From: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Thursday, September 14, 2006 11:24 AM
To: [purged]
Subject: RE: Question

Dear [purged]:

While FDA has a fair amount of information related to risk-based approaches for pharmaceutical drug quality (cGMPs), FDA does NOT have regulations or guidance on using risk based assessments in internal audit programs specifically related to the conduct of clinical research studies. However, we do have some general (internal) guidance on developing and implementing quality systems within the agency that may help you identify issues worth considering as you set up your own audit program.

I'm thinking primarily of FDA's internal Staff Manual Guide on developing and implementing a Quality Systems Framework (SMG 2020). For example, Section 4.4 of SMG 2020 discusses the need for an organization's management to evaluate the consequences of specific actions or inaction related to a particular problem and prioritize activities based on the resulting risk assessment. There are probably other sections that may be relevant, so you might want to do a word search to see all of the places where "risk" is mentioned in the document. Here is a link to the full text of the guidance: 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
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Good Clinical Practice Program
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-----Original Message-----
From: [purged]
Sent: Monday, August 28, 2006 4:57 PM
To: OC GCP Questions
Subject: Question

What would be the best way to develop a risk base
assessment for an internal audit program?
Specifically, the clinical development area.

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