



The Business of Bioscience: What goes into making a Biotechnology Product

By Craig D. Shimasaki

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My journey into this fascinating field of biotechnology started about 26 years ago at a small biotechnology company in South San Francisco called Genentech. I was very fortunate to work for the company that begat the biotech industry during its formative years. This experience established a solid foundation from which I could grow in both the science and business of biotechnology. After my fourth year of working on Oyster Point Boulevard, a close friend and colleague left Genentech to join a start-up biotechnology company. Later, he approached me to leave and join him in of all places – Oklahoma. He persisted for at least a year before I seriously considered his proposal. After listening to their plans, the opportunity suddenly became more and more intriguing. Finally, I took the plunge and joined this entrepreneurial team in cofounding and growing a start-up biotechnology company. Making that fateful decision to leave the security of a larger company was extremely difficult, but it turned out to be the beginning of an entrepreneurial career that forever changed how I viewed the biotechnology industry. Since that time, I have been fortunate to have cofounded two other biotechnology companies and even participated in taking one of them public. During my career in these start-ups, I held a variety of positions, from directing the science, operations, regulatory, and marketing components, to subsequently becoming CEO.

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Editorial Review

From the Back Cover

The Business of Bioscience: What goes into making a Biotechnology Product captivatingly describes the unique and challenging facets within the exciting field of biotechnology business and medical product innovation. Biotechnology is the melding of business and science and, therefore, creates different challenges than those faced by other industries. There are longer development times, costly product development and clinical trials, unique talent requirements, and a changing regulatory environment. In this book you will find practical answers to: Why does it take so long to develop a biotechnology product? What is involved in making a therapeutic or diagnostic? How much money is needed to develop a product idea from bench to bedside? What are the characteristics and backgrounds of entrepreneurs who lead these organizations? How do you go about starting a biotechnology company? This book contains a wealth of technical, business and leadership insights conveyed with a "behind the scenes" look into the everyday challenges in biotechnology product development.

The Business of Bioscience is written in a step-wise fashion building upon precepts and summarizing best practices for establishing and growing a successful biotechnology company. Content is presented in a way that is applicable to the novice, through to the experienced biotech or pharmaceutical executive and will interest all audiences having an interest in this dynamic field. Fundamental topics are covered in informative and interesting detail such as the selection of product development milestones and their impact on the valuation of the company, choosing a company business model and managing risk, hiring a biotech dream team, the virtual company, the regulatory process for approving products through the FDA, clinical trials and objectives and raising multiple forms of capital. Within this book you will also learn practical aspects that can be applied to virtually any organization. Such topics include developing a company culture and its hidden competitive strength; leadership and core values – not just for managers but for all employees; the organizational life stages of a company, when and why management style needs to change. This book is a tremendous resource for scientists, professors, medical researchers, pharmaceutical industry employees, venture capital professionals, biotechnology research analysts, business persons, MBA students and those who have a curiosity about what goes into the development of a biotechnology product. For more information please visit: www.businessofbioscience.com.

About the Author:

Dr. Shimasaki has over 25 years of practical experience in the biotechnology industry and as a serial entrepreneur co-founded three biotech companies. Within these companies he has held a variety of positions, including Director of Project Planning, Executive VP of Research, VP of Operations, Chief Operating Officer, and CEO. He has raised multiple rounds of capital, both private and public and has been involved in most every facet of a biotech start-up. He is intimately familiar with the challenges of product development, and led international clinical testing and regulatory approval processes for multiple products through the FDA. He is an inventor of numerous patents for both diagnostic and therapeutic applications. His passion is for the establishment and growth of biotechnology companies focused on developing life-saving products that significantly impact the health and well being of others. He has written this book to provide insight into the inner workings of biotech product development and the practice of starting and building a biotech

business. His desires is to share his experiences in the dynamic business of bioscience to help others gain wisdom so they can better manage the risks associated in building a biotechnology company. Dr. Shimasaki received his B.S. in Biochemistry from the University of California at Davis and his Ph.D. in Molecular Biology and Biotechnology from the University of Tulsa and his M.B.A. from Northwestern University's Kellogg School of Business.

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