From: OC GCP Questions
To: [redacted]
Subject: RE: 21 Part 11 Audits
Date: Thursday, August 13, 2015 10:45:00 AM

Dear [redacted],

I checked with my colleagues, and have a response to your questions:

1. Are sponsors required to conduct a 21 Part 11 Assessment and/or on site audit when a laboratory is CLIA certified?

   Part 11 regulations are intended to protect the integrity of electronic records, and apply 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 and the Public Health Service Act, even if such records are not specifically identified in Agency regulations (see 21 CFR 11.1(b)). CLIA certification does not imply that Part 11 requirements have been met, and there are no FDA regulations that specifically address assessments and audits of CLIA-certified laboratories.

   Please note that validation of a system (see 21 CFR 11.10(a)) refers to the ability of a system to discern invalid or altered electronic records. It does not refer to the validity of a particular laboratory measurement. Additional Part 11 controls intended to ensure the integrity of electronic data include, but are not limited to, system access controls and audit trails. Sponsors may decide on their own vendor selection and qualification policies and procedures, and can use information from the vendor, such as system's requirements and design specification, testing protocols and scripts, validation process, and the results of vendor's validation to establish that a computer system is validated.
   CLIA is regulated by CMS. Information on CLIA can be found at https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index html?redirect=/clia/ More detailed information about research testing and CLIA can be found at https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/Research-Testing-and-CLIA.pdf and http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Categorization_of_Tests html. Contacts for questions about CLIA can be found at https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/State_Agency_and_Regional_Office_CLIA_Contacts.html

   I've listed below a few FDA guidance documents that you may find helpful:
   FDA's *Guidance for Industry – Computerized Systems Used in Clinical Investigations* found at:
   http://www fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070266.pdf

   FDA's *Guidance for Industry – Electronic Source Data in Clinical Investigations* found at
   http://www fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM328691.pdf

   FDA's *Guidance for Industry -- Part 11, Electronic Records; Electronic Signatures --Scope and Application* found at
   http://www fda.gov/downloads/RegulatoryInformation/Guidances/UCM126953.pdf
   The Compliance Program Guidance Manual, bioresearch monitoring for GLP (nonclinical laboratories) 7348.808, provides information on what is reviewed in a GLP inspection.
   http://www fda.gov/ICECI/EnforcementActions/BioresearchMonitoring/ucm133789.htm

2. What is the expectation for 21 Part 11 audits for vendors as almost every vendor today is using an electronic system? Should this only be considered when the data is in support of a study endpoint?
   As noted above in my response to Q1, there are no regulations that specifically address vendor audits. FDA supports a justified and documented risk assessment of a system and resulting implementation and configuration of Part 11 controls based on the risk assessment. For example, study endpoints and safety data whose accidental or intentional incorrect alteration in an electronic system would significantly alter the results of an investigation would necessitate a more stringent application of Part 11 controls. It is ultimately up to the sponsor to develop a justified, risk-based plan to meet Part 11 regulation requirements.

I hope this information is helpful to you. If you need further assistance, please feel free to contact the GCP mailbox at gcp.questions@fda.hhs.gov .

Best regards,

Sheila

Sheila Brown, RN, MS
Policy Analyst, Office of Good Clinical Practice
Office of Special Medical Programs, Food and Drug Administration

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From: [redacted]
Sent: Monday, July 20, 2015 4:05 PM
To: OC GCP Questions
Subject: 21 Part 11 Audits

Dear FDA,
Currently our Sponsor practice within our GCP Quality Assurance Department is to send a systems questionnaire (21 Part 11) to every vendor we outsource to for support of our trials and follow up with an onsite audit for further assessment when deemed necessary. Our questions are;

1. Are sponsors required to conduct a 21 Part 11 Assessment and/or on site audit when a laboratory is CLIA certified?

2. What is the expectation for 21 Part 11 audits for Vendors as almost every vendor today is using an electronic system? Should this only be considered when the data is in support of a study endpoint?

Thank you,
[redacted]