$$\frac{a_1a_2(\lambda_1 - \lambda_2)^2}{(a_1 + a_2)^3} = \frac{V_p}{D_{iv}}(k_{12}k_{21}) \qquad \text{(Eq. 32)}$$

$$\frac{a_1\lambda_2 + a_2\lambda_1}{a_1 + a_2} = \frac{V_p}{D_{iv}}k_{21} \qquad \text{(Eq. 33)}$$

$$-\frac{\lambda_1\lambda_2}{a_1\lambda_2 + a_2\lambda_1} = \frac{V_p}{D_{iv}}k_{el} \qquad \text{(Eq. 34)}$$

Derivation of Eq. 13—Using similar equalities based on model III (5, 10) Veng-Pedersen's Eq. 74 may be converted to Eq. 13.

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BOOKS

REVIEWS

Good Manufacturing Practices for Pharmaceuticals—A Plan for Total Quality Control. 2nd Ed. By SIDNEY H. WILLIG, MURRAY M. TUCKERMAN, and WILLIAM S. HITCHINGS IV. Marcel Dekker, New York, NY 10016. 1982. 259 pp. 15 × 23 cm. Price $49.75 (20% higher outside the U.S. and Canada)

In the preface to the second edition of this book, the authors state the following:

> "This volume is a revised and expanded second edition. Substantial changes have been made in organization in order to have the text follow 21 CFR 210 and 211 (43 FR 54076, September 29, 1978). Many examples of violations which led to recall have been added to the text in order to illustrate problems encountered by the industry and to suggest ways in which they could have been avoided. In addition, several new chapters, which are not direct comments on the regulations but which are, nevertheless, pertinent to compliance, have been added. These chapters deal with repackaging and relabeling; FDA inspection; recalls; safeguarding controlled substances; and how the manufacturer is designated on the label, as well as an appendix giving the standards for potable water. These additions, made in response to users of the first edition, should make this second edition even more useful."

This statement fulfills the promises of this excellent book. The authors present each of the parts of the Current Good Manufacturing Practices (CGMP) with clear explanations and discussions. They present, in detail, not only their own interpretation of the regulations, but relevant interpretations by others. The authors also include both their own and FDA views of the underlying CGMP regulations, specifically and overall, in a philosophical vein, a most refreshing approach. In addition, practical examples and court cases are presented where relevant.

Particularly useful are the authors' clear discussion and clarification of the intent of the regulations. These discussions frequently include additional information which can be very useful for professionals in the pharmaceutical industry. Some examples should give an idea of the kinds of material included in this volume:

- Details of screening, hiring, and administrating quality control personnel.
- Details of building specifications and segregation of pharmaceutical manufacturing facilities.
- A comprehensive list of raw material specifications.
- Details of paperwork including records, procedures, flow of records, assignment of control numbers, and storage.
- Receipt of raw materials and certificates of analysis.
- Analytical production and quality control procedures and controls.
- Description of labels.
- In-process controls.
- Laboratory controls: containers (glass and otherwise) and stability (physical, chemical, and container).
- Requirements and recommendations for records and reports. Design of records and reports—what kinds and how long to keep them.
- Numbering system for quality control records and systems.
- Problems with returned or salvaged product.
- FDA inspections and legal aspects.
- Recalls.

The CGMP regulations often are broad in their definitions. This book clarifies the regulations with many practical examples. The authors expand on the regulations, demonstrating their relation and applicability to the function and implementation of the Quality Control department. The authors further expand the discussion by freely offering their own opinions. Although one may not agree with their views all of the time, they are always stimulating and provocative. For example, the philosophy behind the following statement (page 22) could be fuel for a very interesting discussion:

> "The quality control supervisor must have a questioning nature. Some say a supervisor must be naturally distrustful. This applies to all matters in his or her area, including calculations and conclusions reached by peers and superiors from an organization viewpoint. It certainly applies to findings submitted by vendors and vendees of the operation and by its subcontractors. If the supervisor is other than such, the reputation will be that of a buck passer."

This unique and information-packed book should be an indispensable part of the libraries of all industrial pharmaceutical quality control, manufacturing, pharmacy, and legal departments.

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