MessageFrom: Beers Block, Patricia on behalf of OC GCP Questions
Sent: Tuesday, February 28, 2006 8:38 AM
To: [purged]
Subject: RE: seeking clarification

Dear [purged],

Since there is no regulatory requirement that such a position exist at a clinical site, you can pretty much structure the position so that you accomplish your goals/objectives. I'm assuming you are not working for the sponsor as its "monitor" but that you are working for the clinical site as an internal auditor to make certain things are done in accordance with the good clinical practice regulations. Is my assumption correct?

Patricia M. Beers Block
Good Clinical Practice Program (HF-34)
Office of the Commissioner/ FDA
Telephone: 301-827-3340
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.

-----Original Message-----
From: [purged]
Sent: Monday, February 27, 2006 12:09 PM
To: OC GCP Questions
Subject: RE: seeking clarification

Thanks for your kind reply Patricia,
My confusion is our site had a CEO to whom I was reporting as a QA manager, now we do not have CEO from our company but our major share holder company's CEO is also CEO to us.
All site activities are totally independent and has no link to major shareholder company.
In this situation, can I report to Cheif medical officer, which I feel very convinient, as he is the person who is more actively involved in the site business and also PI to our studies
Does FDA see this as conflict of interest??, when there is no regulation and QA is treated as nice to have thing then there should not be any conflict of interest in question?

Can you please clarify .
best regards
[purged]

From: Beers Block, Patricia [mailto:patricia.beersblock@fda.hhs.gov] On Behalf Of OC GCP Questions
Sent: Friday, February 24, 2006 3:34 AM
To: 'Lakshmi Vinnakota'
Subject: RE: seeking clarification

Dear [purged],

Until the regulations for nonclinical research (see "Good Laboratory Practice for Nonclinical Laboratory Studies" regulations found at 21 CFR 58), the regulations governing the conduct of human clinical trials (i.e., 21 CFR 312 for investigational drugs and 21 CFR 812 for investigational devices) do not require the establishment of a quality control or quality assurance unit. Certainly appointing a quality assurance manager can be very beneficial in helping to assure compliance with good clinical practice regulations, but this position is not required by regulation.

I hope this information is helpful to you.

Sincerely,

Patricia M. Beers Block
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-----Original Message-----
From: [purged]

Sent: Monday, February 20, 2006 12:47 PM
To: OC GCP Questions
Subject: seeking clarification

Hello!
Can you please clarify the following queries.

We are an investigator site of 16 beds capacity, conducting only phase-I and Phase II studies.
We handle several projects from different sponsors in parallel.
That means our site handles multiple projects.
We have recruitment data base and coordinator, Business Development group and other supporting services.
We do not do any other service except for drug evaluation, protocol is provided by the sponsor and we implement the protocol.
We have a PI and other supporting medical doctors as co investigators.

In this scenario, how do FDA define our site as a CRO or as an Investigator Site.
Our company appointed a QA - Manager, to whom this QA- Manager should report?
If we are an investigator site which part of 21 CFR describes the required role of a QA department and reporting structure of QA in an investigator site.

In my interpretation there is no requirement for a QA-department in Investigator site by any Federal Regulation (21 CFR code), since our site handles multiple studies and high volume of short span studies, our investigator took a proactive approach to ensure the studies to be compliant by appointing a QA-manager to over see the conduct of studies by QC/QA procedures.
In such a scenario, QA-manager can report to PI who is also Chief medical Officer of the company.
Am I correct in this interpretation?, if not please correct me.
regards
[purged]