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Book Reviews *

Handbook of Reagents for Organic Synthesis: Reagents for Glycoside, Nucleotide and Peptide Synthesis. Edited by D. Crich. Wiley: New York. 2005. 770 + xiv pp. £80. ISBN 0-470-02304-X.

The publication *Encyclopaedia of Reagents for Organic Synthesis*, commonly known as EROS was an eight-volume work of high standard and was widely acclaimed. The publishers have decided to cull from this larger work information which relates to more narrow topics in a single volume, and the present work covers Reagents for Glycoside, Nucleotide and Peptide Synthesis. Of the reagents in the present volume, approximately one-third are taken from the 1995 edition of EROS and are described as classical reagents whose principal use has not changed in the intervening period. The remainder are either updated versions of EROS entries or completely new entries.

The volume opens with a very useful list covering seven pages and over 200 references to recent review articles and monographs involving the three subject areas; some of these are to 2005 references and generally cover the period 1992−2005.

In contrast some of the updated entries only cover the literature to 2002, whereas others (e.g., chloroacetyl chloride) had some 2004 references. The choice of which entries to update I found rather arbitrary. For example, chloroacetyl chloride, triflic anhydride, trichloroacetonitrile, and benzeneselenenyl bromide were chosen as updates, the latter entry being expanded from one and a half pages to 15, much of which had little relevance to the three subject areas. In contrast, widely used reagents such as HATU, HOBt, isobutyl chloroformate, and pentafluorophenol were not chosen for updates, and the latest references were to 1992. Although this may be understandable in terms of the earlier stated policy, it does make for an unbalanced work. Nitrosonium tetrafluoroborate is also an updated entry where the update has little relevance to the title of the book, although the original described its use in glycoside formation. One begins to suspect that the entries have been updated for the main EROS, which is available in electronic format, and not specifically for the new book; therefore, much of the updated material may be irrelevant to the title.

In contrast, the new entries are concise and up-to-date and relevant to the title. However, because they are generally short entries, whereas the original materials (not updated) tend to be longer entries, the percentage of the book's pages which contains new material is surprisingly low. The updated and newer material seems focussed towards glycoside synthesis.

The volume has an appendix containing the names and addresses of contributors, but unfortunately, the publisher has not updated the addresses of those contributors whose sections were not updated. Thus, most of the British academic addresses are incorrect, and I suspect many others are, too.

A reagent formula index and a very comprehensive and excellent subject index complete the work.

In conclusion, the volume is a useful compendium, but the unbalanced selection of topics updated and the irrelevance of some topics to the title mean that it cannot be recommended.

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Organic Reactions, Volume 65. Edited by L. E. Overman. John Wiley & Sons: Hoboken, NJ. 2005. 627 + vii pp. £74.50. ISBN: 0-471-68260-8.

Volume 65 of Organic Reactions contains two chapters, the first (140 pp) being an excellent review of the Passerini reaction (L. Banfi and R. Riva). Although discovered more than 80 years ago, the Passerini reaction has seen a resurgence of interest in the past few years for the synthesis of α-substituted amides with highly functionalised substituents. This comprehensive review covers the scope of the reactions and useful experimental procedures and will be invaluable to all researchers.

The second and final chapter comprises an 80 page summary and over 350 pages of tables covering Diels−Alder Reactions of Imino Dienophiles (G. R. Heintzelman, I. R. Meigh, Y. R. Mahajan, and S. M. Weinreb). This is also an excellent review which covers not only imines but also oximes and imminium salts. The use of this reaction in the synthesis of heterocycles is widespread and intramolecular as well as two-component reactions are covered; stereochemical discussions and enantioselective catalysis complete the chapter.

In the experimental procedures, it is unfortunate, in 2005, that in some of the procedures the use of benzene as solvent is recommended; carbon tetrachloride is also used in one instance. For a reaction such as this, surely other, safer, solvents can be found.

Apart from this criticism, the volume maintains the high standard of this excellent series and is recommended to all academic and industrial libraries.

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Good Pharmaceutical Manufacturing Practice: Rationale and Compliance. By John Sharp. CRC Press: London, UK. 2005. 503 pp. List price $229.95 (Web price $207). ISBN 0-8493-1944-3.

*Unsigned book reviews are by the Editor.

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Published on Web 10/19/2005

GMP has rightly assumed great importance in the modern pharmaceutical industry, influencing research and development as well as manufacturing. Chemists working in this area therefore need a good understanding of the appropriate regulations and guidelines. This new book, by a renowned author and commentator (the editor of the original UK "orange guide" to GMP) provides a thorough grounding not just in the detail of the regulatory requirements but also in the rationale behind them.

The book is structured around line-by-line comparisons of the two most influential "codes" of GMP, namely the U.S. cGMP regulations (21CFR Parts 210 and 211) and the EC Guide to GMP. Thus, each chapter of the book deals with a particular subpart (of the regulations) or chapter (of the guide): Personnel, Premises, Equipment, Materials Control, Production, Packaging, Holding and Distribution, Laboratories, Records, Returned and Salvaged Products, Self-inspection are all dealt with in turn. An additional chapter is interpolated to discuss Contamination Control, a topic not treated in the regulatory documents as an item in its own right, but rather emphasised sporadically throughout. Two chapters are devoted to the particularly stringent requirements for manufacturing sterile products, and a further two chapters, to validation requirements.

For each topic the official texts are set out in full, and points of similarity and divergence are then highlighted in tabular form. This is followed by in-depth discussion of the origin of the requirements and potential consequences of not observing them—consequences, that is for product quality and patient well-being, rather than any regulatory actions that may follow. Most chapters also offer detailed advice on how to comply. For example, there are useful discussions of how to set up and structure GMP training programmes, how to organise storerooms and keep good documentation on material flows, how to devise sampling plans, as well as examples/templates of the countless forms, SOPs, and batch records that must be maintained. In the context of Validation, Sharp refreshingly debunks many of the semi-mystical practices which have developed, emphasising that this is only one part of a Quality Assurance structure, rather an all-important goal in itself.

In general, Sharp appears to favour the U.S. regulations for their clarity and no-nonsense direct style, in contrast to a degree of wooliness which he detects in their European counterparts. To some extent, this difference in style reflects a subtle difference in purpose; unlike the U.S. regulations, the EC Guide is a guideline, which makes recommendations rather than binding demands. (Albeit those recommendations are difficult to ignore.) Thus, the operative verb is "should" rather than the "shall" which pervades the U.S. cGMPs. On the other hand, Sharp feels that much of the Guide's vagueness can be attributed to the multinational EC and EU committees through whose hands the text has been processed and reprocessed in the years since he wrote the original draft.

The book is somewhat repetitive at times—a drawback when reading it from cover to cover—but it means that each topic can be digested thoroughly as a self-contained unit. A significant shortcoming—particularly from the *Organic Process Research & Development* reader's viewpoint—is the lack of a chapter on active ingredients. The ICH guidelines for APIs (Q7A) are mentioned at several points but without the comprehensive discussion given to other aspects. This perhaps reflects a lack of that personal experience which informs the topics which are discussed. I would still recommend this volume to manufacturing and R&D chemists because there are many parallels between drug product and drug substance manufacture; the issues which John Sharp illuminates here in the drug product context are also relevant (although perhaps marginally less critical) for APIs.

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