From: Toth-Allen, Jean
Sent: Wednesday, February 01, 2006 12:02 PM
To: [purged]
Subject: RE: Pls provide us with the details

Dear Mr. [purged]:

Thank you for your inquiry regarding available GCP guidance.

Presently, the only guidance on GCPs with which FDA concurs is the ICH GCP consolidated guidance available at http://www.fda.gov/cder/guidance/959fnl.pdf. However, you will find that this guidance does not address the specific issues you list below but instead is a general guidance regarding the conduct of clinical studies. While it states it is specific to pharmaceutical studies, FDA believes the general sections of this document are applicable to all clinical studies.

The type of information you are looking for is specific to the nature and size of studies that will be conducted as well as the diagnostic procedures that they will require. From your signature block, it appears you are with a manufacturing company. If that is correct and your company is looking for appropriate clinical sites and/or planning to set up one or more sites, it may be useful to consult with similar firms in your country to see how they dealt with this issue. Local as well as country-wide requirements for medical facilities will need to be considered along with the specific needs of potential clinical studies.

Hope this information is useful to you.

If you need further information and/or have additional questions, please submit them once again to the official GCP mailbox, gcpquestions@oc.fda.gov, in lieu of responding to my personal e-mail address.

Sincerely yours,
Jean Toth-Allen, Ph.D.
Good Clinical Practices Program
OSHC, Office of the Commissioner, US 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.

From: [purged]
Sent: Monday, January 30, 2006 1:52 AM
To: gcpquestions@oc.fda.gov
Subject: Pls provide us with the details

Dear Sir / Madam,

Pls update us where we can find the following information:

1. What are the different rooms / areas to be present in a Clinical Trial Facility as per FDA GCP norms?
2. What all are the equipments required in the facility as per FDA GCP?
3. What does a bed in GCP represent? i.e., the supporting infrastructure for each bed as per GCP norms
4. Books published by FDA for building up FDA GCP compliant Clinical Trial Facility

The information you provide would be highly useful and helpful to us.

Anticipating a favourable reply

Thanking you,

With Warm Regards
[purged]