From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Tuesday, April 25, 2006 11:30 AM
To: [purged]
Subject: RE: GCP lab question

Dear [purged]:

Your e-mail was forwarded to me for a response. I apologize for the delay in getting back to you.

FDA does not have any specific regulations applicable to clinical laboratories supporting clinical trials, so I cannot provide a regulatory citation. As you have already discovered, FDA's official guidance, the ICH E6 "Good Clinical Practice: Consolidated Guidance," recommends that investigators and sponsors maintain records related to "certification or accreditation or established quality control and/or external quality assessment or other validation (where required)" to "document competence of facility to perform required test(s) and support reliability of results."

Because the ICH E6 is guidance, it is not enforceable; however, it does represent FDA's current thinking on this topic. [Guidance does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations.]

You should know that CLIA is enforced by the Centers for Medicare and Medicaid Services (CMS) and applies to just about any clinical laboratory which carries out clinical testing (except for research) in interstate commerce. While 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 http://www.cms.hhs.gov/clia/ .

I hope this is helpful.

Sincerely,
Carolyn Hommel
Consumer Safety Officer
Good Clinical Practice Program
Office of Science and Health Coordination
Office of the Commissioner
U.S. Food and Drug Administration (HF-34)

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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: [purged]
Sent: Thursday, March 30, 2006 1:11 PM
To: OC GCP Questions
Subject: GCP lab question

A client wants to conduct clinical trial laboratory blood work in a lab that is not CLIA certified. The lab has a QA department, SOPs and has conducted GLP studies in the past. According to ICH E6 8.2.12, labs require certification, accreditation or established QC and /or external quality assessment. I want to advise this client not to use this lab but I need to provide a regulation to support this. Could you please give me some guidance?
Thanks,
[purged]