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## **GCP Auditing**

**Methods and Experiences**

Edited by the German Society for Good Research  
Practice with contributions written by 32 experts

2nd, revised and greatly expanded edition 2007

Drug development and the conduct of clinical trials is a complex endeavour which must follow a stringent regulatory framework and Good Clinical Practice (GCP) requirements. GCP audits are an important tool to assure the quality of clinical trials, i.e. the wellbeing of trial subjects, the integrity and validity of the trial data and the transparency of processes followed.

This book provides a comprehensive overview on GCP auditing methods and procedures as it describes all audit steps from planning to completion and outlines all audit types in clinical research and related areas. Anybody in the pharmaceutical/biotech industry, Contract Research Organisations (CROs) and academic/non-commercial institutions will benefit from the vast knowledge offered by the authors who accumulate a wealth of QA expertise in all areas of GCP auditing. Auditors can refine and broaden their audit knowledge, and auditees can learn what auditors are looking for during the various audits.

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