Anurag Singh Rathore, Gail Sofer (Eds.), Process Validation in Manufacture of Biopharmaceuticals Guidelines, Current Practices and Industrial Case Studies (Taylor & Francis, USA – New York) $ 199.95, ISBN 1-57444-516-2

Process validation is always a complex multi-disciplinary task, and the production and purification of biotechnological APIs has its unique challenging aspects. In 14 chapters written by 38 expert contributors, this book covers a wide range of topics, ranging from broad "Introductory Guidelines to Process Validation" to highly specific ones like "Adventitious Agents: Concern and Testing for Biopharmaceuticals", where the elimination of viruses, bacterial and fungal contaminants, mycoplasms and prion proteins is discussed.

As stated by one of the editors, there is no shortness of regulatory guidelines in this area, but specific examples are not all that common, and they are given in nearly all of the chapters. The book offers a historical perspective including organizational changes in the FDA and their relevance for the industry as well as an outlook to impending developments.

A global subject discussed in several contributions is the risk-based approach to validation, where the FMEA approach is presented in detail and applications to process development and computerized systems are given. Other points in focus are clean-up procedures, where "Scale-Down Models for Purification Processes", "Life Span Studies for Chromatography and Filtration Media" and "Validation of a Filtration Step" are addressed and a broad overview of "Analytical Test Methods for Biological and Biotechnological Methods" is given.

In most chapters, the point of view is that of an experienced industrial scientist and practitioner, but two chapters stand out for their bird's view perspective: "Facility Design Issues – A Regulatory Perspective", where FDA requirements are reviewed in detail and "Validation of Computerized Systems", where the ramifications of 21CFR Part 11 and strategies to take advantage of current and future IT/IS options are presented.

The final four chapters are case studies for the optimization and validation of a viral clearance process and the purification of a bacterial protein, a radiolabelled monoclonal antibody and of a polysaccharide-based vaccine.

The hands-on approach makes this book interesting and a valuable complement to the mandatory reading of official guidelines. The topics are carefully selected and cover a wide range, where some points are elucidated from different perspectives. Representative examples make novices aware of the pitfalls and options and may recall similar experiences in seasoned readers. This is a highly recommended review for a broad readership in Process Development, Quality Assurance, Production and Regulatory Affairs departments and for students and scientists in the biomedical sciences.

Richard Süverkrüp*
Department of Pharmaceutical Technology, University of Bonn, Gerhard-Domagk-Str. 3, 53121 Bonn, Germany
E-mail address: sueverkruep@uni-bonn.de

Available online 22 March 2006

* Tel.: +49 228 7352 33; fax: +49 228 7352 68.
doi:10.1016/j.ejpb.2005.12.002

Jörg Knäblein (Ed.), Modern Biopharmaceuticals. Design, Development and Optimization, Volumes 1, 2, 3, 4, (Wiley-VCH Verlag, Weinheim, Germany) 1866 pp, € 599, ISBN 978-3-527-31184-2

This is a most remarkable set of books. Let me just quote a few lines from the prologue entitled "mens sana in corpore sana". "I have a dream . . .". Once, on an early Sunday morning in 2003, "the 50th anniversary year of DNA discovery", I woke up and had the idea to bring together all the world-renowned leaders from biotech academia and industry, in order to publish a comprehensive book on modern biopharmaceuticals. As learned from nature, some things happen best – if at all – spontaneously. So, I contacted some of my friends, presented the idea, and discussed with them the current hot topics in the Life Sciences arena. Very quickly a list with topics and authors emerged, which I presented to Wiley-VCH – and they spontaneously agreed to publish this book'. One of these friends was Francis Crick, who replied "Nice of you to ask me to contribute to your book on biopharmaceuticals . . . Unfortunately I am in very poor health so do please excuse me. Apologies, Francis Crick." Contributions to the prologue were, however, given by Robert Hubert, James Watson, Aaron Klug, Stanley Cohen, Kary Mullis, and Paul Lauterbur. These scientists are all Nobel prize winners; and I think James Watson needs no further introduction. Let us just pause for a moment to take breath, before I continue with the so-called Executive Summary at the beginning of the first volume.

This more than 50-page long summary of the contents of all four volumes certainly helps the reader negotiate a path through the numerous chapters. The editor cannot resist sprinkling the text with literary citations, starting with Ralph Waldo Emerson's "Men love to wonder, and that is the seed of science". This citation is approximate for the development of modern biotechnology and has certainly evidently inspired the editor of these volumes. Volume 1 contains a brief overview of the current states of biopharmaceuticals, 15 chapters detailing biopharmaceuticals used in molecular medicine. We find here chapters on pharmacokinetics, pharmacogenomics, genetic variation, adenovirus-based gene therapy, DNA-based molecules for gene therapeutics, and other examples of gene- and cell-based therapies. Two particular products, Herceptine and Spheramine, are presented in some detail. These chapters are

comprehensive in their scope, well written, and of high standard. This approach continues into Volume 2 in which the mode of action of biopharmaceuticals is considered, as well as ways of improving the development of biopharmaceuticals. The pharmaceutical technologist finds at least 3 chapters in this volume that will interest him. These are biopharmaceutical drugs from natural sources, biopharmaceuticals as targeting vehicles for in situ radiotherapy of malignancies, and new directions in tumor therapy – amino acid depletion with GlutaDON as treatment for cancer. Further chapters of interest include a description of ultra-high-throughput screening, gene transfer using the so-called Gateway system, and the use of knock-out mice in development of biopharmaceuticals. This is all excellent, detailed work, fully referenced. Volume 3 concerns the production of biopharmaceuticals and contains numerous chapters of general interest for the pharmaceutical reader. Bioreactors containing cultivated mammalian cells are presented in some detail, as well as techniques for deriving biopharmaceuticals from plants. We find further chapters on insulin, insect cell culture processes, producing biopharmaceuticals in the desert, and even a chapter devoted to contract manufacturing of biopharmaceuticals. The second part of volume 3 is devoted to biopharmaceuticals for diagnostics and imaging. The final volume 4 of this series also contains a lot to interest to the pharmaceutical reader. Here we find chapters on advanced application routes for biopharmaceuticals, including descriptions of advanced drug delivery systems, polyethylene glycol conjugates, novel vaccine adjuvants, improving the oral absorption of peptides, microspheres, liposomes, and bionanotechnology. The volume concludes with a "happy end" in which regulatory affairs are discussed as well as global changes in the health care systems and the impact of these on development of modern biopharmaceuticals.

The book contains 77 chapters, which according to the editor recapitulate the 77 electrons in the iridium atom. There is no denying that this is an excellent work. There is a lot of biochemistry and molecular biology to be found which is, perhaps, only of general interest for a pharmacist. There are, however, sufficient chapters of outstanding quality to be found that deal with subjects of relevance to pharmaceutics, biopharmaceutics, and pharmaceutical technology. Now, the potential buyer will be shocked by the price: almost 600, – €. If, however, your departmental library has the available financing, I would strongly recommend purchase of these four volumes. This is a quite outstanding work. And don't forget that James Watson writes "With 'Modern Biopharmaceuticals' Jörg Knäblein presents an outstanding collection of articles from ground breaking scientists, comprehensively describing the many ways cells are being deployed towards human good". There is no possible way that I, as the modest reviewer of this work, can improve on that.

Geoffrey Lee*
Department of Pharmaceutics,
Friedrich-Alexander-University,
Lehrstuhl für Pharmazeutische Technologie,
Cauerstr. 4, 91058 Erlangen, Germany
E-mail address: lee@pharmtech.uni-erlangen.de

Available online 27 March 2006

* Tel.: +49 9131 85 29552; fax: +49 9131 85 29545.
doi:10.1016/j.ejpb.2005.12.003