From: OC GCP Questions
To: [redacted]
Subject: Course outline_GCP & HSP
Date: Thursday, January 30, 2014 11:18:05 AM
Importance: High

Good morning –

FDA regulations regarding the conduct of clinical trials (Title 21, Code of Federal Regulations - 21 CFR - Parts 312 and 812, for pharmaceuticals and devices respectively) are not that specific. They require that sponsors choose investigators who are qualified by training and experience (21 CFR 312.53(a) and 812.43(a)). The level of experience with both the type of product to be studied and the conduct of clinical trials can vary among studies. The sponsor is also responsible for ensuring that all parties have all the information they require to conduct a specific clinical trial (312.55 and 812.45). Therefore, many study sponsors conduct their own training.

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 Learn http:///www.fda.gov/Training/CDRHLearn/default.htm respectively.

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.

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

Kind regards

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

From: [Redacted]
Sent: Tuesday, January 28, 2014 10:31 PM
To: OC GCP Questions
Subject: Course outline_GCP & HSP
Importance: High

To whom it may concern,
Regarding to my course organization about “GCP & HSP course training” for participants who work in clinical trial area; I would like to ask about the course outline of GCP & HSP training.

I would like to update my course and setting all topics training in a professional way, participants of the course will get a benefit, knowledge and well preparing for an audit.
Would you please help to give suggestion?

Best Regards,

[Redacted]