

JOURNAL OF CLINICAL RESEARCH BEST PRACTICES

Vol. 1, No. 12, December 2005

"Can You Handle the Truth?"

"The Global GCP Compliance Report 2006: US, EU, and Japan"

Barnett Educational Services, 2005, 224 pages, \$95.00

Review by Norman M. Goldfarb

"The Global GCP Compliance Report 2006: US, EU, and Japan" is, by far, the most comprehensive review of clinical research GCP compliance programs in the U.S. (FDA and OHRP), Canada, E.U., U.K. and Japan. The U.S. review includes separate sections for CDER, CBER and CDRH.

The 68 tables and charts are very informative. For example:

This book has been selected for
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- In 2004, CDER, CBER and CDRH conducted a combined 629 clinical investigator inspections.
- 22% of CDER inspections in 2004 were overseas, double the 2003 percentage. Further growth is likely because 55% of inspections of foreign research sites found deficiencies in following the protocol, up from 21% in 2003.
- In 2004, CDER received over 200 complaints about investigators, IRBs and sponsors, a 50% increase from 2003. A new anonymous, online complaint form will support further growth in complaints.
- In 2004, 59% of CDER IRB inspections resulted in either voluntary or official action letters, down from 70% in 2003.
- In 2004, 24% of CDRH inspections resulted in official action letters for significant GCP noncompliance, double the 2002 percentage.

Here are some FDA inspection tips based on Barnett's interviews with FDA inspectors: The opening interview with the FDA inspector sets the stage for the entire inspection process, so be prepared to discuss the study's protocol, who did what during the study (in particular the consent process), and exactly how the study proceeded. Investigators and study coordinators should be prepared to demonstrate knowledge of CFR Parts 11, 50, 56 and 312; FDA investigators will likely ask you about them and even watch your body language. If appropriate don't forget to thank the FDA investigator for how much you learned during the inspection.

Through interviews with government officials, the book also illuminates future directions. CDER, for example, is very interested in the root cause of compliance failures. For example, it has discovered that sponsors often do not take action when CRAs report problems at research sites. CDER is expanding its new program of "linked inspections" of a research site, IRB and sponsor. Now, when FDA investigators find problems at a research site, the next stop is increasingly likely be the sponsor. If the root cause is at the sponsor, fixing it can address potential compliance problems at dozens of sites.

The book is available at www.barnettinternational.com.

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