From: Toth-Allen, Jean
Sent: Thursday, September 14, 2006 2:42 PM
To: [purged]
Subject: RE: Delegation of Responsibility

Dear [purged]:

As I stated in my initial response, use of a delegation of responsibility list is not required by FDA-regulations. However, if you do choose to use such a list, it would be advisable to make it comprehensive. If such a list exists for a given study, anyone reviewing that study - the study monitor, an independent auditor, FDA investigators - would expect it to be comprehensive and include all pertinent study personnel, i.e., all personnel involved with essential study tasks. Therefore, even if you have documented who is responsible for certain tasks elsewhere in the study files, those seeking that information might not consider looking beyond the delegation of responsibility list and fault you for absence of pertinent study information.

Your questions with regard to stability testing are best addressed to the review division in the Center for Drug Evaluation and Research (CDER) responsible for the specific product in question. I do not believe your questions can be answered generically, as they could differ depending upon the nature of the drug in question as well as the procedures used to "over encapsulate." To determine which division in CDER you need to contact, you might find the chart accessible at http://www.fda.gov/cder/cderorg/ond.htm useful.

Hope this information is useful.
If you need further information and/or have additional questions, please submit them once again to the official GCP mailbox, gcpquestions@oc.fda.gov, in lieu of responding to my personal e-mail address.
Sincerely yours,
Jean Toth-Allen, Ph.D.
Good Clinical Practices Program
OSHC, Office of the Commissioner, US 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: [purged]
Sent: Thursday, September 14, 2006 2:26 PM
To: Toth-Allen, Jean
Subject: RE: Delegation of Responsibility

Dear Jean Toth Allen,

Thank you for the prompt reply for the query. Just wanted to clarify a little bit more with regards to the same query:

We are a small CRO with many different departments identified for their functions (recruitment, screening, lab etc) in such cases, all individuals who contacted the
potential study subjects are normally identified in other forms in our study records. So with that regards, is it still necessary to identify them in the delegation of responsibility list as well?

One additional question (I am not sure if you are the right person)

For clinical trial, if a marketed drug is bought and over encapsulated (for qualification/screening study), what type of stability study do you have to run on this drug? In terms of stability duration and stability testing.

Also when release testing and stability testing is performed for over encapsulation does the method (such as dissolution testing) need to be validated using reference material or can that be exempted because it is a phase 1 trials?

Regards
[purged]

From: Toth-Allen, Jean [mailto:jean.toth-allen@fda.hhs.gov]
Sent: Thursday, September 14, 2006 1:50 PM
To: [purged]
Subject: RE: Delegation of Responsibility

Dear [purged]:

Thank you for your inquiry regarding documentation of delegation of

responsibility.

While FDA has endorsed the GCP E6 guidance to which you refer, it remains a guidance document. Maintenance of lists regarding delegation of responsibility in a study are not specifically required by FDA regulations, though such lists are definitely useful in maintaining proper control of study conduct and therefore considered an element of good clinical practice, as reflected by their inclusion in the referenced guidance document. With regard to your specific issue, documents and activities involved with the recruitment of study subjects are considered to be part of the informed consent process for the study in question, as potential subjects are receiving information pertinent to their decision to participate. As a result, individuals responsible for such calls need to have adequate knowledge of the study in question and be qualified to answer questions in that regard. Therefore, personally I would consider such individuals to be performing a significant trial-related task and would document who was involved with these calls as a part of the study files. Including them on the delegation of responsibility list would be one way to do so.

Hope this information is useful.
If you need further information and/or have additional questions, please submit them once again to the official GCP mailbox, gcpquestions@oc.fda.gov, in lieu of responding to my personal e-mail address.
Sincerely yours,
Jean Toth-Allen, Ph.D.
Good Clinical Practices Program
OSHC, Office of the Commissioner, US FDA
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From: [purged]
Sent: Wednesday, September 13, 2006 10:35 AM
To: OC GCP Questions
Subject: Delegation of Responsibility
Hi,

I have a general question to ask with regards to delegation of responsibility by the Principal Investigator in Clinical Trials (phase 1)

GCP E6 consolidated guidance section 4.1.5 states "Investigator should maintain a list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties", under this section would recruitment activities (calling volunteers that are interested in participating in a trial by phone prior to start of a clinical study) be considered significant trial related duty and does that need to be documented as well.?

Thanks
[purged]