issues, all discussed in preceding chapters are already discussed in more detail. A flow chart shows how all these activities are tracked by the validation master plan. In Chapter 8 (pp. 105–110), all those who still might have reservations against the validation concepts outlined so far are informed about 'What are the Consequences of Not Validating?'. In Chapter 9 (pp. 111–116) 'For Whom Are We Validating?', we learn a little more on the C.V. of David Kessler and on the fact that a 'FDA inspector is a highly trained, overworked, little rewarded person who has the job of protecting the public from venal commercial interests of the major and minor drug companies'. Chapter 10 (pp. 117–150) teaches 'Preparing Standard Operating Procedures and the Validation Master Plan'. For this purpose forms of the first 8 pages of a SOP, two flow charts showing the Evolution of a Validation Master Plan (VMP) are given. In this context the different elements to be included into the VMP are discussed once more. Chapter 12 (pp. 151–156) is a Lexicon of Validation Terminology. In a series of Appendices (A–G) issues as 'Quality Control', 'Regulatory Approaches to GMP', the complex problem of 'Validation vs. Verification, Testing, Calibration and Qualification', 'The commitment to Validate', 'Validation vs. Verification', 'Revalidation and Requalification Studies' as well as 'ISO 9000 and Validation' are discussed.

It is not surprising that in a book of this kind the term 'quality' can be found on each page several times. However, it is surprising that nowhere in the book, a definition of the term 'quality' is given. Due to statements such as the following ones 'In-process materials shall be tested for identity, strength, **quality**, and purity as appropriate' (p. 25) or 'a drug product must be tested to ensure the safety, integrity, strength, performance and quality of the drug product' (p. 26). I am not sure whether the authors really know what 'quality' means. They define analytical validation as 'the evaluation of product quality attributes through testing' (p. 26). It is said nowhere who is defining quality, and at what stage of the product life cycle this has to happen. It is somehow remarkable that development is never mentioned in an entire book on validation. Product quality is not a product characteristic, per se, and therefore, it can not be tested for it. Product quality is defined by the extent to which predefined product quality attributes are realized. The list of performance related product quality attributes has to be defined for each drug product individually, in the course of its development. Reproduction related product quality attributes are defined partially by the different pharmacopoeias or again have to be defined during the upscale and transfer process of manufacturing into production.

In the development of a new testing procedure or of a new manufacturing process, validation has to be an integral part of the work and has to be performed by the same scientist. That is why we talk about good scientific practice or good manufacturing practice. In consequence, the validation life cycle begins at the moment when the decision to develop a new drug product is taken. User requirement specifications shall be defined as early as possible in the product development. However, in many cases, the final specifications can be defined only when the product development is almost completed. If process and analytical or equipment and utilities validation, is not performed on the basis of specifications and methods defined in the course of product and process development, there is a great danger that it turns into bureaucracy.

The book can be recommended to people who are experienced in drug product development. Without this experience the reader may get the impression that developing SOP's, protocols and reports is the most essential part in the development of a new drug product. Many of the flow charts are very helpful as a check list.

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Methods in Biotechnology (Natural Products Isolation, Vol. 4)
R.J.P. Cannell (Editor), Humana Press, Totowa, 1998. 479 pp., $89.50, ISBN 0-89603-362-7

Researchers from both industry and academia, present techniques for the extraction and isolation of natural products. The book is divided into 15 chapters. The first chapter, *How to Approach the Isolation of a Natural Product*, written by the editor himself, is an introduction to the natural products chemistry and to the principle of chromatography. Chapter 2, *Initial Extraction and Product Capture*, by F.P. Gailliot, is aimed at extraction of microbial fermentation broth and is divided into four sections that focus on laboratory-scale capture steps: solids removal, solvent extraction, solid phase extraction and expanded bed adsorption. Chapter 3, *Supercritical Fluid Methods*, by E. Venkat and S. Kothandaraman, is a broad overview of the use of supercritical fluid extraction (SFE) as a general extraction strategy. It also includes commercial applications of SFE of natural products. There are four chapters dealing with the isolation of natural products by chromatography. In Chapter 4, *Isolation by Low-Pressure Column Chromatography*, written by G.M. Salitburo and C. Dufresne, retention mechanisms are described, the type of stationary phases and the approaches to selecting column operation. A practical guide to packing and developing a column, as well as practical examples are provided. Chapter 5, *Isolation by Ion-Exchange Methods*, by C. Dufresne, gives up-to-date information on this popular technique, frequently used for the isolation of natural products. A

selection of commercially available ion-exchange material is presented in four tables. Chapter 6, *Isolation by Preparative HPLC*, by P. Stead, addresses the practical application of laboratory-scale preparative of HPLC to the isolation of natural products. It comprises a discussion on the practicalities of carrying out a preparative HPLC-base natural product isolation. Chapter 7, *Isolation by Planar Chromatography*, by S. Gibbons and A.I. Gray, describes the basic principles of planar liquid chromatography (PLC) of which thin-layer chromatography (TLC) is the most common form. Centrifugal preparative TLC and over-pressure TLC are also mentioned. Numerous examples of PTLC from plants are also presented. Chapter 8, *Separation by High-Speed Countercurrent Chromatography*, by J. McAlpine, is a short overview of the separation of natural products by high-speed countercurrent chromatography (HSCC), a modern separation technique since instruments became commercially available in 1980 only. Chapter 9, *Crystallization and Final Stages of Purification*, by N. Shankland, A.J. Florence and R.J.P. Cannell, describes the final stages of a purification process. The discussion is focused mainly on the crystallization of small organic molecules for X-ray and neutron diffraction experiments. Chapter 10, *Dereplication and Partial Identification of Natural Products*, by F. Van Middlesworth and R.J.P. Cannell, is a summary of different techniques allowing rapid identification of compounds to avoid duplication of earlier research. With the increasing number of new natural products discovered each year, there is no doubt that these techniques will play an ever-increasing role. Chapter 11, *Purification of Water-Soluble Natural Products*, by Y. Shimizu, deals with a general extraction procedure of small molecular weight water-soluble compounds. Two examples of application of water-soluble compounds are presented. Chapter 12, *Special Problems with the Extraction of Plants*, by G.L. Silva, I.-S. Lee and A.D. Kinghorn, is exclusively dedicated to the analysis of secondary metabolites of plant origin. A general procedure from the selection, collection and identification of the plant material to the extraction method to obtain a crude plant extract is presented. Particularly useful is a section describing general reagents for a few of the most common types of natural products found as plant secondary metabolites. Chapter 13, *Isolation of Marine Natural Products*, by A.E. Wright, provides an outline of the general approach used in the author's laboratory to collect, store and extract marine organisms, as well as to purify natural products derived from them. Chapter 14, *Scale-Up of Natural Products Isolation*, by M.S. Verrall and S.R.C. Warr, deals with two aspects of increasing the output of the product: increasing the scale of operation and increasing the concentration of product in the starting material. Chapter 15, *Follow-Up of Natural Product Isolation*, by R.J.P. Cannell, ends the book with a description on the most important approaches to obtain more of the compound of interest. The discussion is focused on further extraction on a larger scale, maximizing gene expression, alteration of the biosynthetic process, biotransformation, combinatorial biosynthesis and combinatorial synthesis.

Most chapters include a series of notes outlining valuable practical hints which are rarely found in conventional experimental manuals. Altogether this volume provides a broad overview of isolation techniques of natural products, and will be extremely useful as a reference tool to those involved in natural products chemistry: chemists, phytochemists, microbiologists and biotechnologists. Furthermore, it can be highly recommended for institutional library purchase.

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Novel Surfactants: Preparation, Applications and Biodegradability

K. Holmberg (Editor) Marcel Dekker Surfactant Science Series, New York, USA, 1988, 362 pp.

This is the latest volume in an extensive series of books dealing with all aspects of surfactant science and technology. Not surprisingly, with the current concern about the environmental effects of surfactants, this is a major theme throughout the chapters of this book. With the huge range of different surfactant systems under investigation in laboratories, this volume can only examine a small number of surfactant types, and the emphasis is on surfactants which are biodegradable and of low toxicity. As a result, many of the systems discussed, fall into the range of interest of the formulation pharmacist.

Initially the book concentrates on specific families of surfactants; *N*-dodecanoyl-*N*-methylglucamines; alkyl polyglycosides; arginine-based species; esterquats; sulfomonocarboxylic esters; sterol surfactants; silicone surfactants. Later chapters are more general in focus and cover gemini surfactants, enzymatic synthesis, and polymerizable and cleavable surfactants. In the earlier chapters, extensive information is supplied on the synthesis of the materials, and on their physical properties and applications. Naturally the surface properties, micelle formation, adsorption, etc. are presented in detail and one gets a very complete picture of the behaviour of the materials. In the later chapters so many systems are surveyed that it becomes impossible to present more than a brief summary of their properties, and here the emphasis is on providing a brief outline of the many systems under consideration (for example, the chapter on cleavable surfactants covers 15 different families of materials, and a complete coverage would require a separate volume).

If this book were to have one major fault, it must be the index. Although I fully appreciate the difficulty of indexing