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Book review

Development of Biopharmaceutical Parenteral Dosage Forms (Drugs and the Pharmaceutical Sciences, vol. 85)
Edited by John A. Bontempo, Marcel Dekker, New York, 1997. ISBN 0-8247-9981-X

The ability to develop and produce pharmaceutically acceptable formulations of biopharmaceuticals is increasingly important. These materials present major challenges, not least because they are inherently physically and chemically unstable and may possess widely differing properties. These themes run throughout the chapters of this book which provides a comprehensive guide to the formulation and production of safe, stable, sterile liquid biopharmaceutical products.

The book begins with a short general introduction to the development of biopharmaceutical formulations. Chapter two describes the features of the initial fermentation production process that impinge on the quality of the biopharmaceuticals. This includes useful tables of licensed products and those currently under investigation. The isolation, purification and characterisation of recombinant proteins and peptides are discussed in Chapter three, with particular emphasis on the industrially relevant issues of scale up, process control and validation. Chapters four and five cover the key aspects of preformulation and formulation development, including mechanisms of degradation and formulation requirements, such as protein stabilisers and other excipients. Chapter six describes the practical application of chromatographic and electrophoretic techniques to purify biotechnology products, together with techniques for determining bioactivity. Chapter seven provides an extensive introduction to the application of membrane filtration, including integrity testing and validation, to pharmaceutical liquids in general and protein solutions in particular. The final chapter describes the application, problems associated with, and testing of elastomeric closures for biopharmaceutical products. Further information on the selection and testing of appropriate packaging materials per se might have been usefully included here, though there is some limited relevant information in previous chapters.

This is a well written and edited text, though prospective readers should be aware that this book pertains only to liquid formulations for parenteral administration and that the development of lyophilized products is not covered. The book is extensively referenced, well illustrated and contains summary tables, which I found particularly helpful and informative. Reflecting the authorship of the chapters, *Development of Biopharmaceutical Parenteral Dosage Forms* will be of particular interest to readers seeking to learn more about the successful industrial development of biopharmaceutical products.

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