

BOOK REVIEW

Drug Biotechnology Regulation - Scientific Basis and Practices

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This wide ranging book has contributions from over fifty contributors! Not surprisingly therefore there is variety of styles, approaches and levels of treatment. A significant number of the contributors are from the Federal Food and Drug Administration and their specialist expertise undoubtedly supplies most useful input to the book. Although some contributions are lightweight and almost superficial surveys others are thoughtful, in-depth reviews which summarize complex situations in a masterful manner. Some chapters (e.g. nine) include extensive lists of pertinent, references - some as recent as 1990.

Among the topics covered in this book are: Production Facilities, Drug Manufacture, Characterization of Proteins Recombinant DNA Manufacture, Safety and Efficacy Evaluations and International Harmonization. There is a useful Appendix which reviews the current status of Government Regulation of Biotechnology. The subject index is rather sparse and the absence of an author index may well be regarded by some readers as a distinct disadvantage.

Overall this book is likely to prove a helpful reference for anyone involved in the development of protein drugs or devices. It will be useful to both scientists and regulatory affairs personnel.

STAFF REVIEW