

**From:** [OC GCP Questions](#)  
**To:** [REDACTED]  
**Subject:** Update on Risk based monitoring  
**Date:** Thursday, July 24, 2014 1:35:14 PM

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Good afternoon –

The FINAL guidance was issued in August 2013. Generally *draft* guidance is issued and published for public comment. After the comments are received a final guidance is issued. Please see the link to the final guidance. My office was not involved in developing this guidance so I don't have any specifics. There are contacts at the beginning of the guidance for you to review.

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM269919.pdf>

Kind regards,

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**From:** ~~GYXUM/XQ~~  
**Sent:** Wednesday, July 23, 2014 4:01 PM  
**To:** OC GCP Questions  
**Subject:** Update on Risk based monitoring

Hi,

Can you give me an update on the Risk Based monitoring guidance?

I know there was a guidance that was issued, I believe, in 2011, and there is also a guidance from August 2013. Does this represent a new approach? Or is this more of a clarification of the previous guidance? Were there questions and concerns from industry that prompted another document?

I would appreciate knowing if there has been a change of advice to the industry regarding risk based monitoring.

Thank you for your kind assistance,