From: OC GCP Questions
To: [redacted]
Subject: ISO 17025 or CLIA
Date: Tuesday, May 29, 2018 11:38:00 AM
Attachments: [redacted]

Good morning –

FDA does not have any specific regulations or guidances applicable to clinical laboratories supporting clinical trials including ISO 17025 and CLIA.

There are a number of organizations, accreditation bodies, and other government agencies, however, that do have various standards for clinical laboratories. As you may know, the principal government standard, enforced now by the Centers for Medicare and Medicaid Services (CMS), is certification under the Clinical Laboratory Improvement Act (CLIA). CLIA applies to just about any clinical laboratory which carries out clinical testing (except for research) in interstate commerce.

Although CLIA certification is not required for a clinical lab to participate in an IND study, it does represent a standard that is acceptable to FDA for the purposes of clinical diagnostic testing. To learn more about CLIA, you can visit their website at www.cms.hhs.gov/clia/

Kind regards,

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Office of Good Clinical Practice
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U.S. FOOD & DRUG ADMINISTRATION

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information 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: Monday, May 28, 2018 10:41 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: ISO 17025 or CLIA

Dear FDA,

While acknowledging that FDA does not have any regulations or guidances applicable to clinical laboratories supporting clinical trials, I have encountered many differing opinions on FDA expectations. I would appreciate your opinion on the following matter:

A Sponsor of a Global clinical trial (IMP) contracts with a European laboratory that is ISO 17025 accredited for the specific (critical) assay/test. The laboratory is not CLIA accredited.

The Sponsor has approved the laboratory in accordance with their Supplier approval/audit processes.

It has been suggested that the laboratory must be CLIA accredited and that ISO 17025 in lieu of CLIA would not be an acceptable standard for a clinical laboratory supporting a clinical trial.

Is this the opinion of FDA?

Has data obtained supporting clinical trials from Sponsor qualified laboratories accredited to ISO 17025 (but not CLIA) ever been rejected due to lack of CLIA accreditation alone.

Kind Regards

[redacted]