

**From:** OC GCP Questions  
**To:** [REDACTED]  
**Subject:** Seeking information to partner with the FDA  
**Date:** Thursday, February 23, 2017 6:42:00 AM  
**Attachments:** [REDACTED]

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Good morning –

Please see the FDA's inspection metrics. (Link below). It will give you common deficiencies during FDA inspections. 2016 metrics are not currently available.

[Clinical Trials and Human Subject Protection > BIMO Inspection Metrics](#)

GCP training is universally recognized necessity to protect human subjects in clinical trials. As our website states –

Adherence to the principles of good clinical practices (GCPs), including adequate human subject protection (HSP) is universally recognized as a critical requirement to the conduct of research involving human subjects. Many countries have adopted GCP principles as laws and/or regulations. The Food and Drug Administration's (FDA's) regulations for the conduct of clinical trials, which have been in effect since the 1970s, address both GCP and HSP.

Please see the link to our website below. It has many useful links to guidance and information sheets.

[Clinical Trials and Human Subject Protection](#)

Please also see the E-6 Guidance for Good Clinical Practice -

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf>

Additionally below is what we have said in the past regarding GCP training –

FDA regulations regarding qualifications for those involved with the conduct of clinical studies are very broad. Both Title 21, Code of Federal Regulations (21 CFR) Part 312 (for drugs and biologics) and 812 (for medical devices) simply state that sponsors are required to choose clinical investigators and monitors that are qualified by training and experience. Logically, clinical investigators and monitors need to be knowledgeable about applicable regulations as well as specific areas essential to the conduct of the particular study.

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. As noted, the 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. This is the sponsor's responsibility.

Additionally what training is needed and how it is documented depends to some degree on the nature of the study. Some protocols need extensive training and others may need minimal, also dependent upon the background and experience of study 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,

Doreen M. Kezer, MSN  
Senior Health Policy Analyst



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:** Wednesday, February 22, 2017 1:53 PM  
**To:** OC GCP Questions  
**Subject:** Seeking information to partner with the FDA

Hello!

I am in the process of setting up a consultant business helping companies build better GCP, GMP, GLP within their processes. I want to provide reliable training, and quality assurance services that efficiently provide the assistance needed to help my clients succeed and warning letters.

1. What are current hot-spots or issues that companies are failing repetitively now?
2. Do these issues fall under one category more than another? (i.e. drugs more than vaccines or food?) Please direct me to your website that has this information.
3. Other than being certified in GMP, GCP, and GLP through your site, what other certifications do you recommend that I complete to become a better partner for those companies in need of help.

Yours Sincerely,

[REDACTED]