From: Toth-Allen, Jean
Sent: Monday, March 20, 2006 9:01 AM
To: [purged]
Subject: RE: QA Program

Dear [purged]:

Thank you for your inquiry regarding quality assurance.

FDA does not have guidance with regard to the design of a quality program for the conduct of clinical trials. The ICH GCP guidance, available at http://www.fda.gov/cder/guidance/959fnl.pdf, does give FDA's present thinking regarding the conduct of clinical trials and can be used as a guide for establishing such a program, though it does not specifically talk about multiple study coordination. While it states it is specific to pharmaceutical studies, FDA believes the general sections of this guidance are applicable to all clinical studies.

While FDA does not endorse non-government sources, you might find useful information available regarding the development of a quality assurance program from the Society of Quality Assurance whose website (www.sqa.org) provides general information as well as information regarding related resources and training opportunities.

Hope this information is useful.

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: Wednesday, March 15, 2006 1:52 PM
To: OC GCP Questions
Subject: QA Program

Good Afternoon:

I have been charged with designing a quality assurance program for my department. I have done this on a much smaller scale for a few projects. As this is a large project with over 20 clinical trials, I am somewhat uncertain as to how to approach this task. I have reviewed the FDA website. Would you be able to refer me to a website or books for guidelines, sample outlines, and/or a list of steps in achieving this task?

Thanks in advance,

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