## **Contents**

Key Note Address Gabriele Schwarz	7
Preface for the 1st edition Hans Günther Stelzer	9
Preface for the 2nd edition Hans Günther Stelzer	10

1 upor	
Quality Management in Clinical Research and the Value of Audits Rita Hattemer-Apostel	11
Clinical Quality Management in a Medical Department of a Multinational Pharmaceutical Company – an Enhanced Approach to Quality  Jürgen-Hans Schmidt, Martin Gebauer, and Thorsten Gorbauch	33
Audit Schedule and Project Auditor in a Clinical Project Eva Beate Ansmann, Ilona Fleischhauer, Jürgen-Hans Schmidt, Christine Korbmacher, and Christiane Ehmer	41
Audit of Protocol, Written Information for Study Participants, Informed Consent Form and Case Report Form Wolfgang Krempien and Roland Scharpf	48
The Investigator Site Audit Carmen Julius, Beat Widler, Elfriede Lindauer, and Friederike Spengler	61
Clinical Investigator Audit as Part of the Systems Audit Beat Widler, Elfriede Lindauer, Carmen Julius, and Friederike Spengler	71
Investigator Site Audits by the Sponsor in CRO-Monitored Studies Jürgen-Hans Schmidt and Martin Gebauer	77
Sponsor Audits at Contract Research Organisations (CROs) – the CROs' Perspective	02
Dagmar Chase and Jürgen-Hans Schmidt	82

Sponsor Audits at Contract Research Organisations (CROs) – the Sponsors' Perspective Jürgen-Hans Schmidt and Dagmar Chase	99
Audit in the Analytical Laboratory Ralf Schaltenbrand, Susanne Plate, Volker El-Samalouti, and Karin Renneisen	109
Audits of Specialised Laboratories: Approaches, Problems and Solutions Andreas Edelmann and Michaela Rittberger	124
Audits of Early Phase Clinical Trials and Clinical Pharmacology Units Rita Hattemer-Apostel and John Norton	146
Systems Audits in Pharmacovigilance Michaela Rittberger, Michael Stegemann, and Jürgen-Hans Schmidt	164
Audits in Data Management, Statistics and Medical Writing: Auditing Clinical Databases, Trial Reports and Related Systems Rita Hattemer-Apostel and Wolfgang Reinhardt	188
Validation of Computer Systems in Clinical Trials Peter M. Kaiser, Per-Holger Sanden, and Thomas Badautschek	206
Electronic Data Capture (EDC) in Clinical Trials from a Quality Assurance Perspective Hans Poland	219
Performing and Reporting an Audit – Administrative and Technical Aspects Beat Widler, Iris Sobol, and Rudolf Löffel	247

Appendix	
Acronyms and Abbreviations	259
Glossary	263
Index	283
Authors' Addresses	285