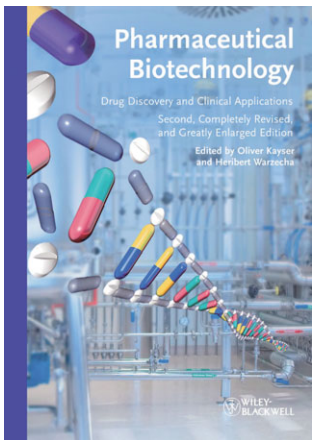
Book review: *Pharmaceutical Biotechnology: Drug Discovery and Clinical Applications* (2nd Edition)



Oliver Kayser and Heribert Warzecha (Editors), Wiley-VCH, Weinheim, Germany, 2012, 676 pages. ISBN: 978-3527329946

Today, many new biological therapeutic drugs can be characterized as mutated recombinant proteins (muteins), or as more significantly backbone-modified proteins, which was the exception in 2004 when the first edition of this book was published. Therefore, this second edition is essential reading.

This completely revised, updated, and greatly enlarged second edition of *Pharmaceutical Biotechnology: Drug Discovery and Clinical Applications* reflects the increasingly important role of molecular biology and genetics in the pharmaceutical industry. The first edition (2004) focused on simple biological molecules as potential drugs, whereas this new edition includes production strategies for novel therapeutic proteins, peptides and vaccines, with an additional section on recent applications in ultrahigh-throughput screening, metabolic engineering, personalized medicine, xenotransplantation and nutraceuticals.

This book consists of four major parts: Part One covers concepts and methods for recombinant drug production in six chapters, beginning with an excellent overview by the editors, Oliver Kayser and Heribert Warzecha (Chapter 1). Chapters 2 and 3 include production of proteins in prokaryotes and in mammalian cells. An interesting overview of the production of natural products in microorganisms is also presented and discussed in Chapter 2. Chapters 4 and 5 introduce the production of biopharmaceuticals in plants and transgenic animals. Part One concludes with Chapter 6, a comprehensive overview of a systems biology approach to new technologies in biomedicine.

This second edition is essential reading

Part Two (Chapters 7 – 14) begins with an overview and classification of approved recombinant drugs, and covers trends in drug approvals. The first chapter in Part Two provides a very informative table of 115 approved recombinant drugs, including the molecular class and type of expression system used to produce each drug (Table 7.1).

In Part Two, drug formulation and manufacturing processes are in focus, as are bioanalytical methods and quality control. Part Two discusses recombinant therapeutic proteins that are currently in clinical use. This section describes European and US drug approval processes (Chapter 11) and legal aspects of drug patenting (Chapter 12). Chapter 12, "Patents in the Pharmaceutical Biotechnology Industry", begins a bit too simplistically; a more in-depth view in the author's area of expertise of bioethics in drug and diagnostic patents with more specific case studies would have been beneficial. While important patent information on biosimilars and follow-on biologics are covered in Chapter 13. Following the chapter on drug patenting, Chapter 13 provides an analysis of biosimilar drugs – especially important as branded biologics go off patent. New and adapted pathways for approval of biosimilars from the regulatory bodies EMA (European Medicines Agency) and FDA (US Food and Drug Administration) are discussed in Chapter 11.

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Recent advances in protein engineering strategies, on which new protein drugs with improved pharmacokinetic and pharmacodynamic profiles are based, are reviewed in Chapter 14. In designing and engineering new muteins, utilizing glycoengineering, post-translational modifications, and non-natural polymers such as polyethyleneglycol (PEG), drug developers have developed modified proteins for approximately 80% of approved protein therapeutics, as described in Chapter 14.

Part Three includes three chapters (Chapters 15 – 17) on vaccines, from research and development to vaccine production and applications. In this section, the emerging diversity of new vaccine research and development is described, including a chapter on nanobiotechnology strategies (Chapter 16). This vaccine section also provides an overview of nanocarriers for cancer vaccines and as future drug delivery systems. Chapter 17 reviews recombinant vaccine development since the 1980s, and employs selected examples of vanguard vaccine technologies to illustrate key issues. This chapter includes a dis-

cussion of the politics involved in executing global clinical trials for a malaria vaccine in sub-Saharan Africa versus in the United States, and a list of five important diseases for which there are currently no adequate vaccines.

A distinguishing feature is the inclusion of nutraceuticals as well as drugs and natural products from medicinal plants and microorganisms

Part Four covers recent applications in pharmaceutical biotechnology, including Chapter 18 on ultrahigh-throughput screening and in silica screening for drug discovery. This chapter describes novel approaches including application of stem cells and model simulations for drug screening. Chapters 19 and 20 review metabolomics of medicinal plants for characterization and production of natural products, including a discussion of transgenic plants as future green factories.

Chapter 21 is devoted to the integration of biotechnology and personalized medicine, including recent developments in personalized cancer vaccines. The discussion of xenotransplantation in Chapter 22 provides insight into the possibilities for growing, in pigs and other organisms, human organs for transplant, and the potential of stem cell therapies and tissue engineering for xenotransplantation. Finally, Chapter 23 describes nutraceuticals for improving human health and preventing disease. Two distinguishing features of *Pharmaceutical Biotechnology* are the inclusion of nutraceuticals and a review of the development and production of drugs and natural products from medicinal plants and microorganisms.

The extensive index is quite useful for the seasoned drug development professional and for the new researcher.

The design of engineered proteins and integrated manufacturing processes continues to increase in complexity, including new technologies such as nanobiotechnology, synthetic biology, and de novo protein design in silico. As well described within this book, the pharmaceutical biotechnology industry is based on discovery and development of innovative and safe drugs, and also on cost effectiveness and performance. Embedding synthetic biology and integrating biotechnology and genomic sciences into the drug development process, as described here, enhances the prospects of bringing drugs to the market earlier and more cost efficiently. Perhaps missing from *Pharmaceutical Biotechnology* is a chapter on the economics of recombinant protein production and the insights and parameters for pricing newly approved protein drugs.

***Pharmaceutical Biotechnology** is in touch with the industry's needs and challenges*

Pharmaceutical Biotechnology is in touch with the industry's needs and challenges, and provides answers to questions about new developments in recombinant protein production, host organism selection, and future platform organisms for biosynthesis and vaccine production. This book also provides insight into biological generics, drug formulation, and legal aspects of biotechnology.

Overall, this second edition of *Pharmaceutical Biotechnology* provides an excellent "primer" for the interested student reader and an update for the seasoned professional in this fast moving field of science.

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About the book editors

Oliver Kayser received his PhD at the Free University Berlin, Germany in 1997. Following his fellowship at the University of Gainesville, Florida, USA, whereupon he entered the pharmaceutical biotechnology industry. He was appointed as Associate Professor at the University of Groningen, the Netherlands, and he took over as the Chair of Technical Biochemistry at the Technical University Dortmund, Germany in 2010. He is Guest Professor at the Medical University of Poznan, Poland, and his research fields cover pharmaceutical biotechnology, synthetic biology and plant biochemistry.

Heribert Warzecha studied pharmaceutical sciences at the Johannes Gutenberg-University, Mainz, Germany. After completing his PhD in 1998, he worked first as a postdoctoral fellow at Cornell University, USA, and from 2001 at the Department of Pharmaceutical Biology in Würzburg, Germany. Since 2007 he is Professor for Plant Biotechnology at the Technical University Darmstadt, Germany. There he works on the production of pharmaceuticals, both small molecules and proteins, in plants.