

Biotechnology Entrepreneurship: Leading, Managing and Commercializing Innovative Technologies. Edited by Craig Shimasaki

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Article History

Received: 18/03/2021
Accepted: 05/05/2021

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ABSTRACT

Biotechnology Entrepreneurship aims to serve as a practical guidebook for readers interested in starting, growing, and managing biotechnology companies. The book is written to provide a comprehensive guide about several concepts required to operate and thrive in the biotech industry to the next generation of biotech entrepreneurs. It is an invaluable companion to research and business executives, current entrepreneurs, and students in the biotechnology industry. This book would also appeal to professionals serving the biotechnology industry, government leaders, and policymakers in the life-sciences sector. Biotechnology Entrepreneurship: Leading, Managing, and Commercializing Innovative Technologies highlights key concepts and issues in biotechnology entrepreneurship necessary to build and manage successful biotechnology companies.

Biotechnology Entrepreneurship¹ aims to serve as a practical guidebook for readers interested in starting, growing, and managing biotechnology companies. The book is written to provide a comprehensive guide about several concepts required to operate and thrive in the biotech industry to the next generation of biotech entrepreneurs. It is an invaluable companion to research and business executives, current entrepreneurs, and students in the biotechnology industry. This book would also appeal to professionals serving the biotechnology industry, government leaders, and policymakers in the life-sciences sector.

The book is divided into 9 sections having overall 42 chapters. Section I and Section II

provide an introduction to biotechnology entrepreneurship and an overview of the industry. Section III to Section VI explore the role of human capital, technological innovation, enterprise framework, and financial capital in a biotechnology venture. Section VII to Section IX focuses on practical aspects such as the Development and Commercialization of products, Market outcomes, and Corporate strategies for a biotechnology company.

Chapter 1, by Craig Shimasaki, introduces the subject of Biotechnology Entrepreneurship to the readers. It starts with establishing the importance of skilled entrepreneurial leaders in the biotech industry. Next, the chapter outlines the unique aspects of entrepreneurship in the

biotechnology industry. Finally, the author discusses an ideal biotechnology entrepreneur's background and characteristics. This chapter has done commendable work in extending these concepts for intrapreneurs within a biotechnology organization who do not intend to start their own company. Such an inclusive outlook appeals to several readers who are exploring a variety of roles in the biotechnology industry.

Chapter 2 and Chapter 3 provide case studies of three biotechnology entrepreneurs - Henri A. Termeer, Dr Magda Marquet, and Dr Francois Ferre. In chapter 2, Genzyme's former CEO and legendary entrepreneur, Henri Termeer has shared his entrepreneurial journey in transforming Genzyme from an early-stage start-up to an international biopharmaceutical company. He has also shared his views and advice on the characteristics of a successful biotech entrepreneur which are derived from his own experiences of the biotechnology industry. Chapter 3 discusses the experiences of two San Diego life-sciences entrepreneurs - Dr Magda and Dr Francois in founding and managing Althea Technologies, a successful gene therapy company with over 24.1 million USD in funding later acquired by Ajinomoto group. Overall, both these chapters provide inspirational guidance and advice about how to become successful biotechnology entrepreneurs to the readers.

In Chapter 4, Dr Langer describes the seven characteristics of successful biotechnology leaders. He outlines the required skillset in leaders of biopharmaceutical companies to face complex challenges such as regulatory

affairs, extreme product development costs, and organizational growth. This chapter reiterates the need to be adaptable and lead effectively using different styles of leadership in this highly dynamic industry. Section II provides an overview of the biotechnology industry. Here in Chapter 5, James Greenwood discusses the components and several dimensions of the modern biotechnology industry which is estimated to be a 400 billion USD global industry as of 2017. This chapter outlines some of the breakthrough innovations impacting human life in Health Biotechnology, Agricultural Biotechnology, Industrial Biotechnology, and Environmental Biotechnology. Finally, the chapter concludes by discussing the role of public policy in supporting biotechnology innovation and summarizes some foundational laws and policies that have nurtured the robust biotechnology industry in the United States.

Chapter 6 discusses the strategy for creation and development of biotechnology clusters in a region. The author has provided insights and suggestions about the role of different factors in the growth and expansion of biotechnology hubs. Such knowledge can be very useful for policymakers, government agencies, and academic institutions that wish to avail the economic benefits, job growth, and quality-of-life impact accompanying biotechnology cluster growth in their area.

Section III discusses the human capital component of biotechnology entrepreneurship. Chapter 7, by Dr Boni, Dr Todorova, and Dr Weingart, presents the principles and approaches for creating and managing a skilled workforce that builds the

innovative and entrepreneurial culture in an organization. This chapter also fairly presents the innovation ecosystem and organizational culture of the biotechnology industry. The readers would surely hone their entrepreneurial leadership skills from the strategies and knowledge discussed on building collaborative and interdisciplinary teams in this chapter.

Chapter 8, discusses the role of networking and creating purposeful relationships for entrepreneurial success. This chapter also outlines the value of the right advisory boards and board of directors in the growth of a biotechnology company. Senior-level executives and experienced professionals in the biotech industry would have a keen interest and benefit in forming productive business relationships following the content of this chapter. Chapter 9 presents the aspects and role of mentorship in a biotechnology entrepreneur's career path. Individuals can use the knowledge provided in this chapter to learn the mentoring process and engage in robust mentorship relationships.

Section IV presents the technological innovation component of biotechnology entrepreneurship. Chapter 10 provides an overview of the biotechnology product sectors. Here, Dr Shimasaki has provided the cost estimates and timeframes required for the development of various biotechnology products in the major sectors of the biotechnology industry. This chapter is a good reference to understand the technical and regulatory hurdles in different biotech sectors. Chapter 11, presents a framework to evaluate the commercialization and market potential of

new technology product ideas. A more unique aspect covered here is the due diligence approaches to assess the underlying science of a technology and determine a product's market potential for best market application. The criteria established in this chapter for technology evaluation would be very insightful for investors, commercialization executives, and technology transfer managers in the biotechnology industry. However, this chapter could have provided more utility to the readers if the author had outlined the valuation models and procedures used to perform these technological assessments in a practical application.

Chapter 12 discusses relevant business models for companies operating in different biotechnology sectors. This chapter outlines common business models employed in the biotechnology industry and also discusses the merits and drawbacks of each model. Also, each section of this chapter provides examples of companies that operate on a particular business model. Such examples are very helpful for readers looking to gain inspiration from companies with similar ideas and operational structures of their own start-up. Finally, this chapter concludes by discussing strategy for the selection of optimal business models that provide sustainable competitive advantage and minimize the risks of failure. Here, the author has provided the Biotechnology Company Evaluation Tool to assess any company's risks, which is very helpful for early-stage entrepreneurs in creating a business plan for their idea.

Chapter 13 complements the concepts discussed in the previous chapter by

presenting tools such as Business Model Canvas to optimize business models of prospective companies. The author has emphasized the need to identify the underlying platform technology and direct the technology towards a market problem by providing a case study of Selexys pharmaceuticals. This chapter has provided an excellent demonstration of the use of the Business Model Canvas for understanding the nine business model segments to ultimately create an optimal hybrid business model. Such an approach can be utilized by biotech entrepreneurs to recognize the true need and value of their innovation and would also generate greater interest from funding and strategic partners in their company.

Section V presents the structure and framework for the emerging biotechnology enterprise. Chapter 14 discusses entity formation, ownership structure, and fundraising for biotechnology start-ups. This chapter introduces several factors such as the tax implications, governance, securities laws, and investor requirements to decide on the choice of an entity and organizational structure of a company. Chapter 15 by Steven Ferguson and Uma Kaundinya has focused on technology transfer from universities and federal labs. This chapter provides an overview of the licensing and technology transfer practices at these non-profit organizations. Bioentrepreneurs interested in accessing research and inventions from such federally funded sources would highly benefit from reading this chapter. The readers employed in technology transfer offices of these organizations would equally benefit from

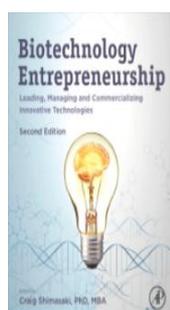
understanding the licensing principles of different technology transfer vehicles.

Chapter 16 by Gerry Elman and Jay Zhang provides information on Intellectual Property protection strategies and Product lifecycle management for biotechnology innovations. This chapter can aid the readers in understanding the patenting process, patent prosecution strategy, and other forms of Intellectual property in the industry.

Section VI discusses the financial capital component of biotechnology entrepreneurship. Chapter 17 outlines the sources of capital and financing stages for biotechnology companies. The funding alignment principles and financing strategies discussed in this chapter can help biotech entrepreneurs secure ideal funding partners for their companies. This chapter is a must-read for individuals looking to raise money for their company. Chapter 18 by Konstantin Kostov discusses the factors that influence the investor decisions in financing a company. This chapter communicates the role of cognitive biases, emotions, and intuition in the investment decision process with the infamous example case study of Theranos.

Chapter 19 outlines funding from angel investors and angel networks. A biotechnology entrepreneur can learn to engage with angel networks and understand their motivation for investment from this chapter. Chapter 20 can help an entrepreneur understand how to raise capital from Venture Capital partners. In particular, the section that provides general guidelines about raising capital for biotechnology companies is very insightful.

Chapter 21 by Stephen Sammut has explored the financial ramifications of funding a biotechnology venture by providing a relationship between investment terms and valuation. This chapter provides a valuation exercise for a



Biotechnology Entrepreneurship: Leading, Managing and Commercializing Innovative Technologies, 2nd Edition

Edited by Craig Shimasaki

Hardcover ISBN: 9780128155851

eBook ISBN: 9780128155868

Imprint: Academic Press

Published Date: 16th May 2020

Page Count: 682

Reviewed by Rahul Khetan

hypothetical company to illustrate the capital needs, value inflection points, venture capital valuation method, and capitalization tables. Chapter 22 by Lowell Busenitz provides a guide to biotech entrepreneurs for communicating their business plans to potential investors and stakeholders. Interested readers can use the business plan outline given in this chapter to articulate a well-written business plan for their idea. Chapter 23 focuses on biotech investor pitch decks. Shimasaki outlines 18 topics that are required in an investor presentation and suggests the type of information that should be presented by these slides.

Section VII provides Drug development workflow and commercialization process for biotechnology products. Chapter 24 discusses the standard phases of drug discovery, development, and clinical trials for therapeutic drugs. Chapter 25 discusses the regulation of diagnostic products and

the development of companion diagnostic products. Senior executives and managers in the biotech industry can explore the field of clinical diagnostics and understand its important role in determining healthcare outcomes and clinical decision-making by reading this chapter. Chapter 26 focuses on the development and commercialization of medical devices. This chapter is very informative for entrepreneurs developing new medical devices. Chapter 27 outlines the commercialization and regulation of agricultural biotechnology products.

Chapter 28 and Chapter 29 are new additions to the second edition which discuss the role and impact of Machine Learning and Artificial Intelligence tools in the biotechnology industry. These chapters outline the machine learning concepts relevant for drug and biologics R&D and finally provide regulatory guidance and commercialization framework for these computational tools. Chapter 30 explores the regulatory pathways and compliances for biotechnology products. This chapter is crucial for any reader who seeks to understand the acts and regulations pertinent to the license and approval of biotechnology products. Chapter 31 outlines the biomanufacturing process for biopharmaceuticals. However, this chapter is not very relevant in the context of this book and does not connect with the theme of biotechnology entrepreneurship. The technical information presented in this chapter could have been summarized in a separate section in a previous chapter.

Chapter 32 discusses market research and assessment tools for developing a successful market strategy for biotechnology products.

However, this chapter is more suitable for Section VIII that focuses on biotechnology market development. Therefore, section VIII can be reviewed in the third edition to include Chapters 32 - 34. Chapter 33 provides an overview of the reimbursement system to help the reader in developing a coverage, coding, and reimbursement strategy for their products. This chapter is a good reference to understand the pricing and reimbursement mechanisms in the biotechnology industry. Chapter 34 discusses the public relation strategies and communication tools to support the business objectives of a company. Media relations and social media strategy has also been outlined in this chapter to aid the reader in creating and maintaining positive relationships with their target audience.

Section IX discusses relevant topics in biotechnology entrepreneurship for established biotechnology companies. Chapter 35 outlines the development and transition stages of a company and establishes the value of corporate culture in a biotechnology company. In particular, this chapter has illustrated the role of the leadership team of the company in each development stage for setting a corporate culture in the organization. Chapter 36 focuses on licensing and partnering deals in the biotechnology industry.² This chapter would be of particular interest to business development executives and senior managers in biotech and pharma companies. Chapter 37 provides the case study of Centocor to communicate the importance of strategic alliances for the survival and growth of biotechnology companies. This case study-based approach used in this chapter has been very effective in inspiring

the readers to pursue R&D partnerships and collaborations for their own company.

Chapter 38 provides an overview of the evolution of China's biotech industry. This chapter depicts the significance of government policies and vision in the transformation of the biotechnology sector to the readers. Chapter 39 discusses the ethical considerations in biotechnology entrepreneurship. Here, the readers can explore the ethical issues and dilemmas that may occur for their idea or company. Chapter 40 reviews the diversity of careers for new graduates or current biotechnology professionals seeking a variety of job functions within the life science industry. Chapter 41 outlines seven common biotechnology entrepreneur mistakes and the methods to avoid these entrepreneurial problems. Finally, Chapter 42 provides a summary of all the concepts covered in the previous chapters in this book.

In summary, this book represents a major step towards compiling the essential elements necessary to build and manage successful biotechnology companies. The chapters are all generally well written and illustrated, and supported by extensive and timely literature citations. These chapters have fairly communicated tactical and strategic insights in topics such as idea assessment; intellectual property strategies; product approval processes; reimbursement strategies; biotechnology partnerships; careers in the life science industry and even bioethics.

The unique feature of this book is that it captures the insights, guidance, and experiences from seasoned experts within its

chapters. Such knowledge and inspirational guidance from biotech pioneers provide the reader an understanding of the best practices and common pitfalls during entrepreneurial endeavors in biotechnology. This book, therefore, provides a more practical approach than other related works in biotechnology entrepreneurship.³ *Biotechnology Entrepreneurship: Leading, Managing and Commercializing Innovative Technologies* highlights key concepts and issues in biotechnology entrepreneurship in a framework that students, industry professionals, researchers, and entrepreneurs can understand.

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