From: Toth-Allen, Jean
Sent: Thursday, January 12, 2006 9:45 AM
To: [Redacted]
Subject: RE: FDA requirements for CROs

Dear [Redacted]:

Thank you for your inquiry regarding contract research organizations (CROs).

There is no FDA regulation that requires the use of a CRO or any other contracted party for the conduct of a clinical study. In addition, FDA cannot recommend non-government entities, not even generically. Therefore, I am not sure what FDA document your American partner is referring to in this case. However, all FDA guidance is available on the internet, so you may want to start with the home page for the Center for Drug Evaluation and Research (CDER)(http://www.fda.gov/cder/index.html) to search for appropriate guidance regarding the conduct of your pharmaceutical studies.

Hope this information is helpful.

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.

-----Original Message-----
From: [Redacted]
Sent: Monday, January 09, 2006 10:30 AM
To: gcpquestions@oc.fda.gov
Subject: FDA requirements for CROs

Dear Sir/Madam,

I wonder if you could advise me whether there is an FDA document stating that US pharma companies are advised to work with hospital-based CROs (our American partner mentioned that there is some sort of guidance regarding this matter, but I cannot find anything on your website). Thanks a lot.

KInd regards,

[Redacted]