From: OC GCP Questions
To: [redacted]
Subject: On Site GCP Training
Date: Tuesday, September 16, 2014 2:13:41 PM

Good afternoon --

Both the Center for Drug Evaluation (CDER) and the Center for Devices and Radiological Health (CDRH) provide online training relevant to clinical trials on their respective websites. These training programs are accessible at CDER Learn http://www.fda.gov/Training/ForHealthProfessionals/default.htm and CDRH (Center for Devices) Learn http:///www.fda.gov/Training/CDRHLearn/default.htm respectively.

The expectation is that investigators, sub-investigators, and study staff will be knowledgeable about good clinical practice, including human subject protection, data integrity, recordkeeping, etc. Note that sponsors have discretion in determining what qualifications will be needed to conduct a study and may identify in the protocol a required frequency of GCP training, in which case the investigator and sub-investigators would be expected to meet that frequency of training in order to comply with the sponsors requirements. Every effort should be made to train the investigational sites.

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.raps.org/personifyebusiness/), the Drug Information Association (DIA) (http://www.diahome.org/DIAHome/Home.aspx), and the Society of Quality Assurance (SQA) (http://www.sqa.org/). Several of these associations also have certification programs for clinical trial staff.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.go v should you have additional questions.

Kind regards,

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

From: [redacted]
Sent: Tuesday, September 16, 2014 1:00 PM
To: OC GCP Questions
Subject: On Site GCP Training

I am a new regulatory coordinator for a private clinic participating in clinical trials. We are a relatively new practice to clinical trials and I am trying to find GCP training that I can print and hand out to our staff during monthly staff meetings – do you have any suggestions for where I can find

such training? While sponsors will send their own version of GCP training, it is not accepted by all sponsors since it has another sponsor's name attached to it.

Thanks for your help.

Sincerely,

[redacted]