Book review

Guide for Clinical Trial Staff – Implementing Good Clinical Practice, 3rd printing

G. Fortwengel Published by S. Karger AG, Basel, 2007. 108 pages, soft cover. ISBN-10: 3-8055-7655-2, ISBN-13: 978-3-8055-7655-0

The ICH Guideline for Good Clinical Practice (GCP) defines the standards to which investigators and their staff must adhere to when conducting clinical trials. This standard ensures adequate protection of subjects participating in clinical trials; furthermore, it ensures that all trial activities and data are meticulously documented and reported. However, the interpretation and practical application of ICH GCP guidelines can be very daunting for inexperienced trial staff. This book was written with the primary aim of providing investigators and their staff with a summary of the information they require in order to facilitate the conduct of clinical trials in accordance with ICH GCP.

The presentation of the book is a series of chapters covering all key elements of GCP in clinical trials, from the organization and planning, regulatory and ethical approvals, subject recruitment, right through to close out and archiving. Each chapter has an introduction summarizing the element of GCP to be covered. This is followed by a summary of responsibilities of the clinical site staff, cross-referring to the relevant section of the ICH GCP guideline. Thereafter follows a list of detailed actions subdivided into

activities to be performed before the start of the study, during the study and after completion or termination of the study. There are check boxes alongside this section with other useful information; for example, what to do/who to consult in case of difficulties, examples of best practice, consequences of not following the requirement. Finally, there are some hints and tips for implementation at the site level, a cross reference to other relevant chapters and an action item list for personal use.

Each chapter is presented in a clear, concise format which is highly readable and can be quickly assimilated. The chapters follow a logical order of the activities to be undertaken at the study site level. References to investigator and sponsor responsibilities are included throughout, also guidance on when to consult the study monitor.

The book achieves its primary aim of providing clinical trial staff with a reference source for conducting trials in accordance with ICH GCP. It may be recommended to all staff involved in the management of clinical trials as an easy-to-use, quick check summary of the activities required throughout the clinical trial process.

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