

Commercializing Successful Biomedical Technologies

Second edition

Transform your research into commercial biomedical products with this revised and updated second edition.

Covering drugs, devices, and diagnostics, this book provides a step-by-step introduction to the process of commercialization, and will allow you to create a realistic business plan to successfully develop your ideas into approved biomedical technologies.

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- Additional real-world case studies, updated to include emerging technologies such as regulated medical software and artificial intelligence (AI), offer insights into key challenges and illustrate complex points.
- Tips and operational tools from established industry insiders, suitable for graduate students and new biomedical entrepreneurs.

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Second edition

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Cambridge University Press is part of Cambridge University Press & Assessment, a department of the University of Cambridge.

We share the University's mission to contribute to society through the pursuit of education, learning and research at the highest international levels of excellence.

www.cambridge.org

Information on this title: www.cambridge.org/9781316510063

DOI: 10.1017/9781108186698

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First published 2023

Printed in <country> by <printer>

A catalogue record for this publication is available from the British Library.

Library of Congress Cataloging-in-Publication Data

Names: Mehta, Shreefal S., author.

Title: Commercializing successful biomedical technologies / Shreefal Mehta.

Description: 2nd edition. | Cambridge, United Kingdom; New York, NY: Cambridge University Press, 2022. | Includes bibliographical references and index.

Identifiers: LCCN 2022011773 (print) | LCCN 2022011774 (ebook) | ISBN 9781316510063 (hardback) | ISBN 9781108186698 (epub)

Subjects: MESH: Biomedical Technology—economics | Marketing—methods

Classification: LCC HD9999.B442 (print) | LCC HD9999.B442 (ebook) | NLM W 82 | DDC 660.6068/8—dc23/eng/20220528

LC record available at <https://lcn.loc.gov/2022011773>

LC ebook record available at <https://lcn.loc.gov/2022011774>

ISBN 978-1-316-51006-3 Hardback

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To Gauri, whose continuing support and encouragement, and patience and willingness to shoulder my share of parenting when necessary, and more, made the completion of this book possible. Without your love and help, there would have been no book.

For this 2nd edition, I would like to add a dedication to the readers, students, teachers, scientists, engineers, technicians, executives, and entrepreneurs who work with such zeal to generate ideas and develop new biomedical products every day. Your efforts are the inspiration for this book.

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Preface

This book will give you an overview of the steps involved in taking a new biomedical invention and making it into a commercially available product. The products covered are drugs (both small molecules and biologics), medical devices, diagnostics, and their combination products. These product definitions are given by the Food and Drug Administration (FDA) – the regulatory agency responsible for overseeing the world’s single largest healthcare market in the United States. The term “biomedical technologies” refers to the collective technologies underlying these FDA-regulated products: biotechnology, various engineering technologies, chemistry, and materials science, etc.

The book’s goal is to highlight key issues that will help improve chances of success through the complete commercialization process for biomedical technologies and products. This book aims to help you understand what questions to ask as you go through the planning and processes involved. In addition, the text will highlight issues to expect when you launch your invention from the laboratory into a business for commercialization.

This text started as an expansion of a series of lectures given to students at the Lally School of Management and Technology, Rensselaer Polytechnic Institute in Troy, New York, in a course titled “Commercializing Biomedical Technology.” The course filled a gap in biomedical and biotechnology engineering and science education by providing practical information about the process in commercializing the engineered ideas and bringing those solutions to the people that need them.

This content in this book could be used to bring science and engineering students together with business and law students, showing them the benefits of approaching this complex process as a team. Many students who studied the book in courses have found the information useful in securing positions and fitting into the work environment of the biotech industry and its service sectors from day one. In addition, the book helped them better understand the big picture context within which they were working. It turns out that the overview provided by this book is also useful as a quick reference guide for strategic planning or for career transitions for senior executives.

I have attempted to keep a practical perspective in selecting the content, so that scientists and managers in the industry can apply these concepts, issues, and exercises within the context of their job functions in industry. What’s more, aspiring entrepreneurs may walk through all the steps and exercises found here, to create a commercialization plan and form a business plan for a new venture (Figure 1). Business models and financial plans vary with the economic or personal context and goals of the founders. However, any business model, to be successful, must come from an understanding of the complete commercialization path for the regulated product.

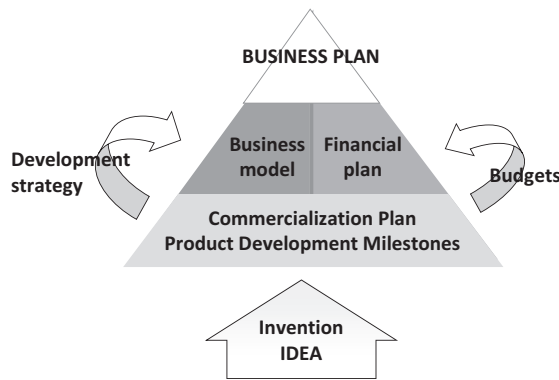


Figure 1 First you have to understand how your idea will be developed into a product and identify key development milestones on the critical path to reach the paying customers. That gives you a budget and financial plan. Then you can choose a business model and prepare a business/financial plan to execute that development strategy. It all starts with thoroughly understanding the product commercialization path.

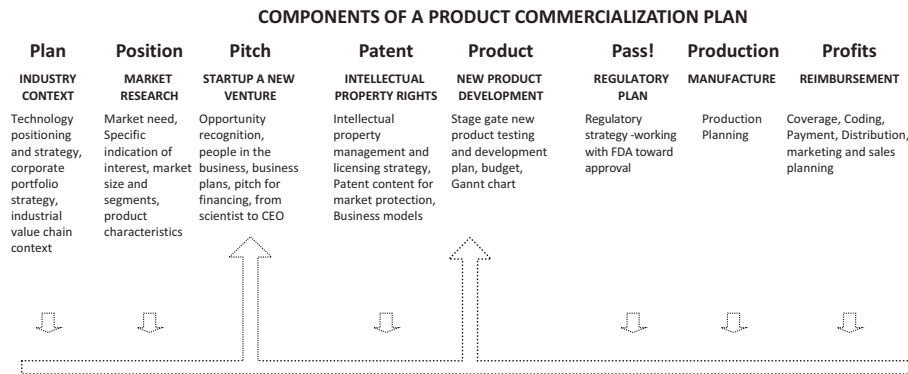


Figure 2 Roadmap to creating a commercialization plan. The linear stages shown here reflect the layout of the book chapters. Figure 3 represents the iterative feedback from various areas that would eventually define and launch an idea into a viable commercial product

The linear roadmap in Figure 2 shows the components that must be assessed to build a sound commercialization plan. The planning is carried out iteratively as you proceed through the chapters, with increased understanding of the needs of each step. The arrows below the specific chapters in Figure 2 illustrate the fact that all these components feed into a successful commercial and product development plan. The planning component on starting a business – Chapter 3 on pitching an opportunity and founding and financing a new venture – is new in this edition. Chapter 3 was written in response to queries from readers who asked in some manner to include a practical guide to ease the transition from scientist to company founder and executive (CEO, CSO, CTO, COO, etc). I had the benefit of also drawing from my own experiences

decide the opportunity is the right one and launch the new venture, stepping through Chapter 3 in greater detail. Many companies start with a novel technology and a general idea about the market application. While that will not change in this innovation-driven, science-based industry, the steps outlined in this book highlight how important it is to define the specific indication (application) within the context of regulatory and reimbursement gateways.

I hope that this text, in addition to serving as a reference to industry executives and practitioners, continues to be taught at the undergraduate, graduate and executive education levels. Courses that teach this book will, it is hoped, create a more conscious and self-aware breed of scientist and engineer who will use this foresight to better guide their inventions to become useful products in the world. Finally, it is my hope that better thinking and planning in the development of regulated products will help improve the efficiency, success, and quality of biomedical technology commercialization, increasing the number of innovative products that can be delivered to help people.

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