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Focus Compliance & Validation Services

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SyberWorks and Focus Software Validation Webinar

Attendee Questions

1. Do you have to validate the hardware that software runs on?

Response: The short answer is yes. However, the level of validation will vary depending upon the type of hardware. For a standalone PC, the validation will include an IQ to verify that the system meets the requirements and specifications that have been determined as necessary. In addition, the validation will verify that the basic functions are functioning as required (printing, mouse and keyboard input, barcode reader, scanning input as examples).

- For a networked system, network connectivity, security, and related functions will be validated depending upon your identified user requirements and intended use.

- For client / server applications, both client and server will require validation.

- For hosted systems, review the host's validation of the system as part of the procurement audit is important for the server. The client will still require you to validate. Bandwidth, stress testing, connectivity, continuity, failover and other requirements may be verified as part of the validation.

The test protocol should guide the verification of the key application functions to assure that your system is functioning as intended. If your hardware platform is a medical device, process control system, automated testing system or similarly functioning system, then your hardware validation will be much more involved.

Back to the basics: the user requirements must be identified and documented first. The intended use must be identified and documented. These need to be clear, concise, and verifiable or testable. This will lead to developing the test protocols to examine that the system implementation or product meets these requirements.

2. Do security systems (that given how users are given access to computer process controls) need to be validated too? Can you give an example?

Response: Short answer - Maybe. If the security system is automated (computerized) and this security system allows users to access process controls that are used to control the manufacture/production of the product or components of the product that are used for diagnosis, cure, mitigation, treatment, or prevention of disease and users' access can have a detrimental effect on the process, production, or product, then validation will be required. Define user requirements, specifications and intended use when putting the validation program together.

3. All your software needs to be validated, but when is it necessary for the software to be 510K cleared?

Response: *When the software is or is part of a medical device that requires premarket application (PMA).*

"Section 510(k) of the Food, Drug and Cosmetic Act requires device manufacturers who must register, to notify FDA of their intent to market a medical device at least 90 days in advance. This is known as Premarket Notification - also called PMN or 510(k). This allows FDA to determine whether the device is equivalent to a device already placed into one of the three classification categories. Thus, "new" devices (not in commercial distribution prior to May 28, 1976) that have not been classified can be properly identified. Specifically, medical device manufacturers are required to submit a premarket notification if they intend to introduce a device into commercial distribution for the first time or reintroduce a device that will be significantly changed or modified to the extent that its safety or effectiveness could be affected. Such change or modification could relate to the design, material, chemical composition, energy source, manufacturing process, or intended use."
http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/default.htm

GSA

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4. **How do you maintain the validation of a system built on the Windows OS that requires constant patching/changing?**

Response: As part of your change management, you should control the roll-out of these changes. You must identify when the patch, change, upgrade or service pack has the potential to impact the system and cause the requirements or intended use of the system to not achieve expected results. Full validation should not typically be required. Execution of a test protocol to check the system after these changes to verify that the system still performs as expected with appropriate documentation should suffice to demonstrate that the change did not materially affect the performance of the system with regard to the requirements, specifications and intended use.

5. **For a Learning Management System, is the installation finished once the system is turned on or after all courses have been entered and assigned?**

Response: In general, installation and configuration should be completed to consider the system installed. Entering courses and assignments, training records, course records, etc., would be considered the "data" that the system is utilizing and we would approach the validation from that perspective. However, it depends upon your system and your approach to validation.

6. **What are Tom and Marks interpretation of electronic Signature in part 11**

Response: Part 11 is a topic to which entire forums are devoted. It is not something that can easily be addressed in the space and time here. Having said that, here is some information for your consideration. The regulation provides the basis for defining an electronic signature.
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=11

Guidance from the FDA provides insight into what they deem to be the important and salient points.

"Part 11 applies to records in electronic form that are created, modified, maintained, archived, retrieved, or transmitted under any records requirements set forth in Agency regulations. Part 11 also applies to electronic records submitted to the Agency under the Federal Food, Drug, and Cosmetic Act (the Act) and the Public Health Service Act (the PHS Act), even if such records are not specifically identified in Agency regulations (§ 11.1)."

A.   "… For example, we intend to enforce provisions related to the following controls and requirements:

- limiting system access to authorized individuals

- use of operational system checks

- use of authority checks

- use of device checks

- determination that persons who develop, maintain, or use electronic systems have the education, training, and experience to perform their assigned tasks

- establishment of and adherence to written policies that hold individuals accountable for actions initiated under their electronic signatures

- appropriate controls over systems documentation

- controls for open systems corresponding to controls for closed systems bulleted above (§ 11.30)

- requirements related to electronic signatures (e.g., §§ 11.50, 11.70, 11.100, 11.200, and 11.300)

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We expect continued compliance with these provisions, and we will continue to enforce them."

http://www.fda.gov/RegulatoryInformation/Guidances/ucm125067.htm

7. Can a database overload be considered a "software wear"?

Response: If the question is, should you know the capacity of a database, to avoid failures in the system and be considered a specification or part of the intended use, the answer is yes. Stress testing of the Computer System is something that should be part of the computer system validation effort.

8. Should the least burdensome approach be used most of the time?

Response: The FDA Modernization Act of 1997 introduced the concept of Least Burdensome Approach. FDA has stated that we "should consider the least burdensome approach in all areas of medical device regulation." In the reviewing the guidance issued by the FDA, the intent of this provision is to reduce the information burden in the premarket application process. However, it does not relieve manufacturers from compliance with the requirements of the quality system regulation which includes verification and validation. You should generate the appropriate level of documentation and scientific evidence for your product. However, the FDA may not require this information be submitted with the PMA. Only you as the manufacturer can determine the appropriate level of validation and documentation necessary for assuring your product is safe and effective. As a manufacturer, you must strike the appropriate balance. This is why Focus CVS emphasizes risk analysis and management as an integral part of the validation process, so that you as a manufacturer can devote the resources to address the highest priority hazards. (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085994.htm)

"to ensure the timely availability of safe and effective new products that will benefit the public and to ensure that our Nation continues to lead the world in new product innovation and development."

"…FDA believes the least burdensome concept to be one that could affect almost all premarket regulatory activities, including presubmission meetings with industry, premarket submissions, and the development of guidance documents and regulations. The Agency believes that this interpretation most accurately reflects the spirit of the new law.

In order for the least burdensome approach to be successful, it is important that industry continue to meet all of its statutory and regulatory obligations, including preparation of appropriate, scientifically sound data to support applications. …"

"Reliance on postmarket controls (e.g., compliance with the Quality Systems (QS) regulation, postmarket surveillance, and the Medical Device Reporting requirements) should be considered as a mechanism to reduce the premarket burden for 510(k)s and PMAs, while still ensuring the safety and effectiveness of the device."

"The Quality Systems (QS) regulation requires device manufacturers to perform design verification and validation testing, as appropriate, on new devices as well as on modifications to existing devices. FDA should ask, however, only for test results that are necessary to make an equivalency determination. For example, in Special 510(k)s, manufacturers submit certain design control information to establish substantial equivalence. Routine submission and review of design verification and validation data generated in accordance with the QS regulation, however, would delay review of 510(k)s without contributing to the SE determination."

9. What do you use for validation determination (e.g., when would you determine a product requires validation)?

Response: This should be identified in your change control procedures. Often, this procedure includes a change control committee composed of various department representatives. This committee would make the final

determination when validation is required. In addition, a risk-based approach would assist further the significance of the change and help determine what level a validation would be necessary.

10. **When validating a COTS hosted by the vendor (used for consumer complaint management and reporting on OTC cosmetic products), is it necessary to 'validate' the browser used to access that system?**

Response: Basic functionality of the browser for your intended use needs to be verified as part of the validation process. This is a black box approach to show that you can do what you need to do with the browser.

11. **For software like ChemStation, if it is new to us and we have no idea what to validate and how, is it a normal practice that we just take what the vendor supplies as our own protocol and report? Will this be a problem with FDA?**

Response: Regardless of what validation the vendor has performed, you will need to identify your requirements and your intended use and perform your own validation to verify that the software performs as you expect it to. The vendor's validation will be useful as part of the vendor audit under your procurement policies.

12. **What is your feeling about using vendor deliverables as a supplement to a CSV?**

Response: Using vendor deliverables as a supplement to your CSV to document from the procurement phase that the system meets your requirements and intended use is a valid approach providing supplemental documentation. It does not replace your validation efforts—it merely augments them.

13. **What things do we have to watch out for when validating databases?**

Response: Validating a database is not very different than other types of software. The approach is the same as previously stated. The key is defining the requirements correctly and ensuring that you appropriately test the boundaries of the requirements. Stress testing can be a challenge.

14. **Should the FVR be issued before, after or at system deployment?**

Response: The Final Validation Report can be issued in phases. It should be completed and issued at the point that the project plan calls for it and at the point that makes logical sense for the project at the milestone where appropriate decisions can be made. If the FVR is to be issued after system deployment, a release to production confirming at the minimum successful Operation Qualification of the system would be necessary.

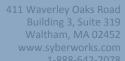15. **Is Part 11 more stringent than the federal e-signature rules?**

Response: It is difficult to say what is more stringent, because that is determined by use. However, I would say that Part 11 is more complex.

16. **Can they address software validation for apps such as SAS?**

Response: A tool similar to SAS for statistical analysis or other complex calculation can be very useful. In considering validation of an application like this, I ask the question of why do you validate. Yes, you may have a regulatory requirement that says that you have to. The other is, what assurance or evidence do you have ensure that the application performs as you expect it to? Or, the application may work correctly in certain conditions but not others—garbage in garbage out? The approach to validation of this type of application would be the same as other COTS systems.

17. **Where does functional testing fit into the process – (i.e. executing test scripts that validate the software can be used to carry out the functions intended)?**

Response: Test scripts may be executed during any and all phases of the project including design qualification, installation qualification, operational qualification and performance qualification, depending upon your lifecycle model, your project/product, and your validation documentation (requirements, specifications, master validation plan, project plan, etc.). You know your needs and requirements. Fit the testing into a logical pattern to develop assurance that the results are satisfactory to your requirements.

18. What does the FDA require from a validation stand point regarding Microsoft Excel and Microsoft Word

Response: Such computer systems must be validated to ensure accuracy, reliability, consistent intended performance, and ensure that it will perform as intended in their chosen application.

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085281.htm#_Toc517237968

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073778.htm#_Toc458569117

19. Working in a hospital we have numerous FDA regulated systems and experience resistance from vendors with regard to regular application of Windows patches and anti-virus definitions.

Response: See response to question 4. The hesitation by vendors is understandable. However, the hospital has the final responsibility and authority with regard to use of the numerous systems and should adopt policies and procedures to manage change control.

20. Is there an available list of core systems (e.g. applications such as Oracle) that the FDA acknowledges as having been validated...such that one would not be asked for such during an audit (this would include the application's ERES functionality)?

Response: We are not aware that the FDA maintains such a list as the burden for validation falls on the user consistent with their intended use.