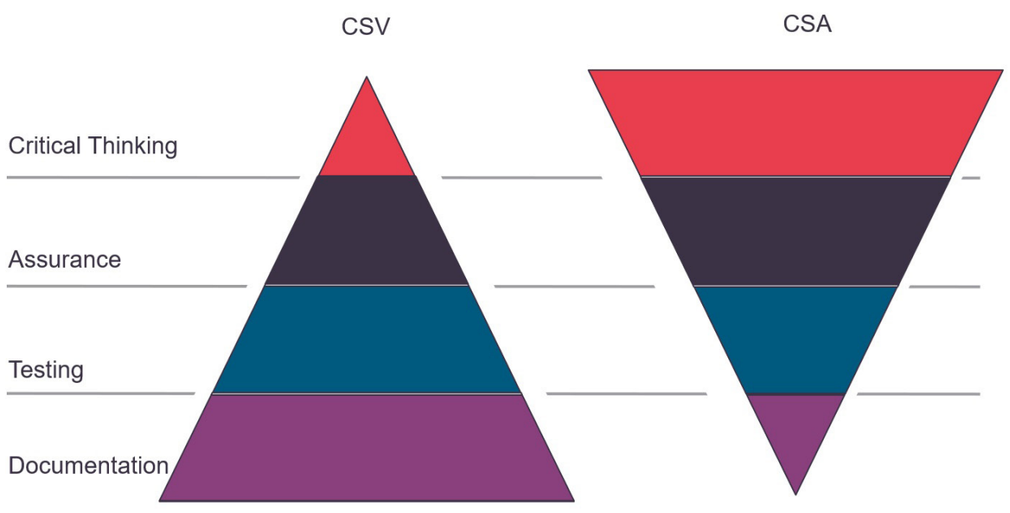
CSV focusses on computerised systems and includes the processes around the system.

Current CSV regulations resulted in a focus on documentation and less on critical process thinking. The majority of the efforts were spent on validation, testing, documentation and reconfirming previous testing and CSV efforts, also from suppliers. The approach was often to test and document all, to satisfy inspectors and auditors, instead of focusing on the high-risk processes.

CSA lays the focus more on the software and the computer system. In CSA, critical process thinking is key and reduced documentation is possible: much of the effort is spent on risk evaluation and prioritised testing (sometimes even automated). Furthermore, the utilization of previous work (e.g., by the software provider) is possible.

This can strongly reduce the workload, shorten the process time, and assure focus on high-risk areas of the system. The total effort on validation and the output of documentation can be reduced.

Computer System Validation versus Computer System Assurance



> “The risk-based testing approach can significantly reduce assurance efforts and documentation needs”

2 CSA Testing Approach

Risk based testing can reduce the testing effort and focusses more strongly on the high-risk processes in view of patient safety, product quality and data integrity. A thorough and documented risk analysis will allow for identifying the risks in the system.

As confirmed by Aetna, Kaiser Permanente in the UThen, only the high-risk features of the system are tested using the Scripted Test System we know from the CSV approach. For medium risk features and low risk features it is acceptable under the FDA CSA approach to apply unscripted (medium risk) and ad Hoc testing (low risk) procedures.

For selected processes it is acceptable to accept vendor documentation, but of course only when sound and documented.
The risk-based testing approach can significantly reduce assurance (validation) efforts and documentation needs.

3 CSA Customer Benefits

In summary: Computer Software Assurance can reduce your validation and assurance efforts, as it

- focusses your organization on the high-risk parts of your systems.
- leverages on vendor documentation.
- speeds up the process.
- reduces efforts for testing and documentation.
- Saves time and costs.

CSA ultimately assures improved patient safety, product quality and data integrity in your systems.

How our experts can support you

Arcondis can support you according to your needs – from individual guidance to full end-to-end solutions.

CSA Assessments

We offer guidance and support during and after the change from CSV to CSA. We shall jointly assess your validation framework and recommend how to adopt to Computer Software Assurance. Quick wins and long-term improvements will be identified.
As a service, Arcondis offers to validate and assure your systems according to the CSA regulations.
Arcondis can support you in assessing your vendor assurance and qualification processes and how to include these in your company's CSA program.

CSA Methodology & Execution

Arcondis will assist your organization in developing and executing pilot programs and implementing process improvements. Standard operating procedures (SOP) and work instructions (WI) will be updated.

CSA Education & Training

To increase awareness and knowledge about CSA principles and benefits in your organization, Arcondis offers "Management & Team Briefings" on the subject, manage workshops, and further train your teams on how to apply CSA to your business processes.

About

Arcondis is a global consulting company with an exclusive focus on the healthcare and life science industries, with their particularly demanding requirements on quality and regulatory affairs. We have been addressing challenges and solving problems for our clients in the areas of compliance, business processes, information technology, and digital transformation since 2001.
We create value through cross-functional, sophisticated delivery methodologies and intelligent implementation.
Our clients love to work with us because of our unique skillsets, our pragmatic approach, and our will to win.
Arcondis is headquartered in Switzerland and has offices near Frankfurt and Munich, Germany, in Boston, USA, and in Singapore.
An industry survey conducted by Statista ranked Arcondis as one of the Top 10 Healthcare consultancies in Switzerland for 2021.

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