

Book Reviews

Guidelines for Hazard Evaluation Procedures, 3rd ed. Center for Chemical Process Safety, New York. Wiley Interscience: Hoboken NJ. 2008. 542 + xxvii pp. £78.50. ISBN 978-0-471-97815-2.

The third edition of these important guidelines has now appeared, considerably expanded and enhanced. As with most Center for Chemical Process Safety (CCPS) guidelines, they are aimed mostly at the bulk chemical industry, though the fine chemicals industry will benefit from their perusal. I find these CCPS books excellent for reference, but their guidelines should contain more examples to illustrate the issues and to help the chemist and engineer in decision making. This one does, and it makes it so much more readable.

This is a book for safety professionals and for all libraries to have available when discussing hazard evaluation, HAZOPs, and fault-free analysis. It has some excellent checklists at the back of the book which will be widely used. As such, it is a must-buy for every safety professional.

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Modern Biocatalysis: Stereoselective and Environmentally Friendly Reactions. Edited by W.-D. Fessner and T. Anthonen. Wiley VCH: Weinheim. 2009. 375 + xxiii pp. £105. ISBN 978-3-527-32071-4.

This multiauthor work summarises work done as part of the European Union-funded COST network D25, entitled “Applied Biocatalysis: Stereoselective and Environmentally Friendly Reactions Catalysed by Enzymes” over the last five years. It is interesting that the editors chose not to include the word “applied” in the book title. This is appropriate since the majority of the chapters in the book are by academics, and unfortunately for OPRD readers, little from industry is included.

However, there are some excellent chapters which industrial chemists should read. Ulf Hanefeld (Delft) reviews “Immobilisation as a Tool for Improving Enzymes”; Vicente Gotor (Oviedo) covers “Biocatalysis Applied to the Synthesis of Nucleoside Analogues”; and a group of authors from Milan Polytechnic describe “Chemo-Enzymatic Deracemisation Methods”; all of these make excellent reading.

However, the chapter on “Biocatalytic Asymmetric Oxidations with Oxygen” by R. Wohlgemuth (Sigma-Aldrich) only really covers the surface of this interesting topic.

References are generally to 2007 with an occasional 2008 reference, and so a lot has happened in Applied Biocatalysis since these chapters were written.

*Unsigned book reviews are by the Editor.

In conclusion, this volume is worth reading for one or two chapters, but at £106, there are not many who will buy personal copies.

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Inherently Safer Chemical Process: A Life Cycle Approach, 2nd ed. Center for Chemical Process Safety, New York. Wiley: Hoboken NJ. 2009. 411 + xvii pp. £56.50. ISBN 978-0-471-77892-9.

The Center for Chemical Process Safety (CCPS) was established in 1985 to specifically develop and disseminate technical information for use in the prevention of major chemical process incidents. This second edition of the book, devoted to inherently safe chemical processes, is dedicated to Trevor Kletz, who pioneered the use of the principles of inherent safety in industry.

Overall, it is a useful book but aimed more at the bulk chemical and petrochemical industries rather than fine chemicals and pharma. It is quite a dry read, as many guidelines are. It could have been enhanced by more case studies and examples to illustrate the points being made. As a result, it will only be safety professionals who read it, and this is not, I suspect, what CCPS would have wished!

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Pharmaceutical Dosage Forms: Tablets, 3rd ed. Edited by Larry L. Augsburger and Stephen W. Hoag. Informa: New York. 2008. Volume 1. Unit Operations and Mechanical Properties, 639 + xiv pp. ISBN 978-084939016-2. Volume 2. Rational Design and Formulation. 546 + xiv pp. ISBN 978-084939015-9. Volume 3. Manufacture and Process Control. 311 + xiv pp. ISBN 978-084939016-6. Price £275.

What a fantastic series of books. Everything you need to know about a subject in 3 volumes—I wish all subjects, especially API development and production were available in such a format.

This is the 3rd edition of this masterpiece, the last appearing in 1990. A lot has changed in the pharmaceutical industry since then, especially in regulatory issues, so this new volume is timely. Although the editors are both from the University of Maryland, the chapter authors are from both academia and industry, and the focus of the whole work is towards manufacture, with most chapters having a very practical outlook.

In volume 1, the chapters that process chemists should particularly read—and you will enjoy reading them—are on sampling, milling, drying and spray drying.

In volume 2, although the chapters are of a uniform high standard, there is less of interest for process chemists and engineers. However the chapter on ‘Approaches for Improving the Bioavailability of Poorly Soluble Drugs’ will be of interest.

Volume 3 is also of a high standard, and process chemists and engineers will enjoy reading about ‘Pharmaceutical Manufacturing: Changes in Paradigms’ which covers quality by design and process analytical technology (PAT). This is immediately followed by a chapter on ‘A Forward Looking Approach to Process Scale-Up for Solid Dose Manufacturing’. Both of these chapters emphasize the importance of

design of experiment (DOE) and other statistical methods for process optimisation, and that the old-fashioned approach of ‘one variable at a time (OVAT)’ methods are past their sell-by-date. Organic chemists—particularly in academia—please take note and learn from our pharmaceuticals colleagues.

Later in this volume, ‘cGMPs for the 21st century and ICH Quality Initiatives’ complement the early chapters, whilst a chapter on ‘Intellectual Property, Patent and Patenting Process in the Pharmaceutical Industry’ contains much of interest for APIs as well as tablet formulations.

Overall a superb set of 3 volumes; they should be dipped into by all process chemists and engineers.

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