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Book reviews

Die Pharmaindustrie

Dagmar Fischer and Jörg Breitenbach (Eds); Elsevier Science, The Netherlands, 2003, ISBN 3-827-413-745, € 1995.

The book “Die Pharmaindustrie, Einblick, Durchblick, Perspektiven” edited by D. Fischer and J. Breitenbach aims at giving a survey over the relevant steps involved in the development of therapeutics. It starts with drug finding concepts and ends with the question ‘Quo vadis? An attempt of a perspective’. In order to ensure a maximum of safety and therapeutic benefit for the patient the pharmaceutical industry is highly regulated. In consequence procedures specific for this kind of business were developed. Their daily use resulted in a huge amount of new terms and definitions which sometimes may be rather arcane for the non-initiated.

In nine chapters the authors together with 11 co-authors try to introduce the various basic concepts governing the daily business in a pharmaceutical company. In the first chapter the authors give a short survey on the development of the pharmaceutical industry. They give a short overview of the various pharmaceutical markets, of the various drug administration organisations. The various types of pharmaceutical companies and their basic strategies are introduced. Well-organised diagrams explain the duration and cost of the development of a new drug product.

In chapter 2 Aigner and Klebe, both of the University of Marburg, explain the modern concepts of drug finding as well as the studies required to demonstrate the safety and efficacy of a new drug product. They discuss the potential mechanisms of action of drug molecules on a molecular level. In this context modern screening methods and subsequent lead optimisation methods as well as basic concepts of pharmacokinetics and pharmacodynamics are introduced. An overview of the various studies performed to demonstrate the safety of a drug product is given. The chapter ends with a discussion of the different phases of the clinical development and the main questions to be answered thereby.

In chapter 3 Becker discusses aspects of the dosage form development. He gives a survey of the studies performed during the preformulation phase which aims at an understanding of the physicochemical properties of a given drug and of their implications on its bioavailability. Special attention is paid to the development of tablets and the excipients used in their manufacture. Stability testing,

process transfer on larger scales as well as therapeutic systems are touched upon.

In chapter 4 Schlemminger gives an introduction into the registration procedures in Europe and the USA. He shortly reviews their legal framework and discusses the different forms of the documentation as well as the different application forms. A short paragraph deals with the role of the international conference on harmonisation (ICH).

In chapter 5 Jung introduces those systems which make the pharmaceutical industry so highly regulated. He explains the concept of Good Manufacturing Practice (GMP), its aims and the regulations developed for its implementation. These regulations have direct consequences on the organisation of the pharmaceutical manufacturing, on the construction of the facilities as well as on the materials and procedures to be used. He discusses the concepts of validation and qualification of processes and of equipment. Special attention is paid to the documentation of all these efforts and to the responsibilities in these processes.

In chapter 6 Sprandel discusses aspects of the pharma marketing being confronted with rapidly changing market structures which eventually are caused by financial limitations of the public health systems. He discusses the consequences resulting from the various target groups of the pharma marketing. Finally he touches upon innovative approaches in the price-finding for the prescription market.

The development of new drug products is a long term highly expensive effort. Patents and trade marks are important instruments to protect the intellectual property of pharmaceutical companies. They are the prerequisite for any financial engagement. In chapter 7 he gives an overview of the different kinds of protection a company can achieve by patents or trade marks.

Despite the highly competitive situation on the markets in the course of the development of new drug products there are intensive cooperations between pharmaceutical companies. In chapter 8 Lewis discusses the various forms of cooperation. He discusses license and option agreements as well as research cooperations. In many cases even marketing cooperations or co-marketing are practised. On one hand cooperations in form of supply and manufacturing agreements are interesting under financial aspects but on the other hand aspects of quality assurance and compliance with all the regulations require sophisticated contracts outlining the responsibilities of the partners. Lewis touches upon the licensing, the licensing teams and different strategies of

payment. As a last issue he addresses the project evaluation and its implications on the process of decision making.

In the last chapter the authors Breitenbach and Fischer ask the question 'Quo vadis pharmaceutical industry'? They try to outline the consequences of modern technologies such as bio- and gene technology, as information technology as well as nanotechnology on therapeutic methods. If the expectations generated by all these technologies would become reality the treatment of patients would become very individual. In many cases therapeutic progress would no longer result in drug products manufactured on a large scale. It is by mergers that in the transition time the pharmaceutical companies try to handle the problems resulting from high costs of development, of production and of marketing on one hand and of limited sales on the other hand. The number of pharmaceutical companies has decreased significantly during the last 10 years. In addition a critical assessment of products under economic aspects will become vital for pharmaceutical companies.

The scope of the book presented by Breitenbach and Fischer and their co-authors is very large. It is a good introduction for people interested in a better understanding of how pharmaceutical products are developed and manufactured. There are a large number of excellent diagrams explaining complex processes. The specific terminology which evolved under the influence of the regulations on one hand and the modern technologies on the other hand is well explained and will be of great help for all those being new in this business.

Ingfried Zimmermann*

*Lehrstuhl für Pharmazeutische Technologie,
Universität Würzburg, Würzburg, Germany*

E-mail address: i.zimmermann@pzl.uni-wuerzburg.de

* Lehrstuhl für Pharmazeutische Technologie, Universität Würzburg, Am Hubland, 97074 Würzburg, Germany. Fax: +49-931-888-4608.

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Cosmetic Lipids and the Skin Barrier (Cosmetic Science and Technology Series/24)

Thomas Förster (Ed.), Marcel Dekker, New York, Basel, 2001, 376 pages, ISBN 0-8247-0664-1 (US\$ 165)

The skin acts as a fascinating interface between us and the outside world. The outer layer, the stratum corneum, is a very thin but extremely effective barrier membrane. In part this is due to the unique lipid composition which resides both on and within its complex heterogeneous structure. The nature and significance of the lipids is therefore of interest to pharmaceutical and cosmetic scientists and also toxicologists interested in the permeation of xenobiotics. It is unfortunate that the opening word in the title of this book is

'cosmetic' as this may deter readers from outside the cosmetics field. In reality the book is of interest to any one concerned with the barrier properties of the skin and the significant role that lipids play.

The book has been edited well and is a multi-authored text covering most, but not all, aspects of skin lipids. It is a well-balanced and structured volume containing 11 chapters. These are divided into four roughly equal parts with the first of these dealing with the chemistry and structure of the lipids. The second considers their biological function and the third analysis of the lipids and their effects on the skin. The final part deals with specific lipids in cosmetic products.

The opening chapter examines the chemistry of the lipids and, as may be anticipated, shows their complexity and variability. This gives rise to the inherent variations that are seen in skin permeability, between sites, between individuals and as a result of disease states. The chapter also deals with the synthesis and structure of synthetic lipids that can be used to mimic the natural materials. The lipids in the intercellular spaces of the stratum corneum are organised into bilayer arrays. This again is important in the nature of the barrier properties of the stratum corneum and alterations in the lipid packing gives rise to changes in skin permeability. The structure of the lipids can be interrogated using small and wide angle X-ray diffraction. This is described and referenced well in the second chapter which also considers the structure of model membranes and the influence of hydration levels on lipid organization. Both in drug delivery and in cosmetic products there is an interest in the role of vesicles; these are reviewed from the standpoint of their effect on permeation and their visualisation. The final chapter of part one considers molecular modelling and how the lipids pack together. Conformational effects and polar head group interactions are clearly important and advances have been made in modelling these. The structures are complex and the interactions require significant computing power for the modelling. In the future it should be possible to use these approaches to predict diffusion through the bilayers and interactions of permeation modulators with the endogenous lipids.

The role of skin lipids in the barrier function is considered in the next chapter and is complementary to the first chapter on their chemistry. Biochemical aspects of lipid synthesis are described and biological effects such as the influence of ageing on lipid composition discussed. In this, the shortest of parts, the final chapter deals with skin equivalent models. This is an important subject given the complexities of obtaining skin samples for experiments. Various aspects are considered such as the different types of cultured skin, their histology and lipid composition.

The third part deals with analysis of the lipids and their effects on the skin. The first chapter in the section deals specifically with direct analysis. It considers the various sources of skin such as biopsy, skin stripping and blister formation. Extraction and separation procedures depend on