"Pharmaceutical Process Scale-Up. Drugs and the Pharmaceutical Sciences Volume 118"

Michael Levin (Editor), Marcel Dekker, New York; 2002, 566 pages, $ 195, ISBN 0-8247-0625-0

This series from Marcel Dekker is still going strong, and shows no sign of loosing quality. I think that this latest addition is a gem. It deals with the procedures of transferring the results from research and development obtained on a laboratory scale to the pilot plant and finally to complete production scale in the pharmaceutical industry. The editor of this volume wishes to provide insight into the practical aspects of such process scaling-up. It achieves this goal admirably, and also provides a sound scientific basis for the scaling-up procedure.

The book starts with a detailed discussion of dimensional analysis and scale-up in theory. This gets right down to the nitty-gritty of what scaling-up is actually all about. It can be a bit tricky in places, especially if you are new to the idea of dimensional analysis. The author tries to make the life of the reader somewhat easier, however, by giving illustrative, simple examples. We thus read "What is the correlation between the baking time and the weight of a Christmas turkey?" The remaining chapters consider scale-up of the various drug delivery systems. We find here good chapters on parenterals, nonparenteral liquids and semisolids, biotechnology-derived products, dry blending, powder handling, granulation, fluid bed technology, tableting and film coating. Each chapter gives a good overview of scaling-up of the particular product concerned and makes reference to the use of dimensional analysis described in the first chapter. The book contains a large number of substantial appendices, which are a guide for the industry. In general, this is a very useful contribution to a rather dry subject. Many readers new to the field will be surprised at just how quantitative a scale-up process can be. If you are looking for a detailed, yet understandable summary of scale-up, then this is the book for you.

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"Medical Applications of Liposomes"

Danilo D. Lasic†, Demetrios Papahadjopoulos† (Editors), Elsevier, Amsterdam, New York; 1998, 794 pages, 236.50 ($ 236.50), ISBN 0-444-82917-2

"The initial interest in liposomes as a model membrane system and also as a drug carrier was based on their innate properties. This is the part in liposome development that can be characterized as serendipity, and includes a long list of useful properties: self assembly to a closed, relatively permeably membrane system; recognition by the RES macrophage system in blood, which can result in antigen presentation, macrophage activation, macrophage killing, and elimination of intracellular parasitic infections; lowering of the surface tension in the lung alveoli; penetration into the skin through hair follicles."

This statement by the editors of the book's content in the last chapter summarizes the various properties of liposomes, which are reported in the book covering the development of liposomal products from "bench to bedside".

For this purpose the editors have selected 77 experts in various fields of liposome research and development to report in 39 chapters on their scientific efforts. The particular chapters do not only show the numerous successes in liposome research, which have resulted in a variety of pharmaceutical products on the market or at least in clinical studies. They all also contain the essential literature, which is indispensable for all scientists interested in this research area. On 770 pages, numerous informative tables, microscopic and electron microscopic pictures, and schematic diagrams support the carefully written text.

In Section I, the editors and G. Gregoriadis, as another outstanding liposome scientist and promoter, introduce the scope of the book and give a list of the recent reviews on liposomes.

Section II covers the research on the stimulation of immune response and vaccination. Among other topics, the chapters show studies on major histocompatibility complex class I and II presentation of liposomal antigens, liposomes for conventional and DNA vaccination, and virosomes (i.e. liposomes mimicking viral envelopes).

In Sections III and IV, the strategies of liposomal treatment of infectious diseases and cancer are summarized including the use of conventional and sterically stabilized liposomes, as well as the possibility of specific targeting.

Section V gives an overview on attempts of the use of conventional and cationic liposomes for gene therapy with DNA or antisense oligonucleotides.

Section VI deals with other liposome applications and gives first an overview. Then particular scientific fields like pulmonary applications, liposomes as blood substitute, liposomes for topical use or as contrast agents are discussed.

The step from scientific efforts to therapeutic application is shown in Sections VII and VIII with industrial manufacturing and clinical testing of liposome pharmaceuticals. Here some companies involved in liposome development describe their products.

In the last section, Section IX, the editors give future perspectives on liposome research and development: size control, tailored release properties, ligand-directed targeting, and sterical stabilization are not novel areas of interest, but are worth further careful and more detailed investigations.

Neither editor is alive. D. Papahadjopoulos died in 1998. After the 'founder' of liposome research, Sir Alec Bangham, he was the scientist with the highest impact on liposome research. D.D. Lasic, who was in the liposome community the most important reviewer, critical evaluator and restless designer of concepts, died unexpectedly in November 2000. This book with a careful selection of contributions in the large field of liposome research and development is a great legacy of both outstanding liposomologists for all scientists in this fascinating area of research.

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"Freeze-Drying"
Georg-Wilhelm Oetjen, Wiley-VCH, 1999, 276 pages, Euros 119, ISBN 3-527-29571-2

Covering both food as well as mechanical applications, the author describes the rules of freeze-drying. Oetjen, who worked for many years in the freeze-drying business, presents important processing steps and process data not only theoretically but explained with regard to practical examples. He states in the preface of his book: "I have tried to show the interconnection between the property of the product, the goal to make it stable and the necessary processes to achieve this". It cannot be denied that he reached his aim.

This volume of the book, published first in 1997 only in the German language, was extended in 1999 by this English version. As in this relatively short interval great progress has been made in the field of freeze-drying, the interested reader might question whether this book is a simple translation of the 1997 volume. Many of the chapters are virtually unchanged over the German edition, but in two integral parts this textbook has been replenished.

Firstly, the initial number of nearly 220 references in the German edition was supplemented by approximately 50 new ones (most of them in the first part) which gives a comprehensive selection of actual information. With this, the reader has a variety of references at one's disposal, having the ability to apply them to his tasks and working out individual problems. Secondly, part 6 was extended with a chapter entitled 'Trouble shooting' (4 pages). In contrast to the 1997 volume Oetjen gives a brief overview about a selection of unexpected or undesirable events during freeze-drying processes. In my opinion it seems to be a completion to the classification of possible failures discussed in part 2. This information is commonplace for an experienced reader, but for a beginner it might be too short to offer first aid, and no literature references are given.

The book is divided into six parts (266 pages), each with up to five chapters. The first part is entitled 'Foundations and Process Engineering' and it is the most extensive one compared with those following. There are chapters of fundamental importance, because they present basic knowledge of the freeze-drying process serving as a basis for understanding the following chapters. At very best, part 1 contains roughly 50% of all references: the other parts have much fewer. The chapter 'Freezing' (56 pages) gives a detailed overview of heat transfer, cooling velocity, structure of ice, influence of excipients, freezing of cells, structure analysis and finally possible changes of structure. For freshmen who are not familiar with pharmaceutical process engineering, the author gives many examples and illustrations for the presented equations and freezing regimes. The principles of primary and secondary-drying are presented in the chapter 'Drying' (51 pages). Also, an excellent overview about temperature and pressure measurements for process monitoring is given in this chapter, discussing their advantages and limits. Sections about collapse or re-crystallization of a product, illustrated by cryomicroscopy, complete this chapter. The conclusion of part 1 is the chapter 'Storage' (7 pages) giving brief examples for measurements of residual moisture, influence of vial stoppers on residual moisture, as well as changes of product structure by time.

The second part combines several chapters dealing with 'Installation and equipment technique' presented with many illustrations and figures. One can read the chapters, and even the single sections, independently of each other. This part can be mostly recommended for experienced readers with a more technical orientation. Chapter 1 (7 pages) gives general ideas concerning large-scale freezing possibilities of pharmaceuticals and food. The second chapter, entitled 'Components of a freeze-drying plant' (40 pages) provides useful information about drying chambers, shelves, water vapor condensers, refrigerating systems, vacuum pumps and control systems. As well as a list of minimum requirements of freeze-drying plants and their control system, Oetjen concludes this chapter with a short overview and explanation of possible problems during freeze-drying processes. In the following chapters the author makes a common division into three categories of freeze-dryers, regarding capacity and freeze-dried product. The chapter 'Installations up to 10 kg ice capacity' (11 pages) deals with laboratory and pilot plants enumerating general guidelines. The short chapters 'Chamber production plants' (7 pages) and 'Production plants for food' (7 pages) conclude this subdivision without allowing the reader to gain a deeper