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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