International Clinical Trials: A Guidebook and Compendium of National Drug Laws, Two-Volume Set

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Regulations and standards involving clinical trials vary from country to country based on different laws, cultures, and social structures. International Clinical Trials: A Guidebook to National Drug Laws succeeds in collecting current guidelines into a single source that allows regulatory bodies in the pharmaceutical industry to prepare product approval submissions and meet international standards for performing clinical trials. It covers regulations in 34 countries in Europe, Austral-Asia, Africa, North America, and South America.

Authored by locally based experts that include government authorities, national Ethics Committee chairpersons, company regulatory affairs professionals, and independent consultants, this book provides the information necessary for performing clinical trials, from initiation to termination and reporting. It includes forms and excerpts from existing regulations and interprets processes as they relate to ICH GCP guidelines. While chapters are presented in a similar format, they differ in their content to reflect the differing requirements throughout the world.

A cornerstone in this field, this book is indispensable to those who must understand and comply with the standards of biomedical research on human beings as the pharmaceutical industry and regulators work to establish a universal set of requirements for performing clinical trials.

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