From: OC GCP Questions
To:
Subject: Clinical Supplies

Date: Wednesday, August 27, 2014 11:03:21 AM

Good morning --

During a BIMO inspection, FDA generally would not look at drug depots or vendor supplies. I don't know of any FDA guidance documents that address this issue.

Kind regards,

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----Original Message-----

From: [redacted]

Sent: Tuesday, August 26, 2014 8:02 PM

To: OC GCP Questions Subject: Clinical Supplies

Are there guidance documents available for auditing Drug Depots and qualifying vendors for clinical supplies? What are the agencies expectations when they conduct these type of inspection?