MessageFrom: Hommel, Carolyn - OC on behalf of OC GCP Questions
Sent: Wednesday, February 01, 2006 10:10 AM
To: CDER DRUGINFO
Subject: RE: Good Clinical Practice Compliance

Christine,

She hasn't really provided enough information to answer her questions, and seems to be confusing things. You might want to ask her to clarify them. But, I'll take a stab at some general comments that you could share with her.

In general, yes, clinical testing in humans should comply with GCP. GCP is an ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects. Although a study may be exempt from needing an IND (see 21 CFR 312.2), one of the requirements for the exemption is to comply with the requirements for institutional review set forth in part 56 and with the requirements for informed consent set forth in part 50, both of which are most definitely a part of GCP. If the testing is subject to an IND or intended for submission to the agency, then FDA might also inspect the study at some point to check for compliance with regulatory requirements.

The questioner then asks about exceptions for testing drugs that are included in "tentative final monographs" and "final monographs." My understanding of the OTC monographs is that they establish which products ARE recognized as safe and effective, which products are NOT recognized as safe and effective, and which products require more study. Use of an ingredient that was identified in a final monograph as "safe and effective" meant that the sponsor did not need to do additional safety or efficacy testing, provided that the ingredient was used in accordance with the parameters (e.g., active ingredient(s), combinations, dose, labeling, etc.) set forth in the final monograph. If she has some confusion about the monographs themselves, she should be put in touch with the OTC drug review staff, and they can help her sort things out; they are in the best position to know the status of the monographs, and if a "final" has issued.

She finally asks whether testing particular products for allergic reactions would require compliance with GCP. I'd give the same answer as I did above. We ALWAYS believe compliance with GCP, particularly institutional review and informed consent, are a good idea.

As I said above, GCP means proper design, conduct, recording and reporting of studies; really, what's her objection?

Anyway, hope this helps--and call me if anything in my response doesn't seem clear to you.

Carolyn

-----Original Message-----
From: CDER DRUGINFO
Sent: Monday, January 30, 2006 12:09 PM
To: OC GCP Questions
Subject: FW: Good Clinical Practice Compliance

Can you provide me with some input?

Christine
-----Original Message-----
From: [purged]
Sent: Friday, January 27, 2006 11:07 AM
To: CDER DRUGINFO
Cc: Poole, Barry W
Subject: Good Clinical Practice Compliance

Dear Sir or Madam,

I was referred with the following questions by Barry Poole.

Is clinical testing in humans subject to compliance with Good Clinical Practices (GCP) for all drug products? If so, are there any exceptions to this requirement for drug products? Are there exceptions to this requirement for drug products which are regulated under tentative final monographs as opposed to final monographs?

Here are some examples:
A sunscreen is analyzed in a human clinical trial using a repeat insult patch test for irritancy. The results will not be used to substantiate any claims. Is this study subject to GCP compliance?
A surgical scrub is analyzed in a human clinical trial using a repeat insult patch test for irritancy. The results will not be used to substantiate any claims. Is this study subject to GCP compliance?
Please respond as soon as possible. I appreciate your assistance.

Sincerely,
[purged]