PHARMACEUTICAL BIOTECHNOLOGY

Second Edition
Preface

In 1992 Mel Klegerman and I edited a textbook with the title *Pharmaceutical Biotechnology: Fundamentals and Essentials*. The present volume is effectively a second edition of this textbook and is designed to provide an update of a subject that has developed into a major component of current pharmaceutical research.

The decision to proceed with this second edition was prompted to some extent by the realization that the original book was out of print in the United States but was being photocopied and circulated in a number of countries, especially in the East and Far East. It is a pure coincidence that a number of my friends who contributed chapters to this volume have emanated from Turkey but one can only hope that copyrights will be respected this time!

Although it is true that the subject has developed over the past decade, some aspects have not changed significantly. Some sections from the original book have been developed and expanded. However, subjects such as fermentation, production, and purification have not changed very much over the years and are not discussed here. Interested readers are referred to the original volume for what remain excellent reviews of these subjects. In addition, the previous emphasis on biological response modifiers seems out of place here and the function and activity of proteins, for example, is better discussed elsewhere.

The chapter on the formulation of proteins has been expanded but the contents will reflect my own personal scientific interests, and the current literature will, inevitably, contain additional information on different approaches to the subject. Two additional chapters are included since some proteins, such as albumin or gelatin, can serve as drug delivery systems in their own right. In addition, proteins and phospholipids undergo characteristic interactions and deserve closer and separate attention.

The major expansion in this present volume concerns the subjects of proteomics and gene therapy, both of which offer so much promise for the future. Pulmonary administration is another likely route of delivery for the future and this is reviewed separately. Conventional wisdom suggests that proteins cannot be delivered orally but there is strong evidence suggesting that this is not always true and this is another exciting area that is reviewed here. The earlier review of vaccines has been expanded considerably since this is another area of current interest with potential for wider future application.

The question of whom this book is written for needs to be addressed. The previous volume was intended for industrial application by the publishers although the editors had the academic market in mind and even provided test questions and answers. This dichotomy has been avoided here since the intention is that students and graduate students would be most likely to gain the most benefit from a review of this type. Of course, scientists without a pharmaceutical background coming into
the biotechnology industry for the first time will also find much to interest them, and it is hoped that a much wider audience both here and abroad will benefit.

The other question that needs to be answered in these days of the Internet is why a book is even necessary when so much information can be gleaned by simple use of a keyboard. In part, this is exactly why a textbook is needed. There is a real danger of students getting “information overload,” with so much information being readily available that they are unable to digest and assimilate it. For example, a recent Google search for “chitosan stability” achieved over 22,000 “hits,” most of which were useless since, for some reason, they were connected with cosmetic applications. Try searching under the term “emulsions” and be prepared for an astronomical response!

Sending a student to the library to carry out an old-fashioned book search in order to learn what has been achieved in a particular subject area is generally unpopular, but how else can the subject be appreciated from what might be called a classical perspective? The vast majority of new students do not seem to appreciate that there was any science prior to 1990. This is about as far back as most Internet databases can reach so, in effect, the student is denied access to the pioneering work that produced the advances in the first place.

Another related issue is the fact that groups of scientists are now putting the results of their research on the Internet which makes for a more rapid publication and, in some cases, this is of interest. However, what most neophytes do not appreciate is that this work has often not been peer-reviewed prior to publication and this can lead to uncertainty since the research may be flawed or even downright incorrect.

Uncritical acceptance of information is and remains the real issue with the so-called information age. The value of textbooks such as the present one is that access to the classical work is provided and much of the information has been digested to an acceptable format. With this in mind, individual chapters have suggested reading lists in an attempt to provide a bridge between the present omnivorous information bases and the subject basics.

I would like to thank the many friends and colleagues who have helped and encouraged me in this project. However, errors are mine and I take full responsibility.

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Chicago
Acknowledgments

I would like to acknowledge with gratitude the help I have received from friends and colleagues in putting this collection of essays together. Specifically I would like to recognize Ms. Helena Redshaw, CRC Press, for the help received in the assembly of the draft and Ms Alina Cernasev for encouragement and assistance with preparation of some of the figures. In addition I acknowledge with pleasure the discussions I have had with Dr. Simon Pickard (University of Illinois at Chicago) on the subject of measuring clinical outcomes. The results described in Chapter 15, however, are mine, and responsibility for errors that may have occurred lies with me.
The Editor

Michael J. Groves, a pharmacist with a doctorate in chemical engineering, has spent much of his career working in industry and academe. Now retired, his scientific interests include dispersed drug delivery systems and quality control issues for parenteral drug products. Editor or joint editor of a number of books, he has published 400 research papers, patents, reviews, and book reviews. He is a Fellow of the Royal Pharmaceutical Society of Great Britain, the Institute of Biology, and the American Association of Pharmaceutical Scientists.
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