From: OC GCP Questions
To: [redacted]
Subject: RE: GCP certificationd
Date: Tuesday, February 18, 2014 2:54:00 PM

Dear [Redacted]-

Thank you for your question. FDA does not issue GCP certificates. FDA, through its bioresearch monitoring (BIMO) program can conduct on-site inspections of both clinical and nonclinical studies performed to support research and marketing applications/submissions to the agency.

FDA uses Compliance Program Guidance Manuals (CPGMs) to direct its field personnel on the conduct of inspectional and investigational activities. The CPGMs form the basis of FDA's BIMO program. The purpose of each program is to ensure the protection of research subjects and the integrity of data submitted to the agency in support of a marketing application. You can take a look at any of the CPGMs to get an idea of how an inspection is conducted find information such as a description of activities before, during and after an inspection – see http://www.fda.gov/ICECI/ComplianceManuals/ComplianceProgramManual/ucm255614.htm.

I hope this information is useful. If you need further information and/or have additional questions, please feel free to contact us at the official GCP mailbox, gcp.questions@fda.hhs.gov. You may also find it useful to access the set of redacted GCP e-mails found at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGoodClinicalPractice/default.htm since we find that many questions and concerns are repeated over time.

Best Regards,

Janet

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Policy Analyst, Office of Good Clinical Practice
Office of Special Medical Programs, Food and Drug Administration

-----Original Message-----
From: [Redacted]
Sent: Thursday, February 13, 2014 11:29 PM
To: OC GCP Questions
Subject: GCP certificationd

Dear Sirs and Madams

I understand that the FDA usually relies on the commitments asured by investigators when signing a 1572 form as to whether clinical studies under an IND have been conducted under gcp,

Adittional assurance of this may be provided by sponsors in the form of audit certificates for those investigative sites actually audited.

Finally, the FDA may directly proceed to perform an inspection on sites involved in particular development programs to confirm whether a. Study has been conducted at a particular site under GCP and to what extent the information generated at such sites can be properly included in the body of evidence to be assessed to decide on the final approval of a new therapeutic resource.

What I am noy aware, though, is whether the FDA routinely issues "GCP Certificates" to indicate that a study has been conducted in adherence to GCP guidelines.

Can you please confirm whether this last notion is true and if so, whethher these certificates are available for specific studies?

I thank you in advance for your guidance in this rgard

With best regards

[Redacted]