From: OC GCP Questions
To: [redacted]
Subject: RE: laboratory qualifications
Date: Friday, October 26, 2018 4:04:00 PM
Attachments: [redacted]

Dear [redacted]

My apologies, I am not sure what type of testing you are referencing in regards to "laboratories generating data that are not used for patient management (non-CLIA regulated)." Some additional information regarding the type of testing is needed for me to address your question.

For clinical testing, FDA expects is that each clinical study site use a clinical laboratory that is qualified to do the clinical testing specified in the protocol. In the US, this will usually be a CLIA certified laboratory. For some highly specialized tests, only a few laboratories may be qualified to perform the test, some based at academia or private laboratories that only do the test in question and therefore have no reason to hold a CLIA certification. Other documentation of their qualification to perform the specific test(s) would then be necessary.

FDA does not regulate clinical laboratories; the Centers for Medicare and Medicaid (CMS) are responsible for compliance with CLIA. For drug studies, clinical laboratories are listed on the FDA Form 1572 so the study sponsor is knowledgeable of the laboratories used should there be concerns, e.g., if a particular study site has laboratory results disparate from the other sites in the study. FDA investigators do not usually question the qualifications of a clinical laboratory when conducting a bioresearch monitoring (BIMO) inspection of a clinical study site. (See the Compliance Program Guidance Manual (CPGM) for the inspection of clinical investigators for what is ordinarily inspected - www.fda.gov/downloads/ICECI/EnforcementActions/BioresearchMonitoring/UCM133773.pdf) However, if the site is being inspected because there is a concern about clinical laboratory results or the results in the marketing application for the study indicated differences from other sites, then the FDA investigator will look for documentation of the laboratory's qualifications. If it is a US site, evidence the laboratory is CLIA-certified is the documentation expected. If the test is highly specialized and thus performed by a laboratory that lacks CLIA certification, appropriate documentation of the laboratory's qualification to perform the specific test(s) would be expected. The type of documentation that would be appropriate could vary depending on the nature of the test(s) and of the laboratory performing it.

Additionally, whether the laboratory is required to be certified or accredited will depend on local laws.

I hope that some of this information is helpful to you.

Sincerely,
Bridget

Bridget A. Foltz, M.S., MT(ASCP)
Health Scientist Policy Analyst

Office of the Commissioner (OC)
Office of Good Clinical Practice (OGCP)
U.S. Food and Drug Administration

This communication is consistent with 21 CFR 10.85 (k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: [redacted]
Sent: Thursday, October 25, 2018 2:51 PM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: laboratory qualifications

Hello:

I have a question regarding requirements for laboratories generating data for clinical trials that are NOT used for patient management (non-CLIA regulated). Are there any other qualification requirements if the results are not CLIA regulated, that are required by FDA? Would that also apply to data generated in a European lab processing samples from countries that don't include the US (again, not CLIA regulated) during global clinical trials?

Thanks for your anticipated help.

Best regards,

[redacted]