From: OC GCP Questions
To: [redacted]
Subject: GCP Information Sheet
Date: Tuesday, April 15, 2014 2:51:27 PM

Good afternoon [Redaccted} –

We do not have a document that directly compares ICH-E6 with FDA regulations. However, a few years back I believe we answered a similar question in a general way. Please see the question and answer below.

Also, we issued guidance in March 2012 that discusses FDA Acceptance of Foreign Clinical Studies Not Conducted Under an IND. Please see the link below.

http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM294729.pdf

Lastly, Here's the link to another proposed rule (Acceptance of Data From Clinical Studies for Medical Devices) published 2/25/2013 (78 FR 12664) that might be helpful as well:

http://www.gpo.gov/fdsys/pkg/FR-2013-02-25/pdf/2013-04201.pdf.

I hope this information is helpful.

Kind regards,

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Office of Good Clinical Practice
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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.

Question 1:
What is the difference between ICH GCP and FDA regulations? Do they refer to each other?

I know you can find difference when you look in details, e.g., Informed consent in FDA regulation requires "Source documentation that informed consent obtained prior to study participation" while ICH GCP doesn't have this wording. Obviously FDA requires 1572 form, financial disclosure, CSV, etc. which ICH GCP doesn't specify on.

As you said [redacted], FDA's newly proposed rule reflects FDA's efforts to harmonize and achieve GCP globally. Does it mean FDA is going to have a global GCP, to replace ICH GCP? As ICH GCP is always, at least in Asia Pacific, recognized as the global standard.

Answer 1:
To answer your question: FDA has been part of the ICH process since its inception. When the E6 (GCP Consolidated Guideline) was developed, it was agreed that there might be differences in some national GCP requirements between the U.S., the EU, and Japan. In particular, ethics committee requirements were more detailed in the U.S. than the EU and Japan --- and EU and Japanese representatives did not believe at that time that they were able to adopt all U.S. regulatory requirements for IRBs/IECs as part of ICH.

The bottom line, then, is that ICH E6 has been adopted as guidance in the U.S. U.S. regulatory requirements (i.e., FDA regulations) must be met for studies conducted in the United States; in some areas, these are more detailed [and, in fact, in a few areas less detailed --- for example, FDA regulations do not address clinical trial auditing] than ICH E6.

For studies conducted outside of the U.S. but in ICH regions, compliance with the provisions of ICH E6 ensure that that the studies will be accepted for review by FDA as non-U.S., non-IND studies (under FDA regulations for accepting such non-U.S., non-IND studies).

Our recent proposed rewrite of regulations for accepting non-U.S., non-IND studies reinforces this position. We are requiring that studies meet internationally accepted GCP standards (citing ICH E6 as one such internationally accepted GCP standard; there may be others, including ICH-similar standards under development by WHO and PAHO) --- no matter where in the world the study is conducted (i.e., not just in ICH regions, but anywhere in the world).

You may want to look at our proposed rewrite of regulations for accepting non-U.S., non-IND studies, which is accessible from our GCP website at www.fda.gov/oc/gcp (link to "Proposed Rules and Draft Guidances"). The preamble to this rewrite explains much of the history that I am describing above.

From: [Redacted]
Sent: Tuesday, April 15, 2014 11:29 AM
To: OC GCP Questions
Subject: GCP Information Sheet

Please send me a copy of the Information Sheet, if available that compares ICH E6 with FDA Regulations.

Thank you.

[redacted]