From: OC GCP Questions
To: [redacted]
Subject: Responsibility for Part 11 compliance
Date: Wednesday, December 09, 2015 10:22:13 AM

Good morning --

Part 11, Electronic Records; Electronic Signatures – Scope and Application
http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm125125.pdf

The guidance link about represents the Agency's preliminary thoughts on the processes needed to validate software..

Briefly, as conveyed in this guidance, the Agency anticipates the need for software vendors as well as the end-users of that software to adequately validate its use in the end user's computing environment. Software developers need to: 1) establish end user needs and intended uses for the software; 2) document the software validation plan, validation procedures and validation report; and 3) dynamically test the software via such approaches as structural testing, functional testing, and modular testing.

End users can evaluate the software's structural integrity by: 1) conducting research into the program's use history; 2) evaluating the supplier's software development activities to determine its conformance to contemporary standards; and 3) performing functional testing of the software that covers all functions of the program that the end user will use.

Another guidance that may be helpful (although it is intended for software that is either regulated as a medical device, or it is used to design, develop or manufacture medical devices) is that entitled " General Principles of Software Validation; Final Guidance for Industry and FDA Staff" dated January 11, 2002. You can find this guidance at the following web address:
http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085371.pdf

Other FDA guidances that are listed below may also be helpful to you.

Computerized Systems Used in Clinical Investigations -

www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070266.pdf

Electronic Source Data in Clinical Investigations -

www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM328691.pdf

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Monday, December 07, 2015 3:58 PM
To: OC GCP Questions

Subject: Responsibility for Part 11 compliance

To Whom It May Concern:

I have a GCP question concerning part 11 compliance. The question is centered around responsibility for part 11 compliance. I am a member of regulated industry trying to determine where the responsibility for part 11 lies.

If a company providing clinical trials services provides software on behalf of the sponsor to a clinical site, who has the responsibility for ensuring that the software is part 11 compliant?

This software is used in conjunction with an endoscope and the data is being transferred back to the clinical trial services organization.

The software is used to record images that will be provided to the sponsor in support of a regulatory submission.

Some sponsors would expect that the software provided by the clinical trial services organization should comply to the part 11 regulations. Meaning as it relates to security, audit trial etc.

If the software does not possess the attributes to ensure the principles of ALCOA, what measures must be put into place to ensure data integrity?

Thank you in advance for the clarity.

Best regards,

[redacted]