



MethodSense News
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MethodSense develops practical and sustainable solutions for your life science company that deliver strategic value.

Practical Validation Tips for SAS Used in Clinical Trials

We often hear that SAS validation projects are either unnecessary or too overwhelming. Unnecessary, some say, because "Off the shelf software does not require validation" or "My version of SAS validates itself." Overwhelming, say others, because SAS validation projects can be mistakenly understood to imply the impossible task of validating a computing language.

Answering the question "should SAS be validated?" is straight forwardly -- YES. The FDA reasonably expects that the data analyzed using SAS in a submission sufficiently and accurately represents the claims of the sponsor. SAS validation when performed correctly will support sponsor claims regarding the sufficiency and accuracy of the data analysis. Furthermore, CDER's publicly stated intention to enforce 21 CFR Part 11 requirements has the industry anticipating a computer system validation renaissance.

The real question: **What does a reasonable and responsible SAS Validation Project look like?**

Here are some tips:

- ***Make it easy on the auditor:*** You should assume that FDA personnel understand SAS and may even be competent users. Create documentation that will easily and quickly demonstrate to the auditor that you are competently managing your SAS system and its environment by following established verification and validation processes.
- ***Make it easy on yourself:*** Remember to focus on your use of SAS as a set of functions, not a language, with a further refined focus on the actual functions and programming that is relevant to your clinical trial. Leverage the relevant automated test scripts in SAS 9.2 as far as possible and take the extra step to ensure that your tests apply to your scenarios of use. Finally, statisticians and SAS programmers in the life sciences are naturally disposed toward best practices. Incorporate how they naturally tend to verify their work into your validation effort, thereby making validation a natural extension of the entire team's effort.
- ***Manage your gaps:*** Identify documentation gaps, the SAS off-the-shelf or programmed functionality relevant to your clinical trial that is not qualified, missing verification processes, etc., and address each gap according to the results of a risk based analysis.

At the end of the day, data and records produced and maintained by computerized systems like SAS for clinical trials must be complete and accurate, and data integrity must be demonstrably maintained.

Case Study: SAS 9.2 Validation for Clinical Trials

Background: A pharmaceutical company using SAS 9.2 to develop applications and analyze statistical information in a clinical trial received notification of an audit from a regulatory body. The audit was scheduled with the expectation that computerized systems would be included in the audit. The pharmaceutical company acknowledged a small 4 week window to assess and ensure compliance with 21 CFR Part 11 and facilitate for the auditor a good experience.

Solutions: MethodSense was engaged, evaluated the company's use of SAS version 9.2 and created a validation plan for the intended use of the system. MethodSense created user specifications, leveraged the existing IQ and OQ tools provided by SAS with additional validation tests specific to the client's use of the system, executed the validation plan and then integrated the process and test results into the company's quality system, which created an easily audited environment for the auditor.

Return: The company achieved for their clinical trial a compliant SAS system in 4 weeks with a repeatable process that integrated the company's standards and best practices.

About MethodSense

MethodSense is a Life Science service company adding value to pharmaceutical, medical device and contract service companies with the convergence of **Quality Expertise, Regulatory Experience** and **Technology Knowledge**. Where technology impacts your company, either as a critical business solution or part of your product portfolio, MethodSense can contribute to your success. MethodSense delivers FDA compliance strategies, quality system development, process and validation strategies and execution, vendor and internal audits, software development methodology optimization, and GxP, 21 CFR Part 11, ISO, HIPAA, CMM expertise. We invite a discussion and your communication today.