

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: Medical monitor/Medical expertise - Qualification requirement
Date: Monday, June 23, 2014 3:08:22 PM

Good afternoon --

This is what we have said in the past regarding GCP training, which would include monitors. Additionally state and local laws regarding medical tasks would be to be considered.

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.

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

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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: Monday, June 23, 2014 11:30 AM
To: OC GCP Questions
Subject: Medical monitor/Medical expertise - Qualification requirement

Hi,
Good morning!

My question is related to qualification requirement of medical monitor/medical expertise in GCP compliant clinical trials conducted in US. I am using the job definition in two functional contexts, one is to design trials and second supervise the conduct of clinical trials from medical perspective.

1. What are educational qualification requirement for these positions if any?
2. Foreign medical graduate who are not registered for medical practice in USA, can they work as medical monitors for trials conducted in US. (Note: Medical monitors are not involved in decision making for patient care but they advise to health care physician for matters related to investigational drug use in clinical trials.

Thanks.
[redacted]