From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Monday, October 30, 2006 11:21 AM
To: [Redacted]
Subject: RE: Quality System approach to GCP audits

Dear [Redacted]:

While FDA has a fair amount of information related to quality systems and risk-based approaches for pharmaceutical drug quality (cGMPs), FDA does NOT have regulations or specific guidance on applying quality systems or using risk based assessments in the conduct of clinical research studies. However, we do have 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 audit program: 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
Good Clinical Practice Program
Office of Science and Health Coordination
Office of the Commissioner
U.S. Food and Drug Administration (HF-34)
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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: [Redacted]
Sent: Thursday, October 26, 2006 11:41 AM

To: OC GCP Questions
Subject: Quality System approach to GCP audits

Hi,

As you know, in the GMP world the FDA audits are based on reviewing 6 systems: Quality, Facilities and Equipment, Materials, Production, Packaging/Labeling, and Laboratory Controls.

Just wondering if there is a system approach in the GCP world.

Thank you in advance for your assistance.

Kind regards,

[Redacted]