Product approval demystified

***Biologics Development: A Regulatory Overview* by Mark Mathieu (ed.). Parexel, Waltham, MA, 1997, pp. 330, $135 (hardcover); *Global Biotechnology Product Registration: EU, US, and Japan* by Mark-Michael Struck, Mark Mathieu, and Hiromi Okabe. Parexel, Waltham, MA, 1997, pp. 392, $395 (paperback).**

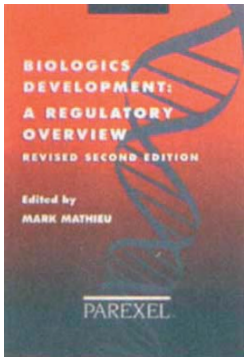
George Morstyn

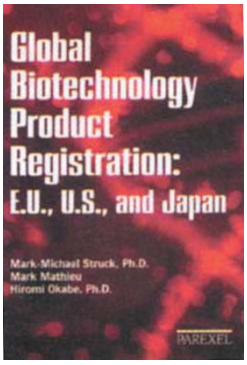
The current rapid development of biologics has resulted in marketing approval for many breakthrough therapies that have proven to be of major benefit to patients with previously unmet medical needs. Successful drug or biologics development requires the achievement of consensus among many groups, including the pharmaceutical or biotechnology company sponsoring the drug, and independent scientists, physicians, patients, and the regulatory authorities that the drug is effective with an acceptable therapeutic window and tolerable side effects. Industry sponsors, patients, regulatory authorities, and physicians have a great incentive to reduce the time required for clinical development of breakthrough therapies, but, at the same time, must ensure that only safe and effective products are approved.

To achieve optimum drug development, it is vital that everyone involved has a good understanding of each others role, culture, and constraints. *Biologics Development: A Regulatory Overview* edited by Mark Mathie provides an excellent insight into the processes used by CBER (Center for Biologics Evaluation and Research) to review and track the drug development process to ensure product identity, purity, potency, effectiveness, and safety.

I found the book to be a very useful compendium of the regulations governing drug development, and the expectations of each phase of development. It can easily be read by students and new staff in preclinical, clinical, and regulatory departments who are preparing their first INDs (investigational new drug applications) and BLAs (biological license applications), and will also serve as a useful resource for seasoned staff in the same departments. Chapters discuss aspects of preclinical assessment, the IND, the CBER review process, and such special aspects of biologic development as the role of pharmacokinetics or the development of antibodies. Such regulatory concepts as the meaning of adequate and well-controlled trials are well presented. There are interesting chapters on vaccine development and the contents of a BLA, and how the US Food and Drug Administration (FDA; Rockville, MD) ensures compliance with the regulations.

The book has a strong focus on the changes to the process that are resulting in reduced review times at the FDA while, unfortunately for the industry, its development times are increasing. *Biologics Development* is well constructed and written by authors who are obviously actively involved in developing or approving biologics and, therefore, can write authoritatively. I highly recommend it, and suggest that it be updated frequently to remain useful.





Global Biotechnology Product Registration: EU, US, and Japan by Mark-Michael Struck, Mark Mathieu, and Hiromi Okabe will be most useful for entry-level regulatory-affairs professionals who are responsible for defining the requirements and coordinating the development of international registration documents. More senior regulatory professionals, as well as individuals in other departments who may be involved in the generation of registration documents (e.g., clinical development, quality assurance) will find this information useful for reference purposes.

The authors appear to accurately describe the current regulatory environment in the United States, European Union, and Japan (although I am less familiar with Japan), and the book clearly summarizes the registration requirements for these regions. Additionally, guidelines for the various areas of biopharmaceutical manufacture, development, and registration are current and very helpful.

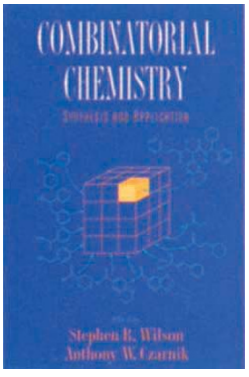
The book is well organized and presents the general requirements in a concise, clear manner. It should be noted, however, that a detailed review of the current guidelines, regulations, and directives should be carried out by anyone attempting to fully understand the requirements in these regions.

George Morstyn is vice president, clinical development, and chief medical officer at Amgen, Thousand Oak. CA.

Getting the chemistry right

***Combinatorial Chemistry: Synthesis and Application* by Stephen R. Wilson and Anthony W. Czarnik (eds). John Wiley and Sons, New York, 1997, pp. 269, $69.95 (hardcover).**

Paul Wentworth Jr.



Combinatorial chemistry is a broad area of research encompassing the technologies involved in the rapid production of chemical compounds for the generation of molecular diversity. It is arguably becoming one of the most useful tools available to research chemists in their quest for molecules with new or enhanced properties. The combinatorial chemistry field is unique in that it comprises a close synergy between academic research and a whole generation of biotechnology and pharmaceutical companies.

Combinatorial Chemistry: Synthesis and Application reflects this union quite well. It is a well-presented volume consisting of authored chapters edited by Anthony W. Czarnik (IRORI Quantum Microchemistry) and Stephen R. Wilson (department of chemistry, University of New York), serving equally well as either a broad text for the newcomer to the area or as a reference book for the specialized researcher. The editors state that although the origins of combinatorial chemistry reside within peptide chemistry, the main focus of the book is on

Paul Wentworth Jr. is an assistant professor at the Department of Chemistry (BCC582), The Scripps Research Institute and the Skaggs Institute for Chemical Biology 10550 N. Torrey Pines Rd. La Jolla, CA92037. (paulw@scripps.edu).