MessageFrom: Lepay, David on behalf of OC GCP Questions
Sent: Thursday, May 27, 2004 2:22 PM
To: [purged]
Subject: RE: QUESTION ON DEVICE GCP INSPECTIONS

Dear Ms. [purged]:
Clinical investigations are required to establish the safety and effectiveness of certain medical devices in support of marketing applications. Such clinical investigations must be conducted in accordance with IDE regulations outlined in 21 CFR Part 812, FDA Informed Consent Regulations (21 CFR Part 50) and FDA Institutional Review Board regulations (21 CFR Part 56). In the Center for Devices (CDRH), there is a Division of Bioresearch Monitoring, which operates as a component of FDA's GCP Bioresearch Monitoring program and assigns (GCP) inspections of investigators, sponsors, monitors, and Institutional Review Boards involved in device clinical investigations to ensure the protection of human research subjects, the quality of data generated in the study(-ies), and overall compliance with FDA regulations for clinical investigations.

Of the 1100+ bioresearch monitoring inspections assigned by FDA in FY '03, 31% were assigned by the Center for Devices.

FDA also has programs for the inspection of manufacturers/manufacturing of medical devices (under device GMP regulations). This program is distinct from FDA's GCP Bioresearch Monitoring program, which focuses on clinical research and was the topic of my presentation at ACRP.

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

-----Original Message-----
From: [purged]
Sent: Thursday, May 27, 2004 2:04 PM
To: 'gcpquestions@oc.fda.gov'
Subject: QUESTION ON DEVICE GCP INSPECTIONS

I am seeking information and clarification on the FDA inspection program for Medical Devices. At the recent ACRP meeting, reference was made to the following:

Speaking to the Association of Clinical Research Professionals' 28th Annual Conference, Lepay said device inspections represented 31 percent of the agency's 1,138 good clinical practice (GCP) inspections in fiscal year (FY) 2003. "This very much reflects the trend that we are seeing of more applications coming into the [Center for Devices and Radiological Health]," Lepay said, and also reflects "the way we are putting our agency priorities together as well."

Could you clarify what a "device GCP inspection is"? In reading the FDA website, it appears to me that devices are governed by GMP, not GCP. Are there specific inspections conducted at the investigator site level specific to devices?

Any clarification you can provide would be most appreciated.

Appreciatively,

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