

Book Reviews

Process Chemistry in the Pharmaceutical Industry. Edited by Kumar Gadamasetti. Marcel Dekker, Inc., New York. 1999. xii + 474 pp. 18 × 26 cm. ISBN 0-8247-1981-6. \$195.00.

This book is divided into two major parts. The first part consists of a dozen case studies that detail the processes used to synthesize a wide variety of target molecules from lab scale to commercial manufacture. All of these case studies, which are selected from a wide range of pharmaceutical companies, contain excellent discussions of the synthetic routes and the types of chemical goals and challenges that are presented to the process R&D chemist. However, the unique aspect of these case histories is that the discussions often go beyond chemistry and leave the reader with a good understanding of other important challenges to the process chemist, e.g., the need to balance the short-term goal of rapid supply preparation against the long-term goal of discovering a low-cost synthesis, consideration of FDA regulatory issues, reduction of process waste streams, and the need to meet very tight purity specifications.

The second part of the book consists of a series of special topics, written by experts in both industry and academia. The uses of enzymatic transformations, phase-transfer catalysis, and asymmetric synthesis in process R&D are discussed with well-documented examples of their use in specific syntheses of commercial drugs. In

addition, emphasis is placed on the opportunities and challenges presented by each of these areas in the development of commercial manufacturing processes. There is a chapter on thermal process safety, drug substance solid form considerations (polymorphism and development of an appropriate crystallization process), and, finally, the use of factorial experiments and lab automation in development of a synthetic process.

Overall, the book successfully achieves its goal of presenting the basic principles and challenges associated with the discovery and scale-up of a commercial manufacturing process of a new drug, but it also makes interesting reading just for the chemistry that it contains. The book will be particularly useful as an educational tool for those individuals who are new to process R&D or who are considering a career in process chemistry and want to assure themselves that the successful process chemist has an outstanding command of modern organic chemistry and the ability to apply that knowledge in a creative manner to complex synthetic targets.

Vance Novack

*Chemical Development
SmithKline Beecham Pharmaceuticals
King of Prussia, Pennsylvania 19406-0939*

JM990629G

10.1021/jm990629g