

From: OC GCP Questions
To: [REDACTED]
Subject: RE: FDA GCP training online
Date: Friday, September 04, 2015 1:06:00 PM

Dear [REDACTED] -

Thank you for your question. The online training referenced on the FDA web page you mentioned is part of the Clinical Investigator Training Course that is made publically available at the following web location:

<http://www.fda.gov/Training/ClinicalInvestigatorTrainingCourse/ucm201459.htm>. The slides for the 2013 and 2014 training sessions can be found by following the appropriate links. Slides for a GCP presentation in 2014 can be found in Session 2.

While FDA does not provide extensive on-line GCP training, there are several center-specific on-line training programs available. These center-specific training programs are accessible at CDER Learn www.fda.gov/Training/ForHealthProfessionals/default.htm, CBER's Office of Cellular, Tissue and Gene Therapies (OCTGT) Learn www.fda.gov/biologicsbloodvaccines/newsevents/ucm232821.htm, and CDRH Learn www.fda.gov/training/cdrhlearn/default.htm respectively.

However, I'm thinking you are likely looking for GCP-specific online training. You may find suitable on-line training available through some of the professional societies. While FDA cannot recommend or endorse non-government entities, it would be useful for you to look into what types of training such societies offer. 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/>), the Drug Information Association (DIA) (<http://www.diaglobal.org/en.aspx>), and the Society of Quality Assurance (SQA) (<http://www.sqa.org/>). We are also aware that some institutions participate in the Collaborative Institutional Training Initiative (CITI) (www.citiprogram.org/index.cfm?pageID=86), which offers online GCP training. You may want to inquire with your IRB or HRPP office to find out if your institution is part of the CITI online training.

Some U.S. government agencies also offer online training. For example, the Department of Health and Human Services' Office for Human Research Protections (OHRP) also offers online training and additional educational materials (<http://www.hhs.gov/ohrp/education/index.html>).

We are also aware that it is not uncommon for various sponsors to have their own GCP training modules that they require their study sites to complete. Your site and institution may also have your own expectations and requirements for GCP training. I suggest you discuss this issue with the appropriate staff at your site and institution, and potentially any sponsor that you are working with to find out if there are any specific requirements you need to be aware of for any given study.

Simply for your information, I want to mention that the Clinical Trials Transformation Initiative (CTTI) is looking into the issue of defining key elements of GCP training, including recommendations on the frequency of such training at sites that conduct clinical trials. CTTI is a public-private partnership developed to help identify practices that may increase the quality and efficiency of clinical trials. CTTI was established by the US Food and Drug Administration and Duke University. Information about CTTI can be found on CTTI's web site at <http://www.ctti-clinicaltrials.org/>. Specific information about CTTI's project to look at defining key elements of GCP training can be found at <http://www.ctti-clinicaltrials.org/what-we-do/study-start/gcp-training>.

I hope this information is useful. If you need further information and/or have additional questions, please feel free to contact us at the official GCP mailbox, gcp.questions@fda.hhs.gov. You may also find it useful to access the set of redacted GCP e-mails found at <http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriesToFDAonGoodClinicalPractice/default.htm> since we find that many questions and concerns are repeated over time.

Best Regards,

Janet

Janet Donnelly, RAC, CIP
Policy Analyst, Office of Good Clinical Practice
Office of Special Medical Programs, Food and Drug Administration

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: Friday, September 04, 2015 8:01 AM
To: OC GCP Questions
Subject: FDA GCP training online

Good morning,

Could you please provide the link to the online GCP training referenced in the page [Does FDA Conduct GCP Training?](#) As per this site the training has been made available online:

Yes, the Food and Drug Administration (FDA) conducts GCP training. As described below, the agency conducts some GCP training on site, but also partners with other federal agencies and organizations across the United States to conduct additional training. **FDA also has recently made GCP training available online.**

Alternatively, is the online training considered to be a component of the Investigator Training courses which are already posted?

Thank you,

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