From: OC GCP Questions
To: [redacted]
Subject: Question on GCP training for a site
Date: Thursday, March 27, 2014 10:52:35 AM

Good morning:

Neither FDA's regulations nor guidance provide guidelines on how often GCP training should be completed and by whom and who can perform the training. This would be up to the sponsor. The regulations require that sponsors choose investigators qualified by training and experience (see 21 CFR 312.53(a)). The regulations also require that investigators commit themselves to personally conduct or supervise the investigation (see 21 CFR 312.53(c)(1)(vi)(c)). FDA's guidance on Investigator Responsibilities - Protecting the Rights, Safety, and Welfare of Study Subjects (available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf) states that, "The investigator should ensure that any individual to whom a task is delegated is qualified by education, training, and experience (and state licensure where relevant) to perform the delegated task."

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.

Additionally, FDA does have information about available GCP training on the GCP website, specifically at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/EducationalMaterials/ucm112925.htm

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.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov 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: Thursday, March 27, 2014 2:00 AM
To: OC GCP Questions
Subject: Question on GCP training for a site

Dear Sir, Madam,

My name is [redacted] and I'm working as study coordinator in an hospital investigator site.

We are going to start new trials, mainly with medical device.

I've been GCP trained in the past, my last training was done in March 2012. Before working at the hospital, I was working as CRA in the pharmaceutical industry. Therefore I have trained as well all my investigator sites on GCP.

I wanted to know if I could deliver now to the medical staff with who I'm working any GCP training, even if I'm the study coordinator?

In fact, who can provide GCP training to a medical staff performing trials, except the CRA? If I want to train my medical team, do I need to be certified somewhere?

I just would like to mention that I have a CRA university diploma, where I had also GCP training.

Finally, can you please kindly confirm that we need to get a GCP training/ refreshment every 2 years?

Thank you so much.

Kind regards,

[Redacted]