From: OC GCP Questions
Sent: Tuesday, January 07, 2014 10:55 AM
To: ████████
Subject: RE: GCP Certification

Dear [Redacted]-

Thank you for your question. Neither FDA nor any other federal agency provides a process for becoming GCP certified. In addition, we cannot endorse those provided by non-government sources.

There are a number of professional societies that offer certification programs and/or equivalent training. You might find it useful to check out information in this regard for the following organizations:

- Association of Clinical Research Professionals (ACRP) - www.acrpnet.org/
- Society of Clinical Research Associates (SoCRA) - www.socra.org/
- Regulatory Affairs Professionals Society (RAPS) - www.raps.org/
- Drug Information Association (DIA) - www.diahome.org/

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

Janet Donnelly, RAC, CIP
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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: ɄYXUWWYXQ
Sent: Thursday, January 02, 2014 4:55 PM
To: OC GCP Questions
Subject: GCP Certification

Good Afternoon,

I was recently applying at a job which required a GCP certification. I am aware of the GCP guidelines however, it was the first I heard of certificate. Is there a certification process ?

If so , can you please forward me to such a resource ?

Regards,

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