

From: Brown, Sheila (OGCP)
To: [REDACTED]
Subject: RE: GCP Auditing Course
Date: Friday, July 24, 2015 9:54:00 AM

Dear [REDACTED],

I am unable to find the course you mention, entitled "GCP Auditing - A Practical Approach" on FDA's website. FDA does, however, have information about available GCP *training* at this web link:
<http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/EducationalMaterials/ucm112925.htm>

Also, 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.

FDA's Bioresearch Monitoring (BIMO) Program has Compliance Program Guidance Manuals (CPGMs) that are used to direct field personnel on the conduct of inspectional and investigational activities. These are available on FDA's website at
<http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm160670.htm>

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.acrpn.org/>), the Society of Clinical Research Associates (SoCRA) (<http://www.socra.org/>), the Regulatory Affairs Professionals Society (RAPS) (<http://www.raps.org/education-training/>), and 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 to you. If you need further assistance, please feel free to contact the GCP mailbox at gcp.questions@fda.hhs.gov.

Best regards,

Sheila

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This communication does not constitute a written advisory opinion under Title 21 CFR 10.85, but rather is an informal communication under Title 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: Wednesday, July 22, 2015 9:06 AM
To: OC GCP Questions
Subject: GCP Auditing Course
Importance: High

Dear Madam / Sir

Hope you are well.

I am inquiring on FDA offering an introductory course on 'GCP Auditing - A Practical Approach!'

May I request additional information on this course subject and cost.

In appreciation.

[REDACTED]