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Book reviews

Accelerating Global Registrations

R.A. Guarino (Ed.), New Drug Approval Process 4th edition. ISBN 0-8247-5041-1.

The successful development, testing, manufacturing, registration, and marketing of medicinal products and medical devices requires a long and costly coordinated effort by specialists with diverse backgrounds in medicine, natural sciences, management, business administration, and law. The fact that this book with contributions by 19 authors is now being published in its fourth edition, indicates the need for a comprehensive view of the complex issues involved. Its 27 chapters are organized in five parts covering

- Regulatory practices and procedures of new drug, biologic, and device development,
- Clinical research development,
- Specific aspects in the process of new product submissions,
- Global applications of good clinical practices (GCPs), and
- Effective and new methodologies in expediting new product approvals in the US and European Union.

Most contributors are in the consultant business, and their experience in working with the FDA and with clients in the pharmaceutical industry is evident from the attention given to matters as broad as the management of clinical trials and to details as trivial as the size of boxes and the addresses for mailing various documents to the FDA. Since the authorities will not accept incomplete documentation, tables and appendices given in several chapters will be helpful as checklists to verify various parts of submissions to the regulatory agencies. On the other hand, the advice given on the presentation of data and communication styles should be as helpful at least to novices. In the same vein, a compilation of points to consider in the cooperation with contract research partners may be valuable for regulatory affairs managers.

The scope of the book covers all aspects of drug approval including regulations for orphan drugs and medical devices. While most of the information is applicable worldwide, the focus is clearly on the United States. This is particularly true for very specific matters like data privacy and the Health Insurance Portability and Accounting Act (HIPAA). Only one contributor is based in Europe, and there may be more to say about the European perspective than what is covered in an excellent chapter by K. Hill entitled 'The European Union Directive on Good Clinical Practice in Clinical Trials: Implications for Future Research'. The last chapter, entitled 'Accelerated New Product Approvals' by R.P. Delamontagne is interesting for its contents, but a striking case of mislabelling: its subject is the on-line university of the FDA office of regulatory affairs (ORA), which offers e-learning courses both to FDA staff members and to external attendees. A weak point of the book is its index, where hot topics like electronic records and signatures are missing, although they are addressed in some contributions. On the other hand, a 17-page collection of acronyms and initalisms is a welcome help for those who are less experienced in regulatory jargon.

On the whole, the book is a treasure chest for those engaged

- in managing a smooth and timely collection and presentation of data for the marketing authorization of medicinal products,
- in preparing outsourcing contracts with Clinical Research and Site Management Organizations, and
- in preparing and conducting site inspections by competent authorities.

It is highly recommended reading for newcomers in regulatory affairs and may offer some new perspectives on recent developments even to seasoned experts.

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Supercritical Fluid Technology For Drug Product Development

Peter York, Uday B. Kompella and Boris Y. Shekunov, editors. (2004, Marcel Deckker, New York – Basel). ISBN 0-8247-4805-0.

This book is one of a series "Drugs and the Pharmaceutical Sciences" and is the 138th volume. The 666 pages are