From: OC GCP Questions

To: Subject: Date:

How can I take the course for GCP ASAP? Thursday, September 11, 2014 2:52:42 PM

Importance: High

Good afternoon --

FDA does not offer certification in GCP training. However, while we cannot endorse/recommend non-government training entities, you may also find the courses provided by a number of the professional societies to be useful. These include: the Association of Clinical Research Professionals (ACRP) (http://www.acrpnet.org/), the Society of Clinical Research Associates (SoCRA) (http://www.socra.org/), the Regulatory Affairs Professionals Society (RAPS) (http://www.socra.org/), the Drug Information Association (DIA) (http://www.socra.org/), and the Society of Quality Assurance (SQA) (http://www.sqa.org/). Several of these associations also have certification programs for clinical trial staff.

Please contact us again should you have additional questions at gcp.questions@fda.hhs.gov.

Sincerely yours,

Doreen M. Kezer, MSN Senior Health Policy Analyst Office of Good Clinical Practice Office of the Commissioner, FDA

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: Thursday, September 11, 2014 1:25 PM

To: OC GCP Questions

Cc: [redacted]

Subject: How can I take the course for GCP ASAP?

Importance: High

Good afternoon:

Could you please send a link to the GCP course that I can be certified ASAP, and for free??! I am currently a [redacted] course and this is required by the sponsor.

Thank you,

[Redacted]