Theorem Clinical Research Releases Booklets to Provide ICH GCP Guidance For In Vitro and Investigational Product Trials

The Associated Press

KING OF PRUSSIA, Pa.--(BUSINESS WIRE)--Feb 27, 2013--Theorem Clinical Research has released two site-level reference booklets for clinical research sites that explain and condense critical International Conference on Harmonisation guidelines related to Good Clinical Practice for the conduct of trials.

Authored by Judith Köhnen and Lee Spurgin, PhD, “Little Advisor ICH GCP for Investigational Product Trials” explains key concepts of the ICH GCP requirements. Their second book, “Little Advisor ICH GCP for In Vitro Diagnostic Trials,” provides guidance on regulations specific to trials involving in vitro diagnostic devices. Both are available for purchase online.

Spurgin, senior vice president for medical device and diagnostic development, and Köhnen, senior project director for medical device and development, have years of experience with the conduct of clinical trials. Both manuals cover topics such as qualifications, regulatory authorities, ethics committees, the informed consent process, safety reporting and more. The information, presented in an easy-to-read format, highlights and explains critical information and provides practical advice.

“We developed these booklets to help investigators better understand the guidelines that govern clinical trials,” said Spurgin. “The guidelines themselves are lengthy and sometimes confusing. These manuals are an accessible resource for clinical research sites.” A third booklet, previously released by Theorem, has been popularly received by sites seeking to understand the International Organization for Standardization’s requirements for medical device trials. “Little Advisor ISO 14155:2011 for Medical Device Trials” is also available online.

All three booklets provide full citations back to the original ISO or ICH GCP documents for those who need more detail. And, all the topics in the original document are included in the respective booklets.

Theorem Clinical Research’s reputation comes from years of focused experience in managing complex studies. By bringing together teams of clinical, regulatory and study management experts, Theorem provides innovative development programs across the entire spectrum. The company has the development and regulatory expertise to execute successful trials across all risk classifications and approval pathways globally. Theorem’s regulatory and health economics experts also develop adjunctive reimbursement and safety surveillance programs and provide ongoing marketing support.

About Theorem Clinical Research

Theorem Clinical Research is a leading midsized provider of comprehensive clinical research and development services with offices in more than 30 countries and a customer base comprised of some of the world's leading pharmaceutical, biotech and medical device companies. A world leader in the most complex medical device and drug-device combination trials in addition to a notable capability in pharmaceuticals and biologics, Theorem has deep expertise in a broad range of therapeutic areas and in all phases of development. Some of the industry's top scientists and most advanced clinical analytics capabilities help ensure smooth-running, successful trials. For a full-service, right-size global research partner, don't think twice.