From: [purged]
Sent: Thursday, October 28, 2004 8:26 PM
To: DLepay@OC.FDA.GOV
Cc: [purged]
Subject: Re: FDA Medical Device GCP

Dear Dave,

Thank you so much for a quick reply. The information confirms what I understood from the Internet info. Since I do not have access to CDRH E-mail database, do you happen to know Kimber Richter's E-mail?

Thank you again,
Carole

"Lepay, David" <DLepay@OC.FDA.GOV>

??: ?????? ??: (????)

2004/10/27 19:41 ??: [purged]
Questions <GCPQuestions@OC.FDA.GOV>
cc: [purged]
??: Re: FDA Medical Device GCP

Dear [purged]
CDRH has worked through ISO toward a harmonized GCP standard for devices. We too have contributed to this dialogue through Kimber Richter in CDRH who has served as FDA/CDRH rep to this ISO GCP initiative.

You may want to contact Kimber for additional information/perspectives. The ISO device GCP standard does not have any official FDA status (in contrast to the ICH GCP Consolidated Guideline, which is official FDA guidance for drugs and biologics). However, in working with Kimber, we (FDA) have sought to make the ISO device GCP standard as internally consistent with ICH GCP as possible (recognizing there are some differences between device/device studies and drug/biologic studies). Otherwise, FDA GCP requirements for device studies are those contained within the regs: 21 CFR Parts 812, 814, 50, and 56.

Hope this is the information you are seeking.

Sincerely, 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: gcpquestions@oc.fda.gov <GCPQuestions@OC.FDA.GOV>
CC: [purged]
Sent: Wed Oct 27 04:52:44 2004
Subject: FDA Medical Device GCP

Hello from Tokyo!

My name is [purged] and I am from [purged]. At present I am on detail as a [purged] until Sept 2005.

Currently, I am training in the Office of Medical Devices and Evaluation (my counterpart office). Japan has new regulations on Medical Device GCP that will take effect this April 2005. The subject came up about any differences in US FDA and Japan's GCP..

To my knowledge as a device reviewer since 1990, CDRH does not have any policy or guidance specific to a document named GCP. However, we follow the IDE Regs which is one of the refereseced "GCP documents" along with other regulations like Informed Consent, Bioresearch Monitoring, etc. My Internet searches led me to your website. After reading all the available informtion carefully and getting a copy of the GCP guidance document, it appears to be harmonized if not identical to ICH Tripartite Guidance. The ownership comes from CDER and CBER and does not include CDRH.

I need your confirmation on this matter or if you have any other information that could be shared with the Japanese regulators on Device "GCP." It would make my assignment a little bit easier.

Any help will bemuch appreciated. Thank you so much.

Best regards,
[purged]