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Applying Risk Management to Computer Validation Webinar Q&A

Attendee Questions

Question: To what extend or how much does this validation apply to Network and other IT Infrastructure on which the GxP applications reside?

Answer: *You must evaluate the impact of and interface to infrastructure (servers, switches, hubs, network, etc.) on the intended use of the computer system. If it is determined that the infrastructure plays a role in the intended use of the computer/software system, you must integrate validation of the various network infrastructure components as you define necessary through your user requirements. Remember to address concerns regarding security, continuity of service, capacity and other operational stresses.*

Q: Anomalies of systems: What is a suggestion for periodic checks for the system, and is it a full system check or partial check?

A: *As we discussed, this is not a once and done exercise and should continue to provide monitoring, assessment and trending of issues with your computer system. Based upon your risk tolerance and the risk of your project, you are in the best position to understand whether a full check, partial or spot checks are needed. Document your basis for establishing your follow-up frequency and level of assessment in risk management plan. Then, be sure to follow up as planned to document your findings. In addition, define in your risk plan how you assess risk when changes are made.*

Q: Isn't PIC/S more a European regulation/guidance?

A: *Yes it is. However, as part of the Global Harmonization, is still is a good guidance for companies in the US.*

Q: I see several references to risk assessment tools. Is there a standard set of tools used for this work, i.e. Nessus, Nmap, EyeRetina, Assured Compliance for example?

A: *Some of the tools that you are referencing are for network vulnerability. The Risk Assessment tools that we referenced in the webinar are directed to identifying risks to patient, product, or user. There are many ways to access that type of risk. A good guidance for this is "Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices Document issued on: September 9, 1999."*

Q: On the comment there is no standard for Risk Management there, would you not start with Special Publications 800 series of the National Institute of Standards and Technology, like SP 800-37, SP 800-66, etc.?

A: *FDA does not recommend or endorse specific standards or tools for risk assessment. However, when you follow a guidance, standard, policy or procedure provided, issued or produced by a national or international organization, that lends credibility to your analysis. With regard to tools, use the tools appropriate to your project. There is no one-size-fits-all and you as the owner are in the best position to understand your needs.*

Q: Can your risk analysis be challenged by the FDA/other agencies, e.g. if you choose a qualitative analysis for a "high-risk" product?

A: *Yes, the agency can challenge your risk analysis, therefore you should strive to perform the appropriate level of analysis commensurate with your product/project, the information available, and the stage of the project.*