

Kezer, Doreen M

From: OC GCP Questions
Sent: Friday, January 16, 2015 10:53 AM
To: [REDACTED]
Subject: [REDACTED], In Animal Facility

Hi [REDACTED] –

I don't work for ORA and not very familiar with GLP inspections but I don't think a company can request and FDA audit. When I worked in compliance at CDRH, we never inspected companies by request. I am also unclear as to what she means by a "blank" audit.

Sorry I could not be more helpful. Doreen

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Office of Good Clinical Practice
Office of the Commissioner, FDA

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From: [REDACTED]
Sent: Thursday, January 15, 2015 3:11 PM
To: OC GCP Questions
Subject: [REDACTED], In Animal Facility

Please assist us with the question below. It would be much appreciated.

Thank you,

Myra Casey
DET-DO
317-226-6500 Ext 104

From: [REDACTED]
Sent: Thursday, January 15, 2015 2:58 PM
To: [REDACTED]
Cc: [REDACTED]
Subject: [REDACTED], In Animal Facility

owned by [REDACTED]. When you and

ly
your colleague arrived at the facility, you

were there to audit a former [redacted] study. Having worked at the facility for over 10 years with the various companies, I was able to guide you and your colleague to the correct [redacted] contact. At the time I was working for the facility owner [redacted]. I now work for [redacted]. and we lease the animal building portion of the facility to conduct CRO services for our clients. We are in the process of setting up our systems so we can conduct GLP studies. My questions for you:

- Does the FDA ever perform complimentary or "blank" audits at the request from a service provider? For example, we ([redacted]) would like to have a "blank" audit by the FDA prior to offering this service to our clients. We would like to make sure our systems are all in place and we are completely compliant prior to initiating the work.
- If this service is something the FDA provides, how do we go about requesting such an audit? And how long is the "wait"?
- Any other advice you can provide is much appreciated.

Thank you for your time,