From: OC GCP Questions
To: [redacted]
Subject: Required training for research pharmacist
Date: Tuesday, October 14, 2014 11:44:49 AM

Good morning --

The sponsor decides what training is needed to dispense investigational product. ICH E-6 Guidance http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf states under Section 5.14 (Sponsor – Supplying and Handling Investigational Products) further says that in supplying the investigational product to investigators, the sponsor should ensure that written procedures include instructions that the investigator/institution should follow for the handling and storage of investigational product(s) for the trial and documentation thereof. The procedures should address adequate and safe receipt, handling, storage, dispensing, retrieval of unused product from subjects, and return of unused investigational product(s) to the sponsor (or alternative disposition if authorized by the sponsor and in compliance with the applicable regulatory requirement(s).

The sponsor is responsible for establishing the appropriate storage conditions for the investigational product, and the investigator is responsible for ensuring that the investigational product is stored as specified by the sponsor. There is also an implication that there should be written procedures to guide proper handling and storage of investigational products.

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."

It also states --It is common practice for investigators to delegate certain study-related tasks to employees, colleagues, or other third parties (individuals or entities not under the direct supervision of the investigator). When tasks are delegated by an investigator, the investigator is responsible for providing adequate supervision of those to whom tasks are delegated. The investigator is accountable for regulatory violations resulting from failure to adequately supervise the conduct of the clinical study. 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 delegation of certain study-related tasks to employees would include pharmacists.

The expectation is that investigators and sub-investigators and well as study 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, sub-investigators and study staff 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.

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

Kind regards,

Doreen M. Kezer, MSN
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Office of Good Clinical Practice
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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, October 10, 2014 2:15 PM
To: OC GCP Questions
Subject: Required training for research pharmacist

Hello,
I am writing to inquire as to what training requirements are expected of a hospital pharmacist that prepares and dispenses an investigational drug.
If there is a specific guidance related to this, please advise.

Thank you,
[redacted]