From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Thursday, November 13, 2003 11:06 AM
To: [redacted]
Subject: RE: need some knowledge
Dear [redacted],

Your question about available training to be certified as a clinical research associate (CRA) was forwarded to me for a response.

There are no certification requirements for CRAs, or for that matter, any party, under FDA's good clinical practice (GCP) regulations. FDA does not conduct or sponsor any formal training or certification programs in GCP nor does FDA itself certify study staff. We are looking into developing such courses in the future, as resources permit.

Some U.S. government agencies do 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. You may access that course by pasting the following URL into your browser:
http://www.nihtraining.com/cc/crt/indexvideo.html
.
There are also many professional groups and organizations that offer GCP training and/or certification 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 cannot endorse any particular training or certification program.
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: Sunday, November 09, 2003 7:08 PM
To: gcpquestions@oc.fda.gov
Subject: need some knowledge

Hi,

Im a [redacted] and I like to [redacted] feild of clinical research as research associate, should I need to get the certificate about "Good clinical practice "by taking some courses offered by some institution?
if Yes, from where I get the list of recognized institutes.
thank you
[redacted]