From: [purged]
Sent: Friday, November 04, 2005 11:25 AM
To: Lepay, David
Subject: Re: FDA Audits - India

Thanks for the quick reply! And have a good trip.
[purged]
-----Original Message-----
From: "Lepay, David" <DLepay@OC.FDA.GOV>
Date: Fri, 4 Nov 2005 11:16:36
To:[purged]
Subject: Re: FDA Audits - India

Dear Mr. [purged]:
I can answer your question quite readily since I will be traveling to India next week on behalf of FDA and the Department of Health and Human Services in cooperation with the government of India -- and have these facts at hand.

FDA has conducted two GCP inspections in India -- both in 2005 and neither yet classified (so I can't provide any further details on these).

I hope this information is helpful.

Regards, Dave Lepay

David A. Lepay, MD PhD
Senior Advisor for Clinical Science and Director, GCP Programs, OSHC, Office of the Commissioner,
US FDA

Sent from my BlackBerry Wireless Handheld (www.BlackBerry.net)

-----Original Message-----
From: [purged]
To: david.lepay@fda.hhs.gov <david.lepay@fda.hhs.gov>
Sent: Fri Nov 04 11:09:03 2005
Subject: FDA Audits - India

Dear Dr. Lepay

I am doing some research on clinical trials in India which is a venue that a lot of pharma companies are moving towards. My company is now patterning with a local Indian CRO to offer such services.

We are proposing a session at DIA to cover this topic.

Clinicaltrials.gov shows that there are over 100 trials either ongoing or just completed in India covering over 54 different indications. We know from public announcements that two FDA approved antibiotics had significant numbers of patients in India - [purged] and [purged]
The question remaining is what level of FDA inspections have occurred in India. If you can provide any information on the following topics it would be most helpful, or if you can point me to another person or source of information, I would appreciate it:

1. What was the year in which FDA first did an inspection in India?
2. How many inspections have been conducted?
3. Is there any data on NAI,VAI, OAI letters?

Again, we presume FDA has inspected Indian sites, but if this is not the case, that is useful information also.

Any other feedback on this topic would be welcome. Thanks

[purged]