

**From:** [OC GCP Questions](#)  
**To:** [REDACTED]  
**Subject:** Setting up / Getting Certified to perform Clinical Trials (Oral Care)  
**Date:** Wednesday, February 25, 2015 2:30:45 PM

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Good afternoon –

It is probably best to look into some basic GCP training for conducting clinical trials. Please see the following information.

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. FDA does not require or provide certification. 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.

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.gov](mailto:gcp.questions@fda.hhs.gov) should you have additional questions.

Kind regards,

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Office of the Commissioner, FDA

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.

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**From:** [REDACTED]  
**Sent:** Tuesday, February 24, 2015 12:16 PM  
**To:** OC GCP Questions  
**Subject:** Setting up / Getting Certified to perform Clinical Trials (Oral Care)

Dear FDA,

My company, [REDACTED] is a teeth whitening products company with distribution both domestically and internationally across a broad platform of sales channels.

We currently outsource numerous clinical trials on the efficacy of our whitening gel. This is a substantial cost that is part of doing business.

I would like to pursue a conversation with you on the process of setting up a business to become certified perform our own trials as well as to do provide this paid service for other companies.

Please let me know if I am on the right track in speaking with you. If not, please recommend with whom I would need to speak with.

Best [REDACTED]