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BOOK REVIEW

NEW DRUG APPROVAL PROCESS

Edited by Richard A. Guarino
Second Edition, Revised and Expanded
MARCEL DEKKER, INC. NY
Price $150, 469 pages

This second edition of what has become accepted as a most useful and authoritative standard text on the New Drug approval process as is currently developed in the United States will be eagerly examined by many pharmaceutical scientists and regulators in industry, regulatory agencies and academia. I think most readers will probably be generally well pleased with the second edition, which has some useful improvements when compared to the first edition.

As with any multi-author book there is some disparity in style and level. There are eighteen authors, eight of whom come from Oxford Research International Corporation which is, of course, the base of the Editor, Dr. Richard A. Guarino.

In general the concepts are well-explained and there does not seem to be an excessive amount of undesirable overlap.

This book will undoubtedly be well-regarded as both a reference book and as a teaching primer, it can function well in both modes. Some readers might prefer more specific advice on the "how to's" of an NDA, others may express surprise that there is no chapter on harmonization of standard between North America, Western Europe, and Japan. However, I suspect that many readers will be very satisfied with this book. Purchase of this book is a necessity for anyone with involvement in the preparation of New Drug Application: it provides a most useful general overview.

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