Book Review

Biodegradable Polymers as Drug Delivery Systems. (Drugs in the Pharmaceutical Sciences Series/45)
Edited by Mark Chasin and Robert Langer
Published by Marcel Dekker, Inc, New York, USA 1990
368 pages
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Over the past decade, the study of the potential of polymers for the controlled administration of pharmaceutical agents has increased dramatically. The emergence of biodegradable polymers has enabled either the site-specific or systemic administration of pharmaceutical agents, without the need for subsequent retrieval of the device, to become a realistic goal. The aim of the text under consideration is, as described by the editors, to take a selection of the biodegradable polymers studied to date and provide a comprehensive review of their properties, syntheses and formulations.

The book contains seven self-contained chapters covering some of the major classes of biodegradable polymeric materials currently being investigated. The general approach in each of the chapters is to overview the properties, synthesis and formulation of the particular class of polymers under consideration. The amount of emphasis placed on each aspect varies considerably from author(s) to author(s) and this causes problems with using the book as a reference source. Similarly, the references vary considerably both in number (from 28 to 139) and quality (some chapters contain only a few references, many of which are in press). The subject of the eighth and final chapter is, surprisingly, liposomes and, even more surprisingly, the types of phospholipids described are not even the polymerizable types. The chapter seems strangely out of place in the book. Even the system of referencing in this chapter does not conform with the rest of the book.

The first chapter on lactide/glycolide polymers is a good, up-to-date review on the subject. The lack of specific details in parts of the text is more than compensated for by the large number of references supplied. In contrast, the second chapter, concerning polyanhydrides, reads like a paper and contains only a few references, making it difficult to supplement the text.

Poly-ε-caprolactone is reviewed more effectively and, although in parts the text assumes considerable prior knowledge of the area, it gives adequate references. The fourth chapter, covering poly(ortho esters), reviews the field adequately but references are rather scarce. Similar comments can be levelled against the next chapter, on polyphosphazenes. The chapter on pseudopoly(amino acids) is very useful although because of their newness, very little information is, of necessity, presented on the formulation aspects of these new materials. A book on biodegradable polymers would not be complete without consideration of natural polymeric material. This last contribution concentrates on the formulation of these polymers and, while useful, it would have been beneficial to review briefly their purification and characterization, especially as this is frequently troublesome.

The last chapter is a competent review but, unfortunately, is not very different from the hundreds of others written on the same subject—although it is perhaps more up-to-date than some.

The reviewer considers that it would have been beneficial to have an index or contents section to each chapter, indicating the relevant portion of each aspect (i.e. synthesis, etc.). It is difficult to find your way around the book and while it is useful, it is certainly not the definitive volume in this subject area. It would, however, provide a worthwhile addition to any scientist interested or working in the area.

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Book Review

Pharmaceutical Product Licensing—Requirements For Europe
Edited by Anthony C. Cartwright and Brian R. Matthews
Published 1991 Ellis Horwood Ltd
328 pages
ISBN 0 13 662883 4 £74.95

At this critical stage in the development of the single European market, the "Pharmaceutical Product Licensing—Requirements for Europe" is a timely publication. Written and edited by a group of assessors from the Medicines Control Agency, it is a useful reference book for anyone involved with product registration. As might be expected from these editors, there is a comprehensive index and a good cross-referencing system. As well as current guidelines, many of the proposed changes to existing requirements in Europe are discussed which should prevent the book from becoming out-dated too soon. Past, present and future systems as well as the planning of registration filings for new products are reviewed in some detail by Tony Cartwright. The chapter on regulatory strategy covers national, concertation and multistate procedures and the product evaluation report (PER) scheme administered by EFTA but now also involving countries such as Canada and Australia.

The book provides a wealth of guidance for research, development and medical staff involved with the provision of data for marketing authorizations. Practical examples and explanations of factors which influence successful dossiers are provided. The importance of good quality expert reports is repeatedly emphasized. There is a 23 page analysis of the defects in applications and some suggestions on "how not to spoil good science with a poor dossier".

Alex Nicholson's chapter on clinical requirements includes some useful comments on good clinical practice. Lengthy sections on medicated devices, radiopharmaceuticals, contact lens products and intrauterine devices will be of interest to specialists in these areas.

Surprisingly readable, final year pharmacy students would do well to study some of the chapters such as Brian Matthews' discussion of the chemistry and pharmacy data requirements and James Ritchie's comments on the importance of a rational and relevant package of preclinical studies.

The book provides a unique insight into the British philosophy of product registration. I wonder whether the editors have considered a translated edition for the French market?

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