From: OC GCP Questions
To: [redacted]
Subject: pre-clinical and clinical
Date: Tuesday, November 25, 2014 12:27:39 PM

Good morning –

I cannot specifically answer your questions as it depends on the study (protocol) and the investigational product (IP). If the IP is a drug, it is best to talk to one of the review divisions in the Center for Drugs (CDER). You can contact CDER at druginfo@fda.hhs.gov. It would be helpful to them if you can be as specific as possible so that they can forward your information to the most appropriate review division.

Kind regards,

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

From: [redacted]
Sent: Sunday, November 23, 2014 1:20 AM
To: OC GCP Questions
Subject: pre-clinical and clinical

Dear friend,

Based in China, I am an industry adviser working on international purchase and marketing of pharmaceutical products.

I am working with some Asia chemical drug product producers with a purpose of exporting their drug products and your instruction will be essential and appreciated.

In China we have done pre-clinical and clinical study for some product and got product license issued by China authority SFDA.

Can we submit the same pre-clinical and study to FDA to get product license there? If we want to get product license from FDA do we have to redo pre-clinical and clinical study and does the repeat pre-clinical and clinical have to be done in the US?

Can this be achieved: Do one time pre-clinical and clinical and file them at the whole world?

Many thanks, have a nice weekend.

[redacted]