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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

divided into three chapters: I. Fundamentals, II. Drug Delivery Applications, III. Other Applications and Scale-up Issues. As is usual in Anglo-American books the fundamental works from Europe, which in this case is Germany, are not mentioned by name. Papers by Stahl and Loth from 80s, which first described the micronization of drugs by means of SCF-techniques are not mentioned, neither are the basic papers on the extraction of drugs from plants. This is a little surprising, as these describe the basic principles which are used for the further application in Pharmacy. However, this book provides a good overview of the present state of technology. For the user or potential user the section particle formation in supercritical phases, and also methods for particle production in chapter I are certainly the most interesting parts. Here the thermodynamic processes, for instance the droplet formation on the nozzle and precipitation are described as are also the different processes such as PCA, SAS and ASES. A core chapter deals with the production of powders for respiratory drug delivery with a very good overview of the drugs which have already been micronized with the aid of various SCF techniques. In a further chapter the possibilities for selective production of polymorphous and pseudo-polymorphous forms of different drugs are described and also the changes in surface properties of particles produced with an SCF-technique are shown. A fairly small chapter deals with the embedding of drugs in polymer carriers. Here the production of solid solutions from drugs with poor solubility is described. The embedding of drugs in biologically degradable polymers and the production of microparticles is described in the chapter "Formulation of Controlled Release Drug Systems". Here the problem of the choice of polymer (glass transition temperatures in the area of the critical temperature of the gas phase) and the particle separation is not described fully (the electrostatic particle separation is missing). A separate chapter deals with the processing of biological materials with SCF techniques. The influence of supercritical gases on the microorganisms are shown, and the influence of the SCF-technique on the processing of peptides, proteins and phospholipids. The chapter "Asymetric Catalysis in Supercritical Fluids" has little to do with the processing of drugs and does not really belong in this book. The chapter "Analytical and Semipreparative Supercritical Fluid Chromatography in Drug Discovery" also is more suited to a different reader target group. These pages would have been better used in a more detailed presentation of the section "Drug Extraction" in which in the reviewer's opinion essential aspects are missing or not adequately described. The chapter "Development and Potential of Critical Fluid Technology in the Nutracautical Industry" permits a brief look at the potential beyond the pharmaceutical field, and the last chapter of the book is dedicated to the problems of scaling up. Here there is a specific bias to the situation of one manufacturing company.

To sum up it can be said that this book gives the current state of knowledge very well and it can be recommended to everyone who is interested in the field of SCF-techniques.

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Antiviral Drugs

John S. Driscoll, Ashgate Publishing Ltd, Hampshire, England, 200 pages, ISBN 0-566-08310-8, Hardback, £60

Antiviral drugs are becoming more and more important. For this reason, this book, "Antiviral Drugs" represents a needed very useful comprehensive overview about these substances. The book starts with a 3 page introduction on "How to use this book" followed by an extensive list of abbreviations. The main part of this book consists of three chapters, one appendix, and two indexes. The first chapter entitled "Infectious Microorganisms" provides a 20 page overview about these microorganisms with a special focus on viruses. The next chapter, "Antiviral Drug Discovery and Development", discusses briefly on 13 pages the history of antiviral drug development and gives a description of the different steps of preclinical and clinical testing, including test systems, screening, rational drug design, lead optimisation, resistance, pharmacokinetics and toxicologic studies, and the three clinical phases. The third and most important chapter, "Antiviral Drugs", contains 78 pages. It describes in an encyclopaedia style the modes of action of all the different classes of antiviral drugs and includes a concise biological and pharmacological description of each of the 72 antiviral drugs covered in this book. The appendix (13 pages) gives a compilation of the chemical date of all of the 72 compounds including a two-dimensional chemical structure, main record name, CAS registry number, Merck Index number, EINECS number molecular formula, chemical name, synonyms, use, pharmacology, toxicity, physical properties, and manufacturer/supplier. The latter data are represented in the Merck Index style. Last not least, the book has an extensive 44 page index. In conclusion, this book provides a comprehensive encyclopaedic reference for everybody working with antivirals.

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