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Structured like a textbook, the second edition of this reference covers all aspects of biopharmaceutical manufacturing, including legal and regulatory issues, production facility design, and quality assurance, with a focus on supply chain management and regulations in emerging markets and cost control.

The author has longstanding industrial expertise in biopharmaceutical production and years of experience teaching at universities. As such, this practical book is ideal for use in academia as well as for internal training within companies.



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Editorial Review

Review

"It is unusual to find a book of such complexity and diversity written by a single author. Clearly Stefan Behme has been involved in all aspects of manufacture of pharmaceutical proteins whilst at Bayer and Bayer-Schering, and this experience shows in the depth of understanding of each topic, and the inter-relationship between the various sections on technology which includes chapters on the manufacturing process and on analytics, pharmacy, QA, pharmaceutical law, production facilities and economy...The author covers a vast amount of material in the almost 400 pages, and this is valuable, since there are few books on pharmaceutical manufacture. His industrial practice and understanding of the multi-disciplinary nature of modern manufacture shines through each chapter. As a result, a highly readable and comprehensive book has been produced. Highly recommended to those needing an appreciation of industrial manufacturing of biopharmaceuticals." (*Organic Process Research and Development*, January 2011)

"This volume will be an excellent introductory course for the subject matter." (*New Biological Books*, June 2010)

"A timely addition ... [to] the field of protein production, analytics, biotechnology and regulatory affairs. The clear layout of figures and the use of color, when needed, help the reader to gain a quick understanding of topics such as production planning ... The large number of topics covered here turns this book into a rich source of information ... Students can benefit from this book by finding answers quickly and familiarizing themselves with topics usually not presented in one text book. Many others involved in the manufacturing and marketing process of biopharmaceuticals such as lawyers and business developers can learn more about technical aspects of protein production. The author contributes with this book to closing the 'language gap' between all disciplines involved in the highly complex manufacturing process of pharmaceutical proteins." (*ChemMedChem*, October 2009)

From the Back Cover

Structured like a textbook, the second edition of this reference work covers all aspects of biopharmaceutical manufacturing, including legal and regulatory issues, quality assurance, production facility design, as well as investment and production cost calculation. It combines these aspects into an holistic view of production concepts, enabling the reader to understand the overall picture of the multidisciplinary factors influencing biopharmaceutical production. The author has longstanding industrial expertise in biopharmaceutical production and years of experience of teaching in universities. As such, this practical book is ideal for use in academia as well as for internal training within companies.

About the Author

Dr. Stefan Behme is the department head of Strategic Sourcing Finished Products, Contract Manufacturing at Bayer Healthcare, Berlin. Before that he worked with biotech operations of Bayer, taking care for external manufacturing cooperations for biotechnological production. Stefan started his industrial career with Bayer in the engineering department, managing healthcare investment projects in Germany and the US. From 2006 through 2010 Stefan worked as lecturer at the Universitys of Dortmund (Germany) and Berlin teaching GMP aspects of biopharmaceutical manufacturing and production processes in life sciences. In 2009 he published the book "Manufacturing of Pharmaceutical Proteins - from Technology to Economy". Stefan received his Master's degree in chemical engineering and worked after that as assistant teacher in the

field of macromolecular thermodynamics at the Technical University of Berlin where he also earned his PhD degree.

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