From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Monday, September 15, 2003 10:58 AM
To: '[redacted]
Subject: RE: Quality Management

Dear [redacted]:

Your question about the availability of formal FDA courses or training on quality control was sent to me for response.

FDA does not conduct or sponsor any formal training or certification programs in Good Clinical Practice (GCP). We are, however, looking into developing such courses in the future, as resources permit.

Some U.S. government agencies offer GCP training online, for example, the National Institutes of Health (NIH). Although NIH developed the course to train its own investigators, it may also be accessed by others to enhance their knowledge of clinical research. [Perhaps this is the course to which you refer in your e-mail, when you said, "I have done the GCP course already"?] In any case, it may be accessed by pasting the following URL into your browser: http://www.nihtraining.com/cc/crt/indexvideo.html.

There are many professional groups and organizations that do offer GCP training programs. We are familiar with programs conducted by the Association for Clinical Research Professionals (ACRP), the Drug Information Association (DIA), and the Pharmaceutical Education and Research Institute (PERI), among others. However, FDA does not endorse any particular training or certification program offered by private organizations.

I hope this information is helpful.

Sincerely,

Carolyn Hommel
Consumer Safety Officer
Good Clinical Practice Program
Office of Science and Health Coordination
Office of the Commissioner
U.S. Food and Drug Administration (HF-34)
5600 Fishers Lane, Room 9C24
Rockville, MD 20857

Phone: 301/827-3340
Fax: 301/827-1169

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: [redacted]
Sent: Monday, September 15, 2003 9:35 AM
To: gcpquestions@oc.fda.gov
Subject: Quality Management

Hello

I am the quality assurance/control person in my site for a [redacted] trial network study in [redacted]. I would like to find out if there is a formal course/ training for quality control that you offer. I have done the GCP course already.

Thanks
[redacted]