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Book review

Pharmaceutical Biotechnology: Fundamentals and Applications, 3rd ed., D.J.A. Crommelin, R.D. Schneider, B. Meibohm (Eds.), Informa, New York, 2007, 490 pp., Hardback: ISBN: 1-4200-6752-4, Textbook edition: ISBN-10: 1-4200-4437-0

It is a commonplace to state that biotechnology-based products are gaining an increasing foothold in therapies and that with this goes the task of formulating and delivering these often difficult molecules. But biotechnology is not a new subject: for example a special report of the UK's Medical Research Council on *Preservation of Proteins by Drying* authored by R.I.N. Greaves was published in 1946; insulin has been used therapeutically for over 80 years. Investment in the area has been enormous and yet still projects like inhalable insulin fail for one reason or another even after launch, as has been shown with Exubera, the inhaled insulin product marketed by Pfizer. It demonstrates the complex physical, chemical and biological nature of these molecules, and also the complexity of the marketplace. The holy grail of oral protein delivery has been fraught with problems, not least extrapolation from animal experiments to the human subject.

Pharmaceutical Biotechnology, now in its 3rd edition is better than ever. When the first edition appeared it broke ground in a textbook primarily directed towards pharmacy students in that it was not only authoritative but beautifully produced with colour diagrams of the sort that have long enhanced biochemistry and cell biology texts. Students nowadays perhaps equate appearance with value: if a book's layout is dull, perhaps the book is dull. Pharmacy students are no exception and have been made to do with a diet of rather lacklustre layouts in many of their prescribed texts. Of course design does not totally define the book in question. This is a very good book, which while written by some 51 contributors has been driven by the editorial eye of three experts in the field. Its 24 chapters range over the basic molecular biotechnology which is at the base of understanding, recombinant protein biophysical and biochemical analysis, through production and downstream processing and formulation and pharmacokinetics to regulatory issues. Chapters of greatest direct interest to readers of *IJP* include those on formulation and processing and also those on individual proteins or biotech classes: insulin, growth hormones, haematopoietic growth factors, interleukins and interferons. On sampling the chapter on formulation, one finds little change from the same chapter in the previous edition published in 2002. In a textbook (rather than a research monograph) this is fair enough as the topics covered are those that deserve attention: *inter alia*, excipients used in parenteral formulations (solubility enhancers, anti-adsorption and anti-aggregation agents, buffers, preservatives and osmotic agents), freeze drying and an exposition of routes of delivery. The four chapters on monoclonal antibodies have been updated in the light of recent advances in their application in cancer, solid organ transplantation and anti-inflammatory therapy. For the pharmacy student dispensing and related issues with biotechnological products are discussed in another chapter.

The chapter on gene therapy is another which has seen extensive rewriting with a new author who cites a large number of recent references. There is a danger that these chapters become research summaries rather than didactic exercises and it is always difficult for authors to draw the line. The slow progress of gene therapy, all aspects of which are described, simply underscores the complexity of the issues dealing with the delivery of labile macromolecules to individual cells, not in culture, but *in situ* in patients.

A comprehensive index assist navigation through this book, which should be the standard textbook in this field, principally because it deals not only with biological aspects of the topic but also with the task of assessing the quality of the molecules concerned, achieving stable formulations, processing these into medicines and determining safe delivery. The textbook edition contains a useful section on "Essential Questions" (and answers are included) to put the finishing touches on an outstanding text.

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