

**From:** [OC GCP Questions](#)  
**To:** [REDACTED]  
**Subject:** Inquiry about Pharmacovigilance activites-reg  
**Date:** Wednesday, June 11, 2014 8:38:37 AM

---

Good morning –

This is a general good clinical practice mailbox. It is best to send your question to the Center for Drugs (CDER) at [druginfo@fda.hhs.gov](mailto:druginfo@fda.hhs.gov)

Kind regards,

Doreen M. Kezer, MSN  
Senior Health Policy Analyst  
Office of Good Clinical Practice  
Office of the Commissioner, FDA

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:** [redacted]  
**Sent:** Wednesday, June 11, 2014 1:29 AM  
**To:** OC GCP Questions  
**Subject:** Inquiry about Pharmacovigilance activites-reg

Dear FDA,

Greetings from India!

My name is [redacted] and I am a clinical researcher since 2009.

I have little confusion with respect to the pharmacovigilance activities in Clinical Trials for concomitant drugs or co-suspect drugs or drug used in response to the adverse event or adverse drug reaction.

Moreover I would also like to clear if the company has got the authorization of the XYZ drug molecule but not commercialized. The same drug molecule XYZ is being used in clinical trial as a non-investigation drug by some company.

What are the responsibilities involved for the company who has only authorized the drug molecule but not commercialized?

Thank you  
[redacted]