From: OC GCP Questions
To: [redacted] bhanu.kanna@fda.hhs.gov
Subject: RE: FDA inspector compliance manual on NDA (New Drug Application)
Date: Monday, June 08, 2015 6:02:00 PM

Dear [redacted] -

Thank you for your question. I hope you enjoyed the SoCRA meeting as much as I did!

A number of the FDA presenters mentioned the FDA Compliance Program Guidance Manuals (CPGMs) during various presentations. The CPGMs provide instructions to FDA personnel for conducting activities to evaluate industry compliance with the Federal Food, Drug, and Cosmetic Act and other laws administered by FDA. The CPGMs for the inspection of the various Bioresearch Monitoring Program (BIMO) entities FDA inspects can be found at the following web link: http://www.fda.gov/ICECI/ComplianceManuals/ComplianceProgramManual/ucm255614.htm.

As mentioned during the SoCRA presentations, the CPGMs can give you an idea of what to expect during an FDA inspection.

I wanted to remind you that FDA's Office of Good Clinical Practice (OGCP) has a central GCP mailbox where you can send your GCP questions. That mailbox address is gcp.questions@fda.hhs.gov. I recommend that you send future questions to this mailbox instead of to multiple FDA staff because the mailbox is monitored daily Monday through Friday and this will prevent having multiple staff working on the same question. The staff in OGCP will do our best to provide you a response, or recommend an alternative contact within FDA to assist you.

I hope this information is useful. If you need further information and/or have additional questions, please feel free to contact us at the official GCP mailbox, gcp.questions@fda.hhs.gov. You may also find it useful to access the set of redacted GCP e-mails found at http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/RepliestoInquiriestoFDAonGoodClinicalPractice/default.htm since we find that many questions and concerns are repeated over time.

Best Regards,

Janet

Janet Donnelly, RAC, CIP
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Office of Special Medical Programs, Food and Drug Administration

From: [redacted]
Sent: Friday, June 05, 2015 2:41 PM
To: Donnelly, Janet; [redacted] bhanu.kanna@fda.hhs.gov
Subject: FDA inspector compliance manual on NDA (New Drug Application)

Hello,
I attended the FDA/SOCra conference in Cincinnati and recall hearing there were FDA inspector manuals available for review. I wanted to know if there was an FDA inspector manual for NDAs?
My organization is wanting to audit potential NDA vendors for our submissions and curious as to FDA requirements and inspection readiness .
Any information would be appreciated!
Thanks

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