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# Book reviews

**Dermal Absorption and Toxicity Assessment (Drugs and the Pharmaceutical Sciences, Vol. 91)**
Michael S. Roberts and Kenneth A. Walters, Marcel Dekker, New York, USA, 1998, 792 pp., ISBN 0-8247-0154-2

Just another book on dermal absorption? Yes and no! As the title indicates, special emphasis is given to the toxicity assessment of skin absorption. This means the possible hazards of absorption are discussed, resulting from the contact of the skin with drugs, ingredients of cosmetics like fragrances, sunscreens and hair dyes and with environmental chemicals like agrochemicals.

Part I (125 pages) gives an introduction to the structure of the skin and the absorption process, the importance of cutaneous xenobiotics metabolism and examples of systemic toxicity. Concerning the absorption process itself, it is clearly pointed out that two variables have to be considered: the barrier permeability coefficient $k_p$ and particularly the maximal flux $J_{max}$. Usually, $k_p$ is related to the stratum corneum, resulting in increasing $k_p$-values with increasing lipophilicity. However, data from the literature show the opposite for lipophilic vehicles.

Part II (141 pages) describes the concepts of dermal risk assessment. Two chapters summarize the applicability of in vitro models and the respective protocols and guidelines. As a matter of fact, artificially cultured human skin seems promising, but is still not really predictive of in vivo results. Physiological and risk models, discussed in two chapters, are based on measurable parameters and pharmacokinetical processes, linked with the understanding of the xenobiotics' action. However, the risk assessment remains highly uncertain if the estimation of the exposure (concentration, duration and frequency) is not known exactly. In a more general approach the physicochemical determinants of stratum corneum permeability are summarized. $J_{max}$, however, more predictive for a risk assessment has also to be considered. Two other chapters give insight into microdialysis for dermal absorption studies and in the large variety of occupational eczematous diseases.

Part III (174 pages) is concerned with cutaneous absorption and risk assessment after application of pharmaceuticals. In more general chapters, in vitro/in vivo correlations, penetration enhancement, iontophoresis and the site of effects are summarized. Concerning risk assessment, drugs used for skin diseases, for pain and inflammation and for wound care are discussed. A further chapter deals with irritancy, caused by drugs, penetration enhancers, and iontophoresis, and its testing.

Part IV (187 pages) provides information on cosmetics. It starts with a chapter on regulation in the USA. Again, in vitro studies are discussed. Besides, the general problems of in vitro/in vivo correlations, the prolonged exposure and the finite dose conditions have to be considered in risk assessment. Three other chapters deal with hair dyes, fragrances and sunscreens. Safety for cosmetics requires that its use is harmless under acute and chronic exposure to the product. Especially sunscreen products, given frequently over long periods of time to large body areas, have the potential of local and systemic toxicity. Polymeric sunscreens without absorption possibility are still lacking.

Part V (126 pages) focuses on environmental exposure to xenobiotics like metal compounds, hazardous substances from soil and swimming/bathing water. For people engaged in bathing and swimming, the factor of surface 'slick', a thin film of oil floating upon the water, is very important. This surface slick with all possible contaminants will cover the entire body surface of a bather. Under the unspecific heading 'Dermal Absorption and Toxicity Assessment' the problems of dermal exposure to environmental chemicals in food animals are discussed. The last chapter describes the influence of solvents on the ultrastructure and permeability of the human skin.

All in all, this book is a rich source of information, with over 2200 references up-to-date. However, how to get this information? Some of the discussed substances are not listed in the index, some items are not sufficiently represented (substantivity: no entry, reservoir effect: 1 entry). The index seems to be a problem in such a kind of book. The 29 chapters are very different in size and content. Some are highly theoretical, others represent a collection of available information, a very good mixture. Only shortly discussed

are phototoxicity and photoallergy, important also in risk assessment. Fazit: highly recommended with the burden to read the book.

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**Pharmaceutical Project Management (Drugs and the Pharmaceutical Sciences Series, Vol. 86)**
Tony Kennedy (Editor), Marcel Dekker, New York, USA, 290 pp., US$ 135, ISBN 0-8247-0111-9

Pharmaceutical industry as a high-cost and high-risk business requires not only thriving drug discovery but also successful drug development to make a drug candidate into a market product. In addition, the time it takes for a drug to move from bench to bedside should be as short as possible. One of the first things scientists in drug development realize is the importance of project management, especially when it comes to deadlines and Go/No Go decision. Project management plays an important role in achieving excellence in drug development and calls for good medical understanding, planning and business skills.

In this book, veterans in pharmaceutical project management share their experience, which makes this edition unique. The 12 chapters are all very eloquently written in a style which makes it a pleasure to read. In the first chapter, Tony Kennedy explains the importance of a target product profile, as the key driver of the development plan using a NSAID as a nice example, followed by a chapter on strategic project management at the portfolio level including risk/benefit/resource assessment. Detailed information is given on how to plan the project starting from defining the target to the right software to use. I very much enjoyed reading Donald Cooper's contribution on how to manage an international team, which explains how to play as a team member and how to lead a group which holds true not only for an international team, but also for a small laboratory group. In addition, application of project management to the particular areas is covered, ranging from joint ventures, clinical trials and manufacturing to how to decide when to outsource and where to go for drug delivery device development. Astrid Seeberg describes in her chapter on implementation of project management, the successful change in management in the case of a middle-sized pharmaceutical company. The book closes with an outlook on the effect of new information technology and future visions. Since this book gathers a wealth of personal experience, the number of references given are few, for some chapters even nil. The small points of criticism to the book are that some charts should have been of higher quality and that the index is not very helpful and incomplete (but you can live with it for a 290 page book). In a second edition, specific aspects and examples on formulation, preclinical and filing issues could be added.

The authors offer much insightful information and you have to be aware that there are not many alternative sources available. This book is an invaluable source for scientists in drug development and research, not only in industry, but also persons from academia will get an understanding of running a project and a team, as well as industrial expectations from collaborations. In addition, people involved on different levels of project management may profit from the experience which is shared. I am pleased to add this volume to my bookshelf.

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**Handbook of Surface and Interface Analysis**
J.C. Riviére and S. Myhra (Editors), Marcel Dekker, New York; 1998, ISBN: 0-8247-0080-5

If I ignore its first three chapters, I can say that this is a very good book. It lives up very well to its title of being a handbook, which implies these days a comprehensive coverage of the theory and practice of a particular technique. In this case the book covers a plenitude of surface and interfacial analysis techniques which can be routinely used in scientific research. Starting with Chapter 4, the following 6 chapters describe in exemplary detail the methods, how they work, and what information they provide. Chapters 11–19 describe various applications of these techniques in particular areas, for example metallurgy, microelectronics and semiconductors, minerals, ceramics, and glasses, composites, corrosion, tribology, catalysts, adhesives, and archaeomaterials. All of the important spectroscopic techniques are covered, making this an excellent reference for anyone considering using these methods in the pharmaceutical sciences. Although there are no pharmaceuticals examples, the applications given describe general principals which will help the pharmaceutical researcher. The methods described are X-ray photoelectron spectroscopy, auger electron spectroscopy, ion scattering spectroscopy, surface mass spectrometry, methods for depth profiling, ion beam effects in thin surface films, ion implantation, and scanned probe microscopy.

This is an admirable book for the specialist, and will also