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GCP Auditing

Methods and Experiences

In the 2nd edition of this booklet all texts have been revised, adopting the current legal provisions and EU Directives. Some new chapters (Audits of Specialized Laboratories, Audits of Phase I Clinical Trials, Electronic Data Capture in Clinical Trials from a Quality Assurance Perspective) have been added. Methods used in the design, implementation and evaluation of audits are described exhaustively. That renders this documentation useful as a current handbook for the pharmaceutical companies and CROs.

Different working areas (investigator, clinic, laboratory, CRO) are dealt with. The subjects cover audits of the trial protocol and of the written information for study participants, Phase I Audits, Investigator's Audits and System Audits up to the tasks of clinical quality assurance in electronic data capture and the audit report.

The authors are working in the pharmaceutical industry or at CROs and have had many years of experience in quality assurance.

Target groups

- R & D scientists and monitors
- Quality assurance staff
- CROs
- Public authorities / administration

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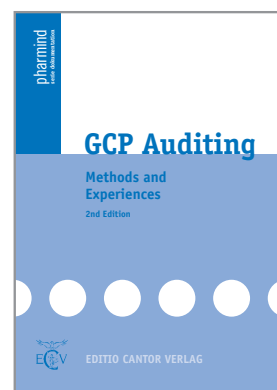
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