

From: [OC GCP Questions](#)
To: [REDACTED]
Subject: regulations
Date: Wednesday, April 02, 2014 1:32:37 PM

Good afternoon --

Please see the link below to the FDA regulations. For drugs and biologics see 312, for devices see 812, for GLP see 58, and for human subject protection see 50 and 56.

[Clinical Trials and Human Subject Protection > Regulations](#)

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

Kind regards,

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This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: FYXUMXQ
Sent: Wednesday, April 02, 2014 10:38 AM
To: OC GCP Questions
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Is there a site which lists the cGCP regulations? Or can you point me to where I may find documentation of what is required for compliance in cGCP (as I can for GLP)

thanks

k