

BOOK REVIEW

Guidelines for Laboratory Quality Auditing

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and

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424 pages, hard cover, \$59.75

This book, which is sponsored by the American Society for Quality Control, Food Drug and Cosmetic Division, is part of the Quality and Reliability series which presently comprises some thirty-nine volumes.

All of us who are involved in auditing laboratories in the pharmaceutical industry are aware of the importance which FDA now gives to this topic. Thus it was with great interest that your reviewer picked up this volume. It is therefore with regret that I have to report that I was somewhat disappointed in the depth of treatment of this topic. Although the book has 424 pages the Appendices start on page 45 and it appears to this reviewer that most of the Appendices represent copies of official documents pertinent to the topic of the book. Readers may find this material to be useful but the fact that the substance of the authors original contribution is distinctly brief is a disadvantage. The treatment of the audit process is somewhat superficial. It would have been useful to have had more specific advice on problems which may be encountered in the auditing of laboratory. Some important topics, eg auditing of contract laboratories for bioequivalence studies, seem to receive little attention.

This book may prove to be useful as a general introduction to the topic and it is certainly modestly priced.

STAFF REVIEW