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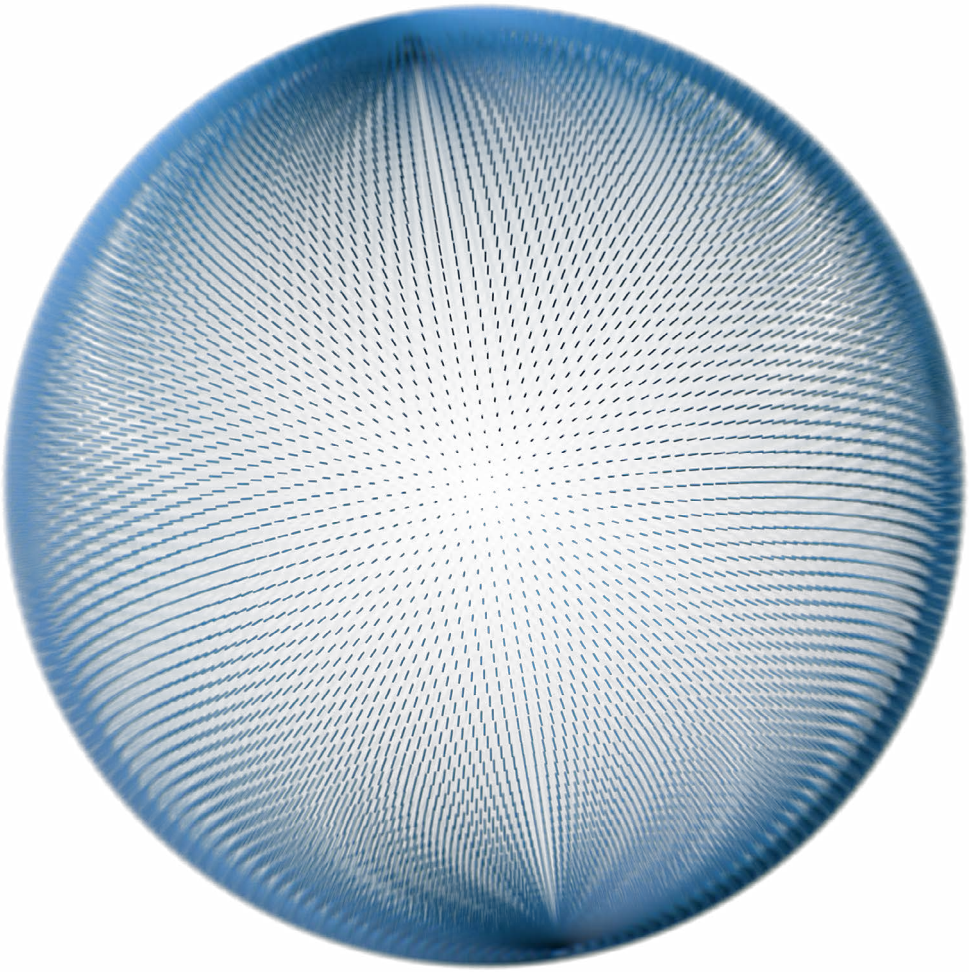

Using Computer Systems Assurance (CSA) for Medical Device Engineering Tools

Making rules and automated workflows more agile and more efficient through changes to the validation process

The use of Computerized Systems Validation (CSV) on engineering toolchains is freezing these tools (especially in terms of displaying data and automated workflows/rules). When we overcomplicate the changes to these tools, it contradicts with the concept of adaptive, automated engineering workflows. It actively prevents teams from making process improvements or automating tedious work. This could suggest to a certain extent that CSV is suppressing innovation in the processes and toolchains of today's engineers. The Computer Systems Assurance (CSA) initiative as promoted by the FDA appears to be an easy way out.

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Effects of Validation

The engineering process for medical devices and health software requires robust risk management and validation that the process automation tools used in the product development lifecycle (PDLC) are effective. This process is often referred to as Computerized Systems Validation (CSV).

Using CSV for modern engineering toolchains can easily result in costs in the six-figure range. There are typically also recurring costs to facilitate tool changes, updates and frequent re-validation. If the process is not done properly, there is also a risk of audit findings. Most companies outsource these activities to consulting firms and simply accept the associated cost as a given. In return, they receive reams of documents, often without meaningful improvement in the quality of the process automation itself.

More critical than the financial impact is the fact that the validation process often prevents engineering teams from improving workflows or adapting their toolchain to reflect their preferred methodology. Even simple changes to UIs, reports or forms are not permitted, because the system freezes after validation. The paperwork involved in change management as well as the burden/cost of re-validation are often the best arguments for not touching the tools and simply accepting obstacles or finding workarounds. While this has always been disruptive in a traditional, top-down engineering approach, it becomes even more critical when the team decides to adopt an agile way of working.

How Computer Systems Assurance can help

Fortunately for the medical device engineering sector – where the toolchains rarely impose any direct risk to patients – there has been a paradigm shift in the validation process. The FDA is replacing the 1997 General Principles of Software Validation with more up-to-date guidelines. Both versions outline an approach to quality assurance for software used in manufacturing, operations and quality systems activities that follow the 21 CFR Part 820 guidance.

Where Computerized Systems Validation (CSV) is built around GxP risk and focuses on a "one-size-fits-all" solution for quality information, Computer System Assurance (CSA) brings the focus back to patient safety and critical thinking. In a nutshell, CSA:

- focuses on extremely critical systems and functionalities, leaving "room to breathe" for tools that do not carry a risk of harm to a patient.
- introduces unscripted (UST) and limited scripted (LST) testing for systems without the potential to directly harm a patient
- advocates for a common-sense approach to identifying risk scenarios (excluding extremely unlikely scenarios)

Especially for complex engineering toolchains, this is a great opportunity to get back flexibility and to push innovative workflows and solutions. The CSA approach allows manufacturers to exclude compilers, workflow systems and other infrastructure from most validation steps (as there is no risk of harm to patients), while still reducing the effort required for systems not directly harming patients. This refocuses the validation process on more critical systems like code generators, code analyzers, etc. This "critical thinking" approach is a win-win situation for both agile engineering as well as quality assurance teams. It allows for:

- more freedom to change workflows and automate engineering tasks, as these can be excluded from detailed validation
- a greater focus on critical systems like code scanners or the SIL/HIL systems, still emphasizing that there is no direct risk to patients
- a reduction in the amount of documentation to a smart minimum with testing methods are not as documentation-heavy

It makes perfect sense to use CSA for all engineering tools and infrastructure. Even if the goal is not to save money (lower validation costs), CSA will give some flexibility back to the engineering team in terms of process automation (make them work more efficiently, while also saving money and turnaround time).

CSA is not a new regulation but rather a smarter interpretation of the existing Code of Federal Regulations (CFR). The quality and engineering teams need to carefully implement CSA in a joint approach, still producing the necessary amount of documentation while reducing the burden of process automation changes (particularly for complex CI/CD environments).

Deloitte offers training, workshops and process advisory services to better understand this important topic and help you speed up the implementation of Computer System Assurance (CSA) in your quality management system.

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