Book Review

Bioprocessor Engineering: Systems, Equipment, and Facilities edited by Bjorn K. Lydersen, Nancy A. D'Elia, and Kim L. Nelson

Wiley, New York; 1994; ISBN 0471-035-440; 832 pp.; $89.95

As indicated by the subtitle, "Systems, Equipment, and Facilities," this book focuses on "plants, system components, and design issues" concerning bioprocess technologies. The spectrum of topics ranges from fermentor design to large scale cell culture, and from chromatography to CIP, WFI, and decontamination.

Let me state right at the beginning that I believe this book has the makings of a classic—my congratulations to the authors and editors for a much needed contribution to public literature. On the other hand, this first issue is not without some shortcomings! The book presents a well-conceived selection of topics, which are covered by a total of 31 authors. Given this large number, it is no wonder that the chapters vary somewhat in coverage and quality.

Overall, the information is topical and practical. In the preface, the editors note that the authors have "relied heavily on the experience gained in...their job—[they] were encouraged to give opinions on what they felt was the best approach [to solving problems]." Accordingly, individual experience and opinion weigh heavily in this book; the presentations provide a great deal of useful data derived from practical needs and experience. Despite the undoubted benefits of experience and opinion, these are subject to personal bias and, as this book illustrates, are sometimes at odds with fact. If opinion is presented as fact, how is the uninformed reader to know the difference between fact and fiction, especially in a book with "Engineering" in its title? Even the editors missed some blatant errors! It is particularly disconcerting when an erroneous statement is given apparent credibility by ascribing the erroneous information to a recognized reference.

One example is the statement on p. 759, "Quality Assurance must always be involved (in validation) to review and approve designs and validation tasks; this is a requirement to the CGMP." The authors would be hard pressed to find a definition of Quality Assurance in the *Current Good Manufacturing Practice Regulations* (US CFR Title 21, Part 211), let alone a definition of its required involvement with respect to design and validation, as indicated in this book. Those trying to define a role for QA based on this reference could find themselves with a weak defense.

In another example, a table (p. 706, Table 18.3) listing some specific "requirements for finishes" for floors, walls, and ceilings, is supported by a fictitious or erroneous reference to FDA Part 211 (presumably meaning CFR Title 21). The FDA had never issued such detailed specifications in a guideline (why should they?), let alone in Part 211, which is very general. I can only imagine that the authors obviously never bothered to read Part 211.

Perhaps what is most disconcerting about these errors is not that they exist—bugs exist!—rather, it is that they were so easy to find! Hopefully, these errors will be corrected in future editions.

Despite these errors and some misleading opinions, the book is still a rich source of information both for the young graduate, as well as the experienced professional.

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