# *Book Reviews*

**Good Manufacturing Practices for Pharmaceuticals (Drugs and the Pharmaceutical Sciences, 6th ed., Vol. 169).** Edited by Joseph D. Nally. Informa Healthcare: New York. 2007. 398 pp. $249.95, £125.00 (Hardcover). ISBN 978-0-8493-3972-1.

This volume will be invaluable to quality assurance managers in the pharmaceutical industry—particularly those with responsibilities in drug product manufacturing and distribution. Its direct relevance to active substance manufacturing is more limited, but its thorough coverage makes it a useful background reference nonetheless.

The preface highlights the extent to which the current good manufacturing practice (CGMP) compliance environment has changed in the 6 years since the previous edition appeared. Within that period the U.S. Food and Drug Administration (US FDA, whose regulations are the main focus of this book) has adopted risk-based regulation, encouraged quality-by-design submissions, and promoted a quality-systems approach and the greater use of process analytical technology. The FDA has also withdrawn previous guidance that appeared to conflict with these "21st Century" initiatives. The authors have updated their chapters with this new regulatory climate in mind.

Chapters 1−12 (just over half of the book) focus on the U.S. CGMP regulations themselves, taking each subpart in turn. The current text of the regulation is presented (usefully, with a distinctive grey background) interspersed at appropriate points with the authors' own discussion and expansion of the topic, thus adding meat to the bare bones of the regulations and providing insight on current interpretations. For example, the short paragraph 211.25 of the regulations, dealing with personnel qualifications, is followed by four pages of advice on the construction of training systems, job descriptions, training requirements, levels of training, qualification of trainers, training materials, evaluation, documentation, and record keeping. Some "suggested readings" are offered, although these references are not as extensive or up-to-date as I would have expected. Each chapter ends with a short section of citations from FDA warning letters relevant to the topic, but these are often very general (e.g., "Failure to conduct GMP training on a continuous basis". It would have been more useful to know something of the particular circumstances behind the citation and to have some editorial comment on it). Some chapters are also augmented with extensive excerpts from FDA Compliance Policy Guides, which give greater insight into their inspectional and enforcement approaches.

The second half of the book (Chapters 13−24) deals with more general topics which are not covered explicitly in the regulations. Among these are "Active Pharmaceutical Ingredients" (Chapter 17), possibly the topic of greatest interest to *Org. Process Res. Dev.* readers. Unfortunately, this short chapter (7 pages) does not follow the pattern set in the earlier part of the book, but only provides a summary of ICH's Q7A guideline; interested readers will learn far more by downloading that document itself. The following chapter on "Bulk Pharmaceutical Excipient GMPs" is more useful, partly because there is less official guidance in this area.

Two chapters are devoted to FDA inspections: Chapter 21 deals with inspections for compliance, Chapter 22 with preapproval inspections. Together, these provide useful advice to "inspectees", and a number of "do's and don't's". On the other hand, a disproportionate amount of discussion is devoted to the legal niceties involved—particularly the situation where a manufacturer refuses entry to the inspectors, requiring them to obtain a warrant. I would also question the relevance—in this particular context—of the extensive section on "Effectively Managing OSHA Inspections". It surprised me to learn (p 326) that in the United States today, 70 years after the passage of the Federal Food, Drug and Cosmetic Act, "perhaps as many as several thousand drug products are marketed illegally, without required FDA approval". Curiously, the manufacturers concerned are also subject to GMP inspections. Some historical reasons for the paradox are explained, and FDA's compliance policy for this situation is given in full.

Chapter 23 briefly considers "Worldwide Good Manufacturing Practices", particularly those of the European Union, the World Health Organization, and Canada. It mainly highlights the (relatively few, and minor) areas where these differ from the U.S. CGMPs—usually a difference in emphasis rather than substance. Other chapters are concerned with Repacking and Relabeling, Quality Systems and Risk Management Approaches, Clinical Trial Supplies (drug products rather than APIs), Contracting and Outsourcing, FDA Enforcement Activities (Recalls etc.), Controlled Substances Safeguards, and Quality Approaches (e.g., ISO9000).

Overall, this is a useful addition to the pharmaceutical library, but it is not essential reading for process or development chemists.

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