

Do you browse the enforcement areas on the FDA's web site? Warning letters and 483's are posted there thanks to the Freedom of Information Act.

This is where the rubber hits the road. The GPSV (General Principles of Software Validation) is a well written guidance document. But, is the FDA really enforcing all that stuff? The word "Software Validation" is only mentioned 2 times in the Quality System Regulation, and that's all you get from the regulation.

Let's take a look at some interesting 483's that the FDA has issued regarding software.

483: "The manual does not adequately describe how the CIC support staff prepares and maintains records of all IRB activities, including meeting minutes, records and reports associated with investigations, and archiving. The manual does not describe how data and information are gathered, stored, and analyzed to prevent research misconduct. Also, the manual does not describe how electronically stored data and information are safeguarded and maintained".

Have no illusions.... Data is software and must be controlled. And remember, document how you do things and follow it.

483: "there were no procedures for review of source codes in design controls for software validation, and there is no assurance that all lines and possibilities in the source codes are executed at least once"

Wow! All lines executed at least once? I could be wrong, but I don't think so. They did not have procedures for code review OR evidence of code coverage. I believe that the FDA expects a good mix of source code review and testing to ensure safety.

482: "Failure to have an adequate validation procedure for computerized spreadsheets used for in-process and finished product analytical calculations. The current validation procedure uses only the values that result in within specification findings, aberrant high findings, and aberrant low findings".

So, a traceability matrix won't do it folks. The test scripts themselves must significantly challenge ranges used in calculations, inside and out.

So, as you can see, the regulation might be saying these things somewhere but software folks have trouble finding it. The enforcement records make it clearer, don't they?

I'm sure you're out of time... and I am too. More in the next issue.