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SyberWorks and Veracord GAMP5 Webinar

Attendee Questions

1. In automated medical equipment, is a PLC recommended over, say, a PC with a Windows XP operating system?

To answer your question adequately, we would need more context. Typically, it is not required that PLC must be used if the functionality can be accomplished by other software. Whatever satisfies the user requirement specification (URS) and meets the functional aspects can be used, provided the intended software is kept under control per GAMP and CFR GxP Guidelines. We cannot answer your question in regards to Windows XP about replacing the PLC type software because more information is required on this question to better explain if needed.

2. Do you have any examples of scalability in the validation approach to system changes?

Small change example: A software patch is required for an MES application. Make an assessment within a change management or change order system, write an IOQ test script to meet the CR or CO test objectives, gain preapprovals to execute, and then execute the test script after deploying the code to validation environment. If it passes, then deploy to production and close out the CR or CO. Typically, companies use Trackwise or ARS Remedy for CR or CO management. Other programs are also available and can be used.

Large change example: A version upgrade is required that changes software from non-part 11 compliant to 21 CFR Part 11 compliant as supplied by the vendor. Treat this as a project and perform complete set of validation life cycle documentation and activities. Combine other changes at this time. This would require a revision to URS, FS. DS and development of VP, IQ/OQ protocol with test objectives and test scripts for each or combinations of test objectives.

3. How is commissioning applied by the industry to reduce validation costs?

GAMP V and ICH Q9 are being used in the industry to roll out a risk based validation approach by using a company's quality risk management processes and supporting tools. Commissioning is a terminology to differentiate from validation. Lower risk functionality or components can be "commission tested" and may not need QA approvals, since QA has already approved the risk assessment and risk control strategy supposedly up front. Higher risk ranking items will require full validation testing and QA will have to review and approve the validation package. Also, see other answers below to gain more understanding on cost reductions. Also, ensure a commonly agreed upon template is in place so that time can be reduced on template issues. Make it simple yet compliant by working with quality organization or unit.

4. Are you just concerned about quality requirements here? What about other regulations: SOX, etc?

In the context of webinar, we were addressing the compliance related to FDA CFR and other international agencies. SOX is a very important and required regulation on its own. In the case of an ERP such as SAP, GxP, GAMP and SOX would be applicable if the financial module is implemented.

5. Does GAMP5 cover quality systems software validation (for example, training software or document control systems) or just manufacturing systems?

It covers all software systems used including learning management systems (LMSs). Since training records are maintained of the staff performing manufacturing tasks, the LMS becomes part of the whole equation of GAMP V. You should use a risk based validation approach to decouple the non-GxP aspects of a training system. It is a bit tricky to validate such hybrid systems. You don't want to over-validate or under-validate.

6. The problem with using vendor documents is normally the way they document execution. If using vendor documents to leverage qualification, will they be required to follow GDP?