

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. Rivière 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 biomaterials. 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

be of value to the pharmaceutical researcher occasionally using such surface and interface analysis techniques. It will not teach you how to use the methods, but will help you to understand the challenges of surface analysis. What is wrong with the first three chapters? The reflections of the editors about the 'good old days' of surface science in the universities I find boring and outdated. Their attempt to describe the problems solving sequence are, I suppose, vaguely interesting. By the time I have read through the text, however, I could have thought out the way to solution of my problem intuitively.

This book deserves thus a half recommendation. If you need to consult it, perhaps it would be better to borrow it from the physics library. \$200 would be better spent for your pharmaceuticals library on other books.

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Pharmaceutical Water (System Design, Operation, and Validation)

William V. Collentro, Interpharm Press, Inc., Buffalo Grove, IL, USA; 1998, 682 pages, US\$ 179; ISBN: 1-57491-027-2

A number of publications have covered various aspects in the design, operation, maintenance and validation of pharmaceutical water systems. As Collentro notes in the preface, his intention was to present the whole subject methodically in a single book in order to improve the vertical and horizontal knowledge of operators, supervisors and managers on all levels. In addition the author, who is a chemical engineer with extensive field experience in pharmaceutical water purification systems, emphasizes the coordination of the engineering aspects with regulatory requirements. The text is carefully written in a concise style and consists of 13 chapters each with numerous, well updated references.

At first the USP definitions and requirements for pharmaceutical water qualities are presented. These specifications and the nature, type and concentration of impurities found in raw water define the water purification systems as briefly described in chapter 2. Subsequently selected water purification units used for pretreatment prior to ion removal are presented. A proper pretreatment scheme can determine the ability of a pharmaceutical water purification system to meet chemical and microbiological requirements. Accordingly, several pretreatment techniques are discussed in detail regarding their theory and application, design, oper-

ating and maintenance considerations. The following chapters 4–6 provide all technical aspects of ion removal techniques: ion exchange, reverse osmosis, electrodialysis, electrodialysis reversal and electrodeionization. Again, useful design and operating considerations and numerous case studies allow the reader to become familiar with these methods. Chapter 4 addresses specific ion exchange applications such as water softening, two-bed, fixed resin bed and mixed bed deionization or cation polishing. Chapters 5 and 6 provide a comprehensive survey of reverse osmosis and other ion removal techniques. There follows a chapter dealing with the important processes in production of water for injection. The basic principles of most of the commercially available distillation units, pure steam generators and condensing units are summarized together with informative data tables and schematic figures. In chapter 8 numerous critical items for storage system and related accessories in pharmaceutical water systems are discussed. Not only size, dimensions, orientation, heat transfer or internal finish of a storage tank are important, but the author also reminds us to carefully consider spray ball systems, control devices, fittings, tank pressure, hydrophobic vent filtration, etc. An excellent description of additional components for a pharmaceutical water system like in-line ultraviolet units, final membrane filtration, ultrafiltration and ozone treatment is given in chapter 9. The author uses the term 'polishing components' for these various unit operations and balances their pros and cons based upon his personal experience. The next chapter is dedicated to design, installation and material selection of distribution systems. Many drawings, parameter tables and material information may help to avoid mistakes in loop assembly or distribution piping. Personally, chapter 9 appears to be misplaced between storage and distribution systems, which are related and closest to the individual points of use. Chapter 11 presents a general overview of instrumentation, monitoring and control issues frequently encountered in pharmaceutical water purification systems. Specific indicators and other control elements including in-line conductivity and TOC measurements for pharmaceutical water purification systems are briefly discussed rather than a thorough control philosophy developed. Some general items which should be included in component and non-component specifications are presented in chapter 12. Collentro offers specification examples for a hot water sanitizable, activated carbon unit and the installation of a stainless steel distribution system, all details are listed in two extensive appendices. The last chapter of this book describes the validation process of pharmaceutical water purification systems, which itself could generate an entire separate volume when discussed in detail. This is taken into account throughout the book by numerous cross-references to the different validation steps, e.g. design, installational and operational qualification. A general discussion is followed by a few examples of complete validation proto-