From: OC GCP Questions
To: [redacted]
Subject: Risk based monitoring approach
Date: Monday, September 21, 2015 2:14:20 PM

Good afternoon ---

This guidance document might be helpful to you or you can contact someone in the Center for Drugs (CDER) at CDER-OSI-GCPReferrals@fda.hhs.gov

Oversight of Clinical Investigations --- A Risk-Based Approach to Monitoring
http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM269919.pdf

I hope this information is helpful. Please contact us again at gcp.questions@fda.hhs.gov should you have additional questions.

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

From: [redacted]
Sent: Monday, September 21, 2015 10:47 AM
To: OC GCP Questions
Subject: Risk based monitoring approach

Hello,

My company is developing an approach to risk-based monitoring along with a software product. My clients are concerned about whether this approach would be accepted by the FDA. Who would I contact or how would I go about talking with the relevant person(s) at the agency to confirm that this approach is an appropriate approach to risk-based monitoring that the agency would accept as and when they review a submission where the monitoring and oversight were based on it?

Thanks for your help!

Regards,
[redacted]