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Good Clinical Practice Q&A: Focus on Medical Devices

Does the ICH GCP guidance document apply to medical device studies?

The International Conference on Harmonization (ICH) is a project that brings together the regulatory authorities of Europe, Japan and the United States with experts from the pharmaceutical industry in these three regions to make recommendations on ways to achieve greater harmonization in the interpretation and application of technical guidelines and requirements for drug products. The FDA Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) recognize ICH guidelines and publish that information in the Federal Register. According to an informal response provided by FDA in 2007, "the CDRH has not formally recognized any ICH documents. However, some of the principles in the ICH documents are general enough to be carried over to the device area. For example, the ICH E6 Good Clinical Practice Consolidated Guidance document contains comprehensive information on monitoring a drug study. A firm may consider using that section of ICH E6 as a starting point when developing its own monitoring plans for device research. We must remember that ICH documents are only guidelines and do not carry the force of FDA regulation or law…."

Source

"Good Clinical Practice: A Question & Answer Reference Guide", Barnett International, 2012, #1.38. The Guide is available at http://www.barnettinternational.com in electronic and paper form.