Book Reviews

Analytical Chemistry in a GMP Environment: A Practical Guide. Edited by James M. Miller and Jonathan B. Crowther. John Wiley & Sons, Inc., New York. 2000. xxiv + 488 pp. 16 × 24 cm. ISBN 0-471-31431-5. $115.00.

This book is the result of training sessions for analysts working in the pharmaceutical field, as a direct outcome of the Code for Federal Regulations (CFR) part 211: "Training in cGMP should be conducted by qualified individuals on a continuing basis and with sufficient frequency". The book can be divided into three sections: (a) an orientation into the drug development process, including issues pertinent to the regulated industry; (b) an overview of the major quantitative techniques (UV, IR, GC, and HPLC) used in the pharmaceutical field; and (c) a discussion of methods required to produce, release, and support marketed products.

The third section includes aspects such as the development, validation, and technical transfers of the methods; the use of qualified instrumentation; calibration; and the handling of data and calculations. HPLC is understandably the focus of much of the material discussed in this section, with a chapter dealing with the selection of equivalent columns.

Four appendices are included. For the uninitiated, the list of symbols and acronyms and the glossary of terms used in ICH documents will be very helpful when reading this book. The appendix dealing with universal tests, dosage form specific tests, and acceptance criteria is useful when writing protocols and setting test specifications.

Surprisingly, sections on how to write accurately in the laboratory notebook and investigation reports, such as is needed when OOS/OOT results are encountered, were not included. A discussion of compliance with the electronic records rule (CFR part 11) should have been included in the chapter devoted to Laboratory Data Systems.

Anyone who has been involved in training exercises and in the task of gathering of pertinent material from different sources will find this book very helpful. As cautioned by the authors, regulatory guidelines issued by the ICH and guidance documents from the FDA must be consulted again before proceeding in any development activity; the references given in the book reflected the status as of November 1997.

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Solid-Phase Organic Synthesis. Volume 1. Edited by Anthony W. Czarnik. John Wiley & Sons, New York. 2001. viii + 164 pp. 16 × 23.5 cm. ISBN 0-471-31484-6. $69.95.

As the editor notes in the preface of the book, this book is done in the spirit and style of the very popular *Organic Synthesis* (*OS*) book series. Like *OS*, this initial volume of *Solid-Phase Organic Synthesis* (*SPOS*) contains solid-phase synthetic contributions from various industrial and academic labs that were all independently checked to make sure that the procedures worked as written. This was always one of the most attractive features of the *OS* series, in that the checked and tested methods always worked as advertised. However, one significant difference from the *OS* series is that the experimental methods compiled in the *SPOS* book series do not focus on the production of a single chemical product but rather on solid-phase procedures that will be general enough to produce libraries of compounds. Indeed, most of the synthetic contributions contain fully characterized libraries of 20−30 diverse compounds. In most cases, this should allow the reader enough information to make reasonable guesses as to what type of diversity reagents will work with a given procedure if larger libraries are desired. More specifically, Volume 1 of the *SPOS* series contains 14 synthetic contributions, each arranged as a chapter. There are author and subject indices at the end of the book. The contributors are predominantly from large U.S. pharmaceutical and biotechnology companies, but there are also contributions from a few Canadian and European academic and industrial labs. Three of the 14 contributions focus on the production of resins which are of general use in solid-phase synthesis. Another procedure describes the production of an allyldimethylsilyl linker that can be used in catalytic cross-metathesis reactions with alkynes. The remaining procedures describe methods for the production of various libraries on solid support using a variety of interesting synthetic reactions. These procedures describe the solid-phase syntheses of 2-aminothiazoles, secondary amines, ureas, dipeptoids, benzoxazoles, hydroxamic acids, quinazolinediones, C-terminal modified peptides, and thiophenes. Each of the 14 synthetic contributions contains a brief reaction scheme with a complete listing of the diversity reagents used, followed by a very detailed experimental section complete with notes explaining the origin of reagents, the apparatus, and finer experimental details. Included is a detailed discussion of the experiment with full characterization of products and associated references. Each procedure was extremely easy to follow and understand, such that anyone with a reasonable amount of laboratory training should be able to reproduce the reported results with minimal difficulty. More importantly, researchers will find these procedures useful foundations for the production of larger, more diverse libraries or as starting points for the design of slightly modified synthetic versions. Volume 1 of *SPOS* promises to be the first in a very successful series devoted to finely detailed and reproducible solid-phase synthesis procedures. This series should become as indispensable to researchers in the field of solid-phase organic synthesis as *OS* has been to the field of solution-phase organic synthesis.

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