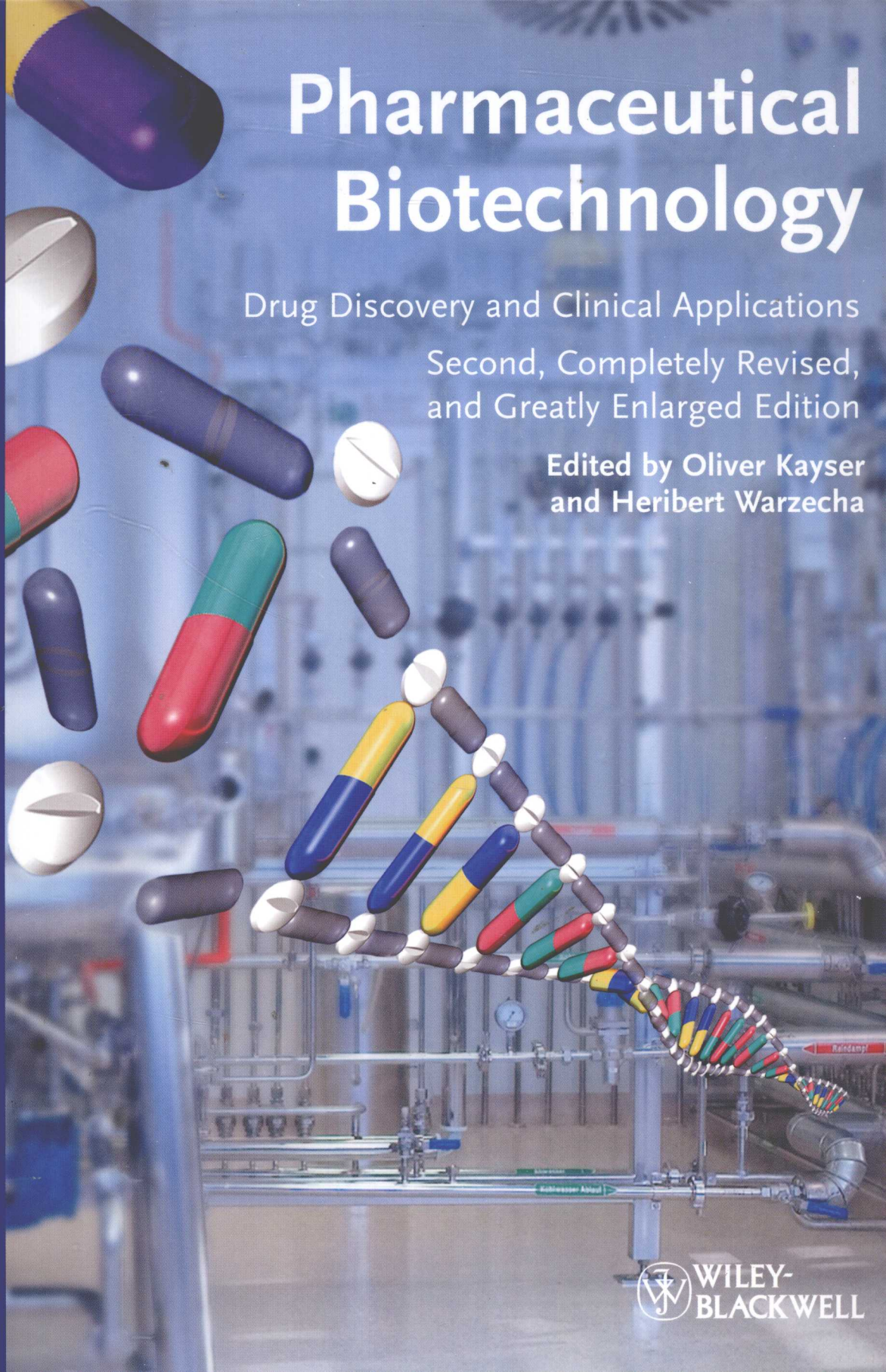
Pharmaceutical Biotechnology

Drug Discovery and Clinical Applications

Second, Completely Revised, and Greatly Enlarged Edition

Edited by Oliver Kayser and Heribert Warzecha



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Preface to the 2nd Edition

Pharmaceutical biotechnology has emerged as one of the major disciplines for drug discovery and development. In the past, the pharmaceutical branch of biotechnology – the former red biotechnology – was limited to fermentation and production of recombinant therapeutic proteins. Today, the shape and vision of pharmaceutical aspects and challenges have completely changed, and the prefix "pharma" can also be accepted as a synonym for integrated life science approaches, ranging from genetics to molecular biology to diagnostics, with the common goal of delivering the best drug to the patient by biotechnological techniques.

If we take a look at the first edition of *Pharmaceutical Biotechnology*, we see that the focus was more on molecules as potential drugs and less on the production strategies and the molecular concepts behind. The completely updated and rewritten second edition reflects the emerging trend in the pharmaceutical industry where molecular biology techniques and genetics play an increasingly important role. Today, many new biological entities can be characterized as muteins or significantly backbone-modified proteins, an exception in 2004 when we published the first edition (see insulin muteins). We are glad that we were able to attract the majority of the authors from the previous edition as experts. They reviewed the latest trends in their subjects of expertise and shared their experience and open opinion about the developments from the recent years to the near future. Pharmaceutical biotechnology and the pharmaceutical industry is a fast moving business and we all know that the future is hard to predict, but we are glad that with the selected contributors being in touch with industrial needs and challenges, we made the right choice to give answers to the readers' questions not only about new developments in protein production, host organism selection, and future platform organisms for biosynthesis and vaccine production, but also on biological generics, drug formulation, and legal aspects of biotechnology. In this textbook you will find updated facts and figures about the pharmaceutical industry and the latest drug approvals. In the first part a detailed discussion is provided about production systems for the biosynthesis of both low molecular weight drugs and proteins in prokaryotic and eukaryotic cell cultures and organisms. In the second part the drug formulation and manufacturing process is in focus, but we also want to highlight quality control and bioanalytical aspects, which have been largely neglected before. Therefore, this second part is now updated and dedicated to the

recombinant therapeutic proteins and vaccines that are already in clinical use, as well as requirements for quality control. In contrast to the first edition we recognized that drug regulation and quality assurance are becoming more important, while the legal aspects of drug patenting, and the drug approval process are again emphasized. In the third part we had a hard task of sorting and structuring the emerging diversity of research and development in this field and bring it under one single chapter. This is nearly impossible, but our aim is to guide the reader through the new upcoming lines of research impacted by genetics, synthetic biology, and nanobiotechnology. Finally we selected chapters showing exemplarily ongoing research trends that, hopefully, will find their way into clinical applications in the future or as approved drugs into the second edition of this textbook. Well-updated by authors from the previous edition, we learn about personalized medicine and xenotransplantation, and we are proud to introduce new contributors telling us about nanocarriers as future drug delivery systems, ultrahigh-throughput screening for accelerated drug discovery, and transgenic plants as future green factories.

The editors want to thank all the authors for their valuable contributions and the time they have invested in this work. We know very well that time was and is a scarce resource and that the chapters were written alongside the authors' regular duties. Special thanks also to the families behind for their patience and understanding why time was spent in this project. Special thanks to Anne Chassin du Guerny and Gregor Cichetti of Wiley-Blackwell for their professional support in the layout, proofreading, and production of this textbook.

We know that this book is far from being complete and we are aware that by the day of publishing it could be updated again. But our intention is to provide a "primer" for the interested reader to start working and to show how exciting research is in this fast moving field of life science.

Dortmund and Darmstadt, January 2012

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