Scaling Up

Industrialization of Drug Discovery: From Target Selection Through Lead Optimization

Edited by *Jeffrey S. Handen*.

CRC Press, Boca Raton 2005. 305 pp., hardcover $ 139.95.—ISBN 0-8247-2391-0

Much has been written about the declining number of NDAs filed each year as a measure of the inefficiency of the drug-discovery progress. This topic is of great interest to scientist engaged in drug-discovery research. There is a concern that, despite the investment of much money and effort in addition to the application of many new technologies, such as high-throughput screening and combinatorial chemistry, increased productivity and efficiency has not been observed in terms of an increase number of drugs reaching the market.

This book is composed of ten chapters, written by scientists and management consultants active in drug-discovery research, that discuss various aspects of the process of drug discovery. In this way, an overview of various aspects of drug discovery is provided in the form of individual commentaries rather than an exhaustive recitation and discussion of the drug-discovery process. Several chapters might be of particular interest to researchers wishing a discourse of specific topics, such as compound-library management and general concepts of knowledge management within drug discovery, for example. The tone and content of the book will be of greater appeal to those who wish to consider drug discovery in terms of management and process functions as opposed to specific scientific, technical, and/or technological topics.

The book begins with an introduction to its premise and the need for more efficient practices in drug discovery; making the case for a clear need to examine how the pharma industry must improve its ways of discovering drugs. This chapter is written in an easy and conversational tone with some jargon and current expressions (e.g., delivering the goods). The first chapter is followed by a commentary on regulatory affairs, including some comments about considerations of risk assessment and historical trends of the FDA. This chapter also contains a checklist for Drug Discovery Regulation. Although seeming somewhat out of place, given the sub-title of the book, this chapter provides an informative commentary regarding regulatory affairs that may be a brief introduction to a drug discovery scientist. Chapter 3 contains a lengthy discussion of the history of the industrial revolution, apparently presented as a useful comparison to the potential "industrialization" of the drug-discovery process.

Chapter 4, the best part of the book, is an extensive and excellent discussion of aspects of compound- library management. The authors of this chapter have considered all basic aspects of this important component of drug discovery. Individuals charged with this responsibility would do well to read this summary of compound-library-management issues and practices. This chapter is a good segue to Chapter 5, which speaks about the high-throughput screening (HTS) process, as it is useful to drug discovery. There are some interesting statistics provided concerning the cost and value of compounds in corporate collections. The premise of this chapter is that it is not so much a concern of technology as it is the organizational placement of this technology in the drug-discovery process. In Chapter 6, the authors discuss efficient lead optimization coordinated with input from ADMET assays at the earliest stages. There is brief mention of toxicogenomics as a new development for consideration in lead-optimization approaches. This section is well written with extensive references.

In Chapter 7, the author summarizes several concepts and aspects of knowledge management (KM). Among several definitions, KM is defined as consisting of "the creation, collection, interpretation, and storage of, as well as interaction with, data". Emphasis is given to the need for organizational changes in order to appropriately address KM issues, as opposed to simply relying on the implementation of new technologies. The contents of Chapter 7 complement the ideas of Chapter 8, where the authors introduce concepts for understanding and evaluating research projects in terms of their potential value and risk for the purposes of prioritization. In this way, it is possible to forecast the value of a company's pipeline. For those in a drug-discovery organization who make project review and prioritization decisions, the concepts of these chapters should be basic and routine practice.

In Chapter 9, the authors present ideas that most modern research is collaborative in nature, and that these collaborations are often across virtual teams. There is some discussion of the factors that account for successful construction of virtual teams. Like Chapter 8, the contents of this chapter are general enough to be applicable to other fields of research than drug discovery. The final chapter is comprised of a presentation of the need to consider ethical aspects of research given the emergences of genomics research in the drug discovery process. Included within this discussion is the need to take into account ethical concepts resulting from bioproperty and royalties.

Robert Goodnow
Hoffmann–La Roche, Nutley (US)
DOI: 10.1002/cmdc.200600022