Conducting GCP- Compliant Clinical Research: A Practical Guide

Wendy Bohaychuk, Graham Ball

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Conducting GCP- Compliant Clinical Research: A Practical Guide Wendy Bohaychuk, Graham Ball Conducting GCP-Compliant Clinical Research Wendy Bohaychuk and Graham Ball Good Clinical Research Practices, UK and Canada The overall aim of this work is to provide a reference book which describes the general framework for conducting GCP-compliant clinical research, particularly pharmaceutical industry clinical research. Wendy Bohaychuk and Graham Ball run a consultancy, GCRP Ltd., which has conducted over 820 GCP audits involving more than 200 companies in the last 10 years. More than 5,000 individuals have been involved in their training courses to help people perform GCP-compliant clinical research. They have authored several books and articles including:
* Standard operating procedures for investigators
* Standard operating procedures for sponsors and CROs
* GCP - an indexed reference
Drawing on their wealth of experience, they have produced this enlightening and practical reference work which fills an educational gap in the understanding of GCP at all levels. Written in concise language simple enough to be accessible to those new in the field, the dozens of real-life stories and detailed case studies at the end of each chapter make the book an invaluable resource for the more experienced, highlighting what can go wrong in a clinical study: A study of prostate cancer in the UK - An investigator brochure was not provided. The company argued that a brochure was unnecessary because the drug was already marketed. Indeed it was - for hypertension! A study of cardiovascular surgery in the UK - The consent dates were changed (by overwriting) to indicate that the patients had provided consent before the study started. The original dates post-dated the start of the study. A study of hypertension in Germany - The investigator brochure predated the study by nine years! Checklists are provided throughout the book to help monitors, auditors and investigators ensure that nothing important is overlooked. The authors present the topic of GCP with remarkable clarity, insight and enthusiasm emphasizing that this code of practice was not designed to make studies more difficult for investigators or more expensive for sponsors and CROs but, in the final analysis, to ensure the safety and well-being of study participants and future patients who will benefit from well-conducted, GCP-compliant studies.

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