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Book review

Development and Validation of Analytical Methods, Vol. 3 of the series, '**Progress in Pharmaceutical and Biomedical Analysis**', Christopher M. Riley and Thomas W. Rosanske (Editors), published by Pergamon Press, 1996, 352 pp., ISBN: 0-08-042792-8, $88.00.

In this volume, the editors have attempted to provide an overview of the various activities which have become associated with the validation of analytical methods and procedures within the present climate of the pharmaceutical industry. At the outset, it is indicated that the book was not intended to be a practical description of the method validation process, but was developed instead as a guide to the critical steps within an overall validation program. This mission has certainly been fulfilled.

The first two chapters deal with the basic concepts of method validation. Part One opens with a chapter on assay validation, and inter-laboratory method transfer (E. McGonigle). This too-short introductory chapter serves to define the analytical performance parameters, especially as these relate to the transfer of methodology from one laboratory to another. In the second chapter of this section, a detailed exposition of useful statistical parameters is provided (C.M. Riley). This extremely useful and well-written chapter provides a practicing scientist with all the statistics that would be reasonably required, and is written in a manner that is easily understood and applied.

Since the requirements for analytical method validation are rooted in regulations, the editors have addressed these concerns in Part Two. The overview of worldwide regulations (I.E. Davidson) is constructed in a highly useful manner, where the sections of regulatory filings are outlined in turn and discussed in light of the requirements made by the various international agencies. Naturally, the latest recommendations of the International Conference on Harmonization (ICH) receive significant attention. In the following two chapters, issues related to the case of the United States vs. Barr Laboratories (C.L. Burgess), and an exposition of Judge Wolin's interpretations of Good Manufacturing Practices (R.J. Davis) follow.

The final seven chapters of the volume constitute Part Three, and treat a variety of ancillary topics touching on specific aspects of analytical validation. The chapter covering drug substances and the dosage forms manufactured from these (P.K. Hovsepian) is sufficiently detailed with ample definitions and illustrations so as to permit one to design a complete program for the proper control of such materials. The remainder of the topics in this section each deal with more specialized concerns, but each of which attempts to fully define its area of coverage and delineate programs of work. The chapters cover dissolution studies (T.W. Rosanske and C.K. Brown), robotics and automated workstations (J.J. Tomlinson), biotechnology products (G.S. Srivatsa,) biological samples (K.A. Selinger), cleaning procedures (T.M. Rossi and R.R. Ryall), and computer systems (J.G. Liscouski).

It can be stated that although this volume covers a widely diverse series of topics, a good degree of harmonization exists within the contents. Each chapter provides an ample definition of the terms used within following discussions, and these often are illustrated with practical examples to bring each precept home. Each chapter

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appears to contain the leading citations needed to introduce readers to sources of additional information, without attempting to quote every written word on the subject. What makes this volume a valuable work is the conciseness with which the authors have set forth their respective subjects, and the attention which has been paid to current and developing events. Since analytical validation will remain a developing area, it is hopeful that the editors will undertake future revisions to keep their coverage fresh and up-to-date. The present volume is a valuable resource to the pharmaceutical community, and should receive favorable placement in libraries of all types. Fortunately, the price of the current volume is reasonable, so it is anticipated that numerous practicing pharmaceutical and biomedical analysts will acquire copies for their own bookshelves.

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