GCP systems auditsFrom: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Wednesday, November 29, 2006 12:40 PM
To: [purged]
Subject: RE: GCP systems audits

Dear Mr. [purged]:

Your inquiry about FDA's expectations related to a company's "GCP systems" audits was referred to me for a response.

Recently a number of presentations, including some by FDA personnel, have stressed the application of "quality systems" to the conduct of a clinical study. This is particularly true with respect to device studies where application of the principles behind design controls (mentioned in FDA's manufacturing regulations for devices: Quality Systems Regulation - 21 CFR Part 820 - subpart C - 820.30), have been used to demonstrate how device sponsors can use already familiar processes to assist them in conducting quality studies.

FDA also has a fair amount of information related to quality systems and risk-based approaches for pharmaceutical drug quality (cGMPs).
While FDA does NOT have regulations or specific guidance on applying quality systems or using risk based assessments in the conduct of clinical research studies, the ICH E6, "Good Clinical Practice: Consolidated Guidance" addresses quality assurance in Section 5.1 ("Quality Assurance and Quality Control").
That section speaks to writing SOPs for the conduct of studies as well as obtaining agreements aimed at ensuring the quality and integrity of data resulting from such studies.

I should also mention that FDA has some general (internal) guidance on developing and implementing quality systems within FDA that may help you identify issues worth considering as you set up your own quality systems. Here I'm referring to FDA's internal Staff Manual Guide on developing and implementing a Quality Systems Framework (SMG 2020). Here is a link to the full text of SMG 2020: http://www.fda.gov/smg/vol3/2000/2020.html .
You might also want to contact some of the industry trade organizations or standard setting groups, (e.g., the Society for Clinical Data Management) to see if they have advice/best practices guidance on this topic.
I hope this is helpful.

Sincerely,
Carolyn Hommel
Consumer Safety Officer

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From: [purged]
Sent: Thursday, November 16, 2006 2:55 AM
To: OC GCP Questions
Subject: GCP systems audits

Hello:
Would there be any way to get information about what FDA expects in terms of a company's internal "GCP systems" audits? Is there even a definition of what a GCP systems audit is (according to FDA)?
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