guarantees a fast access to further information. Moreover, the lively style in which the chapters are written keeps the reader interested along the way.

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Biopharmaceutical Process Validation
Gail Sofer, Dane W. Zabriskie (Editors) Marcel Dekker, New York, 2000; ISBN 0-8247-0249-2

Being the 25th volume of Marcel Dekker's series on Biotechnology and Bioprocessing this book could be rated as an anniversary edition. After so many monographies dealing with almost every aspect of cell selection, fermentation, purification, etc., it is finally time for validation. Discussions on this topic always lead to the same question: how much is enough? Although everybody has accepted the necessity for validation there is no theoretical limit to the extent of validation measures and every person in a responsible position in biopharmaceutical processes is forced to make a decision on that point. It can be said that the book does an excellent job in helping to make such decisions as it provides basic knowledge as well as practical guidance.

Structured into 19 chapters, the contents of the book are clustered into four broader sections. The first four chapters on trends, concepts, regulatory background, experimental design and the approach of operational ranges for processes deal with the more general aspects of validation. Chapters 14 and 15 clearly belong to that section and it will remain the secret of the editors why they put them in the middle of the book. Starting with an historical definition of validation which could be dated 11 October 1974 as we learn here, these general introductions are really helpful for those who are experts in pure biotechnology (as a combination of biology and engineering) but not pharmaceutical development and regulatory issues. How to organize validation and how to deal with deviations and changes in processes over time are discussed.

The general part is followed by eight chapters (the core of the book), where the different process steps like cell line characterization, recovery, purification, chromatography, cleaning, etc., are laid out in detail with the scope on validation of the respective technologies. Chapter 13 is the third section dealing exclusively with the role of analytics in validation. It discusses the role during the typical development cycle of a product from early development to final manufacture, the validation of the analytical methods and finally the critical issue of comparability and equivalence which will be more than ever an issue of analytical data.

The book is closed by four chapters on special issues such as oligos, DNA vaccines and autologous cell therapies; these are emerging technologies where guidance on validation is still rare. With the exception of the aforementioned dislocation of certain chapters, I would rate the edition of the book as excellent; chapters 17 and 18, for example, are both on DNA vaccines and they complement each other with no redundancy at all. Generally, the length of the chapters also indicates a fine balance of weight. There are 40 pages on viral clearance and more than 50 pages on cell lines and cell culture, which gives an idea of the most challenging subjects in bioprocess validations.

In summary, this is a well written book which is full of scientific and development management information. It is recommendable to everybody in the biopharmaceutical industry with an interest in bioprocesses as well as to those still learning about the industry.

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