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.

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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