Biodesign

The Process of Innovating Medical Technologies

Where do you begin as a medical technology innovator? What lessons can you learn from experienced inventors? How can you improve your chances of success?

Learn to innovate, recognize market opportunities, apply the design process, and develop business acumen with this "hands-on" guide to medical technology innovation. The biodesign innovation process begins with careful identification of a clinical need and moves in a stepwise approach through inventing and planning the implementation of a marketable solution. The process is based on the combined experience of literally hundreds of medtech innovators who are featured in the book through quotations, vignettes, and case studies.

- Master the three-phase biodesign process for innovating medical technologies – *identify* → *invent* → *implement*
- Understand the complete picture of medtech innovation through medical, engineering, and business perspectives
- Take action using the step-by-step instructions and supporting resources outlined in the *Getting Started* section for each chapter
- Access thousands of active links and additional information via the online companion to the book – *ebiodesign.org*

"Everything you ever wanted to know about medical device entrepreneurship and more. [The authors] have led an A-class team of experienced device company builders to produce a reference document to guide aspiring device entrepreneurs through all the challenges of getting an idea to market. These are tough times. Whether you're a physician with an idea, an engineer or a businessman, this is a unique and powerful resource."

John Abele, *Founder/Chairman Boston Scientific*

"I don't know of any other text that has the wealth of practical and usable information on the entrepreneurial process as *Biodesign*. This is a much needed 'how-to' book written by people who actually have done it many times themselves. No thirty-thousand foot views necessary or appropriate here. Each chapter has a 'Getting Started' section that will help guide the budding entrepreneur through the necessary steps. This book should be required reading for anyone wanting to develop a new medical device or to start a new company in the medical field. "

William Brody, *President of the Salk Institute and Former President of Johns Hopkins University*

"The chapters are thoughtfully organized. With an excellent blending of scientific information, clinical problems, and examples of solutions, including case studies, the book has succeeded in accomplishing its goal of being very practical . . . *Biodesign* will be the standard in this very important field. It will be of great value in the education of undergraduate and graduate students in biomedical engineering and related fields, as well as for industrial scientists and university faculty who educate/train young bioengineers or want to pursue the process of innovating new medical technologies themselves."

Shu Chien, *Professor of Bioengineering, University of Califonia, San Diego*

"*Biodesign: The Process of Innovating Medical Technologies* is a wonderful guide with lucent case studies that illustrate the critical steps necessary for the translation of ideas into commercial solutions. It is the *Grey's Anatomy* of device innovation."

William Hawkins, *Chairman and CEO of Medtronic*

"*Biodesign: The Process of Innovating Medical Technologies* is direct, clear, and simultaneously sophisticated yet practical as it unravels the many issues related to successfully navigating the entire biodesign path from concept to final product launch. I highly recommend that anyone seriously interested in developing an entrepreneurial venture in the medical products field read this book. It is likely to spare budding entrepreneurs a lot of trial-and-error and painful on-the-job training."

Dean Kamen, *Inventor and Founder/President of DEKA Research and Development*

"In *Biodesign*, the Stanford team has assembled a treasure trove of methods for medical device innovation. The book is certain to become an invaluable reference for students, instructors, and practitioners alike."

Karl T. Ulrich, *CIBC Professor of Entrepreneurship and eCommerce, The Wharton School*

"This comprehensive text provides clear guidance through every step of the biodesign process, from identification of market need to successful entrée into a complex, competitive marketplace. The authors of this book – faculty in Stanford's Biodesign Program – have done innovators a great service in shaping the study of biodesign and training students to put this knowledge into practice. Their expertise is self-evident, and, with this book, is now accessible to anyone serious about succeeding in biotechnology."

Miles White, *Chairman and Chief Executive Officer, Abbott*

Biodesign

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CAMBRIDGE
UNIVERSITY PRESS

CAMBRIDGE
UNIVERSITY PRESS

University Printing House, Cambridge CB2 8BS, United Kingdom

Cambridge University Press is part of the University of Cambridge.

It furthers the University's mission by disseminating knowledge in the pursuit of education, learning and research at the highest international levels of excellence.

www.cambridge.org
Information on this title: www.cambridge.org/9780521517423

First published 2010
9th printing 2014

Printed in the United States America by Edwards Brothers Malloy

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

ISBN 978-0-521-51742-3 Hardback

Additional resources for this publication at www.cambridge.org/9780521517423 and ebiodesign.org

To innovators – past, present, and future – and the patients who inspire them.

Contents

See **ebiodesign.org** for active web links to the resources listed in each chapter, additional references, content updates, video FAQs, and other relevant information.

Foreword

As you begin … a note from Tom Fogarty

Over the years I have spent developing new technologies, and watching innovators succeed or fail, I have identified some basic principles that are critical to success, and those that cause failure. The most important principle is that we innovate to improve the lives of patients. Commitments to ourselves, the institution we serve, and others are secondary. Distractions along the way are multiple. The love of money, the lure of technology, personal advancement, and recognition by our peers are only a few. Even with these distractions and institutional encumbrances, innovators are here to serve our patients first and foremost. If this is done well, benefits to the innovator will follow.

I have always thought that innovation is something you learn by doing. However, I do believe that certain individuals are born with a capacity to innovate that is significantly greater than that of others. It is much like the field of sports; some are innately more capable. Regardless of where one lies in this spectrum, listening to your mentors is probably the most critical component of your success. Persistence is the second most important factor (knowing when to hold 'em and when to fold 'em). Before you give up, reference anybody knowledgeable in the field, including your mentors, friends, and enemies. Yes, enemies – they often have insights and offer perspectives that friends will ignore or not articulate. Seek the truth, no matter where it lies.

An idea, by itself, has no importance whatsoever; it is the implementation of that idea and its acceptance by others that brings benefit to our patients. In this day and age, it is extremely difficult to successfully bring a concept to reality without the help of a myriad of others from different disciplines. The importance of their contributions should never be underestimated. The concept of value allocation becomes very important. Innovators often handle this badly. If there is no implementation of the concept or idea, there might as well be no concept or idea.

How to go about implementation is not intuitively obvious – and this is an area where the *Biodesign* text is useful. There is practical material in these chapters that can make the path to implementation clearer, particularly for the physician or engineer who may have seen only parts of this process before. It is also important that the first third of this book focuses on how to get the clinical need right. There is nothing more critical in the innovation process than starting with a truly significant patient need.

One final thought: the path to successful innovation is very often lonely and frustrating. Innovation by its very definition means something different than what exists. Basically we are defying standards and sometimes basic concepts. Be prepared to be criticized, ostracized, called crazy, inappropriate, outlandish, stupid, intolerable, and bound to fail. I myself have been called all of these names and many more that I can't remember or mention. Take solace from the fact that these challenges can be a useful part of the process of innovation. Overcoming obstacles that you recognize (and those that you don't) will occur. Ultimately, your ability to prevail through these challenges will benefit patients, caregivers, and institutions.

Thomas Fogarty, MD, is a cardiovascular surgeon and one of the most prolific medical device inventors in history, with many of his technologies in active use across a wide spectrum of patient care. He has founded or co-founded over 30 companies and was inducted into the National Inventors Hall of Fame in 2001.

Preface

If you have the desire to develop new medical technologies, there is a world of opportunity available to you. Health and quality of life are central issues for every human being on the planet. Through advances in science and technology, the complexities of the human body are being revealed, creating new ways to solve clinical needs that no one imagined previously. Medicine and surgery are more open for innovation than at any time in history.

Despite this promise, however, medtech innovators face significant hurdles. If not managed skillfully, patents, regulatory approval, reimbursement, market dynamics, business models, competition, financing, clinical trials, technical feasibility, and team dynamics (just to name a few of the many challenges) can all prevent even the best idea from reaching patient care. So, where should you begin as an innovator? What process can you use to improve your chances of success? What lessons can you learn from the inventors, engineers, physicians, and entrepreneurs who have succeeded and failed in this endeavor before? This book has been developed to provide practical answers to these important questions.

The text is based on a simple premise: that innovation is both a process and a skill that can be learned. While some may have more natural ability than others, everyone can be an innovator. The biodesign innovation process, as we call it, is described here in a way that is specific to the development of medical technologies, but the same general approach is followed by successful innovators in many fields.

This process is intended to provide you with a starting point. Each phase, stage, and core activity detailed within the book includes information to help you effectively capitalize on important opportunities and overcome common obstacles. Yet, as an innovator, you should adapt and modify this approach to reflect your own style and personal emphasis. It is our hope that by executing your own version of the biodesign innovation process, you will be able to navigate confidently the many twists and turns that lie ahead.

Genesis of the book

The idea for the book is the result of our experience in developing the biodesign innovation and fellowship programs at Stanford over the past eight years. It began as a collaboration between Josh Makower and Paul Yock, triggered by a chance conversation at breakfast at Il Fornaio in Palo Alto. Makower had previously created a medical devices innovation training program at Pfizer called “Pfreshtech” before launching his career as a serial medtech founder and entrepreneur. Yock, a professor of bioengineering and medicine, was interested in developing a graduate program in medical technology innovation that could leverage the deep medtech expertise and inventive culture of the Silicon Valley. The two agreed to work together to create a training initiative as a part of the Stanford University Program in Biodesign, which Yock directs. Stefanos Zenios, a professor of operations, information, and technology, and an expert in health systems from the Graduate School of Business (GSB), joined the biodesign faculty group and provided the conceptual organization for the biodesign process that is presented here. Todd Brinton, an alum of the fellowship program, current fellowship director, and a medtech company founder, served as an associate editor and contributed his insights. Uday Kumar, also an associate editor and alum of the fellowship, contributed to text from his experience as a cardiac electrophysiologist and founder and chief medical officer of a medtech company. Tom Krummel, chair of surgery, joined as codirector of biodesign and further

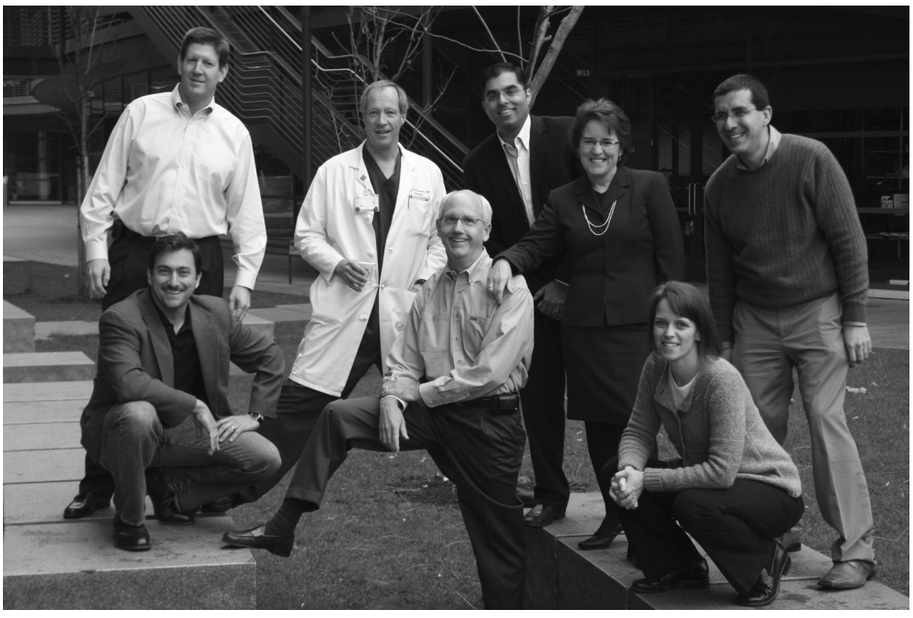

Figure P1 The team. Back row: Todd J. Brinton, Thomas M. Krummel, Uday N. Kumar; middle row: Josh Makower, Paul Yock, Christine Kurihara, Stefanos Zenios; front row: Lyn Denend.

refined the innovation process with a focus on clinical needs finding and validation. Principal writer Lyn Denend, from the Stanford GSB, initially joined us to help develop a series of notes to support the teaching syllabus for the course. Over time, the team worked together to significantly expand and enhance this material for the book. Chris Kurihara developed the web companion to the text, ebiodesign.org (see Figure P1).

In providing the material here, we have drawn from the talks of more than 200 industry speakers who have presented in the class and also, more significantly, from our experience advising more than one hundred project teams over the past eight years. Already ten of these projects have been converted to venture-backed companies, and 20,000 patients have been treated with devices from these organizations. To validate the principles described in the book we have also performed extensive field-based research. Being located in Silicon Valley with hundreds of medtech start-ups within a 50-mile radius of Stanford, we are fortunate to have unparalleled access to seasoned practitioners who have shared their insights with us. We have interviewed dozens of innovators and captured their experience as brief vignettes and more extensive "From the field" case studies to help demonstrate how many of the key issues we highlight manifest themselves in real-world situations.

Organization of the book and its supporting website

Biodesign: The Process of Innovating Medical Technologies divides the biodesign innovation process into three distinct phases.

- **Identify**: How do you identify an important unmet medical need where there is good clinical, scientific, and market knowledge to suggest that a solution to the need will be feasible and will have a reasonable likelihood of commercial viability?
- **Invent**: How do you next develop a solution to this need, taking advantage of the creative group process and the power of prototyping?
- **Implement**: How do you then transform an idea and a prototype into a product that can be used at the bedside to treat patients?

These three phases are further subdivided into a total of six stages and 29 core activities (with a chapter on each one). The diagram shown in Figure P2 summarizes the overall process and illustrates the interaction among the phases, stages, and activities. To help you navigate the content if you are new to innovation, we have organized the book in a linear fashion that parallels the course we teach and the process followed by many of the innovators we have interviewed. The fact that, in practice, many of these activities require a parallel and iterative approach

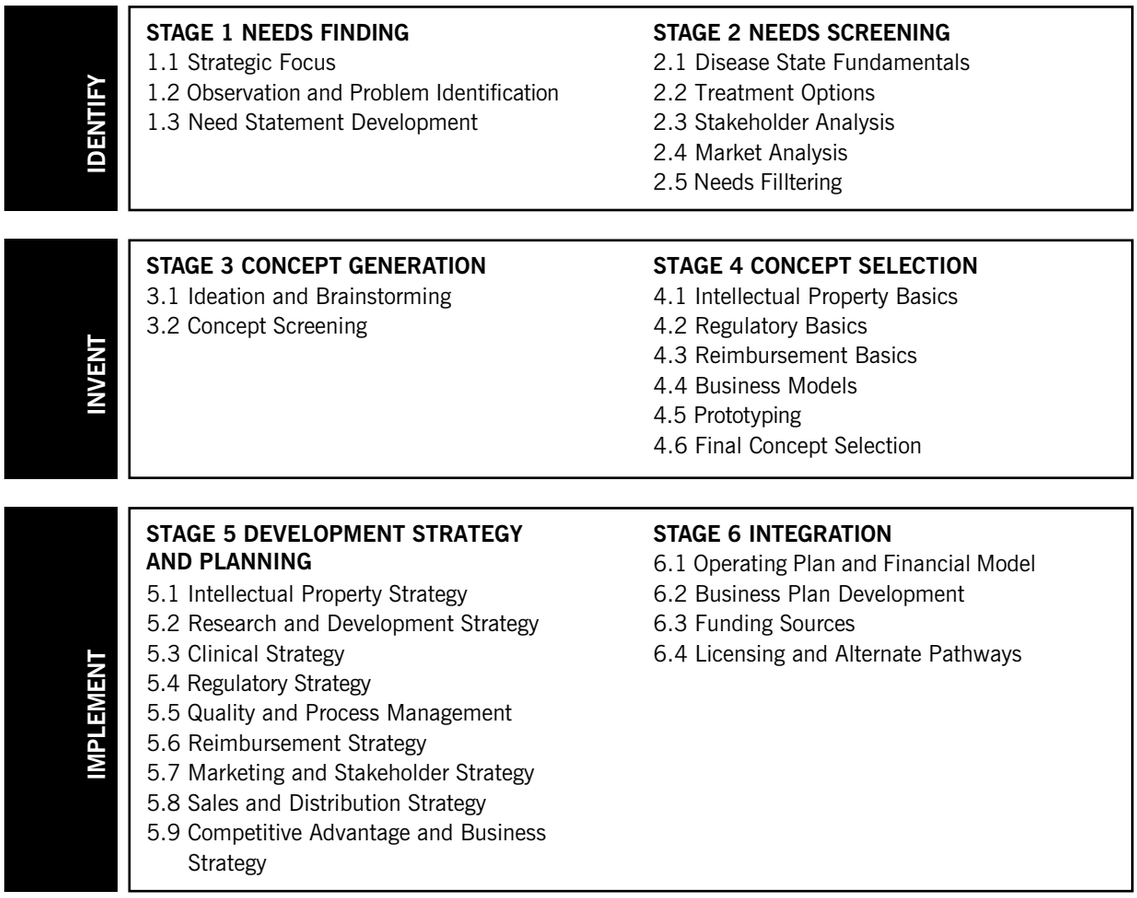

Figure P2 The biodesign innovation process.

is addressed in the chapters where it is most essential. If you are a more experienced reader, we have attempted to make individual chapters as complete and self-contained as possible so you can refer directly to the chapter most relevant to the challenges you are currently facing, without necessarily having to read those that precede it.

At the end of each chapter is a Getting Started section that outlines a practical, action-oriented roadmap that you can follow to execute the steps in the biodesign innovation process when working on an actual project. The roadmaps are supported by lists of resources and references to provide you with additional information, and they are mirrored on the website **ebiodesign.org** with active web links for each step.

Who will use the book?

Initially, this material was developed to support project-based classes in medical technology innovation. Over time, however, we have used the content in a variety of settings and with different audiences, both inside and outside the university, and have found it to be valuable for a much broader cross-section of readers. Certain parts of the text are particularly appropriate for these different groups.

Undergraduates will benefit most from the 16 chapters (1.1–4.6) in the first two phases (Identify and Invent). Students in capstone biomedical engineering design classes can use this book as a primary resource, coupled with an engineering text from the relevant discipline (mechanical, electrical, or biomedical engineering). For classes in which the clinical need is provided up-front, we recommend beginning with Chapter 2.1 in the Needs screening stage.

Graduate students in medicine, business, or engineering can use the book to learn a process for inventing and commercializing medical technologies. The chapters on implementation (5.1–6.4) deal with more advanced, strategic topics that innovators will encounter as they move toward commercialization of their concepts.

Students in business plan courses with a medical product idea will benefit by using the book as a medical-specific template for organizing their business plan development, with the chapters from the Needs screening stage (2.1–2.5) and from the Implement phase (5.1–6.4) being the most directly relevant.

Faculty interested in translational research may follow the steps in this book to develop a research and implementation plan for a technology or an idea with a potential clinical application. Chapters 1.1 to 4.6 will be the most directly useful.

Emerging entrepreneurs and inventors can leverage the book from beginning to end, using it as a roadmap for all steps in their journey – from evaluating a potential area of focus for their venture, to developing an execution plan, raising funds, and beyond.

Investors can draw information from the text to support a detailed due diligence checklist for evaluating opportunities and business plans in the medical device field.

Last, but not least, ***industry executives*** will discover that this book provides an innovation template and nomenclature that they can adopt within their own organization.

Medtech versus biotech and pharma

The book has an intentional focus on medical technologies, which we define as medical devices, diagnostics (including imaging and molecular diagnostics), and drug delivery. Its content is not as relevant to biotechnology and pharmaceuticals, primarily because some of the distinctive features of medical technology innovation do not translate directly to these other sectors. Although much has been made about the ultimate convergence of medtech and biotech/pharma, we believe that, for the foreseeable future, the innovation process for these areas will continue to have fundamental differences.

If you work in the pharmaceutical and biotechnology sector, you will still find that several portions of this book are relevant (e.g., 2.1 Disease State Fundamentals, 2.2 Treatment Options, 2.4 Market Analysis, 5.3 Clinical Strategy, and 5.6 Reimbursement Strategy) but other stages in the process (such as Stage 1 Needs Finding or Stage 3 Concept Generation) do not apply directly. In particular, in medtech there is a distinct emphasis on clinical need identification as the *initial step* in the innovation process. In contrast, most recent innovations in biotechnology or pharmaceuticals start with a breakthrough in the understanding of basic biological mechanisms at the bench, not at the bedside. The

ideation phase is also unique in medtech, both because it starts with an explicit clinical need and because it is characterized by a close, cyclical interaction between prototyping and idea generation. The implementation stage has superficial similarities between medtech and biotech/pharma (such as FDA approval), but the processes and strategies used to overcome these hurdles are significantly different. This applies also to the business characteristics of medtech innovation – a new medtech product can reach the market in less than half the time a drug takes, and is likely to cost a small fraction in development expenses. All these differences mean that a biodesign innovation process can be applied to the pharmaceutical and biotechnology sectors, but it will have fundamental differences from the process described here.

Geographic focus

This material has a primary focus on the United States for two main reasons. The United States continues to be the world's largest medical device market, and our location in Silicon Valley provides us with unique insights from the epicenter of medtech start-ups. However, the overall process is global and can be readily applied by innovators targeting other markets. Of course, there are differences across markets that are driven by regulatory, reimbursement, and clinical policy variations. To address this, the book highlights where such differences exist, provides directional guidance for some important global markets, and gives you resources and ideas for how to further investigate markets outside the United States.

Ethics

As a prospective medical device innovator, your endeavors will involve patients' lives. If you are successful, your inventions may prolong life and alleviate pain, but the process of developing and testing these devices may expose patients to risks. Well-articulated ethical principles should guide the conflicts of interests that have the potential to arise throughout the biodesign innovation process. For this reason, rather than addressing ethics in a single, dedicated chapter, a discussion of ethics is embedded in the chapters where conflicts and ethical issues are most likely to arise. Guiding principles for effectively managing these ethical concerns are also provided to ensure that patients' best interests always come first in your journey.

Web resources: ebiodesign.org

Given the dynamic, fast-paced nature of the medtech industry, we have created *ebiodesign.org* as a companion to this text. Important updates and information about relevant industry changes will be posted here, along with video commentary from experts and frequently asked questions for each chapter. Additionally, ebiodesign.org provides an up-to-date list of active references that support each chapter of the book. We intend this to be a valuable resource and welcome your suggestions regarding useful material to include on the site.

Launching the biodesign innovation process

As the many innovators who have contributed to this book will tell you, biodesign is an exhilarating journey: you have in front of you the opportunity to deliver ideas and technologies that will transform healthcare for generations to come. We hope this book will help you to move more effectively toward that goal.

The Biodesign Community

This book carries the fingerprints of literally hundreds of contributors. One key set of experts who helped shape the material is the Leadership Group for the Program in Biodesign. We particularly wish to thank Richard Popp who heads our ethics and policy section; Craig Milroy who directs the biodesign prototyping collaboratory; Tom Andriacchi who advises on educational programs; Mike Gertner, Geoff Gurtner, and Paul Wang who are members of the core faculty; and Chris Shen, Julian Gorodsky, Jack Linehan, and Peter Fitzgerald who mentor the fellows. Our international focus has expanded recently through a new program called Stanford-India Biodesign, led by Executive Directors Raj Doshi and Balram Bhargava. The Biodesign fellowship program is generously supported by prominent medtech innovators who have also contributed to this text, including Tom Fogarty, Eberhard Grube, Julio Palmaz, John Simpson, and Simon Stertzer. A number of other key individuals and firms provide advice and support to the program, as outlined on the Stanford Biodesign website.

Biodesign is a unit of Stanford's innovative life sciences initiative called Bio-X. We are grateful to the leaders (Matt Scott, Carla Schatz, and Heideh Fattaey) who have provided encouragement and support as biodesign has grown up. The innovation class on which the text is based is hosted in the Department of Bioengineering and the Graduate School of Business (GSB). We have had the great benefit of advice and guidance from founding chair of the department, Scott Delp, as well as the ongoing support of the subsequent chair Russ Altman. Through the department, our experience with the Wallace H. Coulter Translational Research Partnership program has provided valuable experience in university technology transfer in the medtech space.

Our approach to biodesign draws heavily from our colleagues in the design initiatives at Stanford (the Hasso Plattner Institute of Design), as well as their colleagues at IDEO, Inc. We want to particularly acknowledge David Kelley, Tom Kelley, Dennis Boyle, Tad Simmons, and George Kembel for their considerable input into the program and this project. We are also grateful for the support of the Stanford Technology Ventures Program, especially Tom Byers and Tina Seelig.

The development of the biodesign program would not have been possible without the explicit support of Dean Philip Pizzo and Senior Associate Dean Harry Greenberg from the School of Medicine, Dean James Plummer from the School of Engineering, and Dean Robert Joss as well as Associate Deans Dave Kreps and Mary Barth from the GSB. Their camaraderie, willingness to experiment with an unusual interdisciplinary program, and ongoing support were critical to our success.

The text grew out of the biodesign fellowship and class. One of the first fellows in the program, Asha Nayak, developed a manual for the fellowship that contained practical information on needs finding, inventing, and developing ideas. The manual served as a motivation and guide for developing an expanded teaching syllabus and, ultimately, this text. One of the first business school students in biodesign, Darin Buxbaum, played a crucial role in building on Asha's manual to develop a prototype for several of the early chapters and Getting Started sections. Trena Depel and several others helped to develop and refine specific content. Their contributions are individually acknowledged at the end of the relevant chapters. The organization of the weblinks in ebiodesign.org, the online companion to the text, was coordinated by Abigail Garner and was supported by grants from the Kauffman and Argosy Foundations.

Subsequent generations of biodesign fellows and students have been "test subjects" for the material in this book. We are grateful for their input and proud of what they are accomplishing in their careers as innovators.

We wish to thank the staff of the biodesign program for the extensive efforts required to keep the various educational aspects of the program running smoothly. We are particularly grateful to Roula El-Asmar, Andrea Daniel, Mary Gorman, and Dawn Wojick, as well as alumni staff, including managing director Sandy Miller, educational coordinator Teresa Robinson, along with Quynchi Nguyen, Tracy Okamoto, Rebecca Huang, and Laura Dyball. From the GSB, Margot Sutherland of the Case Writing Office and Kim Simmons from Jackson Library were especially supportive of our efforts to develop a comprehensive set of teaching notes for our course, which led to this book. Diana Reynolds Roome and Malisa Young also provided key support in finalizing the manuscript. Michelle Carey, our primary contact at Cambridge University Press, provided invaluable assistance in helping us navigate the publishing process.

Finally, this book has been shaped by input from hundreds of medtech experts who have participated in the biodesign program as lecturers, speakers, mentors, coaches, and advisors. These experts have helped us to frame the biodesign process and hone the teaching material that has evolved into this text. We would like to thank sincerely the members of the community who are listed here – and those in the updated index of contributors found at **ebiodesign.org**.

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Michelle Paganini
Julio Palmaz
Olin Palmer
Bhairivi Parikh
T. Kim Parnell
Jay Pasricha
Ron Pearl
Donna Peehl
Rodney Perkins
Timothy Petersen
David Piacquad
Jan Pietzsch
Peter Pinsky
Moshe Pinto
Philip Pizzo
Hank Plain
Ben Pless
Sylvia Plevritis
Todd Pope
Richard Popp
Stuart Portnoy
Friedrich Prinz
Mary Beth Privitera
Michael Raab
Geetha Rao
Andrew Rasdal
Alok Ray
Mahmood Razavi
Michael Regan
Robert Reiss
Mehrdad Rezaee
Kelly Richardson
Jeff Rideout
Dan Riskin
Robert Robbins
Gregory Robertson
Teresa Robinson
William Robinson
Douglas Roeder
Campbell Rogers
Erica Rogers
Diana Reynolds Roome
John Avi Roop
Susan Rowinski
Geoffrey Rubin
Vahid Saadat
Eric Sabelman
Maria Sainz
Amr Salahieh
Bijan Salenhizadeh
Stephen Salmon
Will Samson
Terence Sanger
Alan Schaer
Carla Schatz
Stephen Schendel
Jeffrey Schox
Bob Schultz
David Schurman
Matt Scott
Randy Scott
Tina Seelig
Matthew Selmon
Bilal Shafi
Ramin Shahidi
James Shapiro
Adam Sharkawy
Hugh Sharkey
James Shay
Chris Shen
Jay Shukert
Kevin Sidow
Kim Simmons
Tad Simons
Chuck Simonton
Carl Simpson
John Simpson
Baird Smith
R. Lane Smith
Yuen So
Roy Soetikno
Sarah Sorrel
Dan Spielman
George Springer
Sakti Srivastava
Fred St. Goar
Richard Stack
Neil Starksen
Bill Starling
Brett Stern
Simon Stertzer
John Stevens
Jackson Streeter
Mitchell Sugarman
Margot Sutherland
Robert Sutton
Judith Swain
Jim Swick
Daniel Sze
Katie Szyman
Raymond Tabibiazar
Karen Talmadge
Beverly Tang
Larry Tannenbaum
Tatum Tarin
Charles Taylor
Hira Thapliyal
Stephen Thau
Patty Thayer
Robert Thomas
Troy Thorton
James Tobin
Ravi Tolwani
Sara Toyloy
Julie Tracy
Alexandre Tsoukalis
Sean Tunis
Sara Little Turnbull
Ted Tussing
P. J. Utz
J. Sonja Uy
Brad Vale
Sigrid Van Bladel
Jacques Van Dam
Machiel Van Der Loos
Jamie van Hoften
Vance Vanier
Richard Vecchiotti
Ross Venook
Claude Vidal
Kenneth Waldron
Amrish Walke
Jeff Walker
James Wall
Mark Wan
Paul Wang
Sharon Lam Wang
Tom Wang
Kevin Wasserstein
Jay Watkins

The Biodesign Community

Steven D. Weinstein	Parker Willis	Kenneth Wu	Christopher Zarins
Eric Weiss	Jim Wilson	Walter Wu	Mark Zdeblick
John White	Dawn Wojick	Alan Yeung	Robert Zider
Ken Widder	Scott Wolf	Malisa Young	
Bernard Widrow	Timothy Wollaeger	Philip Young	
Allan Will	Russell Woo	Reza Zadno	

Names of other members of the biodesign community can be found at **ebiodesign.org**.

Biographies

Stefanos Zenios is the Charles A. Holloway Professor at the Graduate School of Business, Stanford University. His pioneering work on maximizing the benefits of medical technology to patients when resources are limited has influenced policies in the United States and Europe. His research was featured in the *Financial Times* and Times.com. At Stanford University, he was the first to introduce courses on the interface between medicine, engineering, and management in the MBA curriculum. Dr. Zenios advises medical device and biopharmaceutical companies on health economics and outcomes studies for marketing and reimbursement strategies. He is also a co-founder of Culmini Inc., a company funded by the National Institutes of Health. It develops web-tools for patients and their families. He has published more than 30 papers and received numerous research grants and awards from professional Societies. He holds a Ph.D. in operations research from MIT and a B.A. in mathematics from Cambridge University.

Josh Makower is the founder and chief executive officer of ExploraMed, a medical device incubator. He is also a venture partner with New Enterprise Associates, a consulting associate professor at Stanford University Medical School, and a co-founder of Stanford's Biodesign Innovation Program. Dr. Makower has founded several medical device businesses including Moximed, Vibrynt, NeoTract, Acclarent, TransVascular, and EndoMatrix. Up until 1995, he was founder and manager of Pfizer's Strategic Innovation Group. He holds over 61 patents in various fields of medicine and surgery, an MBA from Columbia University, an M.D. from NYU, and an S.B. in mechanical engineering from MIT.

Paul Yock is the director of the Stanford Biodesign Program and the founding co-chair of the Department of Bioengineering at Stanford University. He is known internationally for his work in inventing, developing, and testing new medical devices, including the Rapid Exchange™ balloon angioplasty and stenting system, which is now the principal system in use worldwide. He also authored the fundamental patents for mechanical intravascular ultrasound imaging and founded Cardiovascular Imaging Systems. In addition, he invented a Doppler-guided access system known as the Smart Needle™ and PD-Access™. Dr. Yock holds 55 US patents and has authored over 300 papers, mainly in the area of catheter-based interventions and technologies. He has been elected to membership in the National Academy of Engineering and has received several prestigious awards, including the American College of Cardiology Distinguished Scientist Award.

Todd J. Brinton is a clinical assistant professor of medicine (Cardiovascular) and lecturer in Bioengineering at Stanford University. He is an interventional cardiologist at Stanford University Medical Center and investigator in interventional-based therapies for coronary disease and heart failure. He is also the fellowship director for the Biodesign Program, and co-director of the graduate class in Biodesign Innovation at Stanford University. Dr. Brinton completed his medicine, cardiology, and interventional training at Stanford University. He holds an M.D. from the Chicago Medical School and B.S. in bioengineering from the University of California, San Diego. He is cofounder of BioParadox, Inc., a venture-backed medical device company and serves on the advisory board for a number of early-stage medical device companies. Prior to medical school he was the clinical research director for Pulse Metric, Inc., a medical device start-up company.

Uday N. Kumar is the founder and chief medical officer of iRhythm Technologies, Inc., a venture-backed medical device company focused on developing new devices and systems for the detection of cardiac rhythm disorders. He is also the associate director for Curriculum of Stanford-India Biodesign and a lecturer in Bioengineering, and has served as an adjunct clinical instructor of cardiovascular medicine, all at Stanford University. In these capacities, he mentors, advises, and teaches students and fellows about the biodesign process. Dr. Kumar completed a Biodesign Innovation fellowship at Stanford, cardiology and cardiac electrophysiology fellowships at the University of California, San Francisco (UCSF), an internal medicine residency at Columbia University, and his medical and undergraduate education at Harvard University. He was also chief medical officer and vice-president of Biomedical Modeling Inc., a medical start-up company.

Lyn Denend is a research associate at Stanford University's Graduate School of Business, where she has authored numerous case studies for use in graduate-level and executive education programs in areas such as strategic management, international business, supply chain management, healthcare, and biodesign innovation. Previously, Ms. Denend was a senior manager in Cap Gemini Ernst & Young's management consulting practice and vice-president of Operations for a start-up providing human resource services. She has an MBA from Duke University's Fuqua School of Business and a BA in Communications from the University of California, Santa Barbara.

Thomas M. Krummel is Emile Holman Professor and chair in the Department of Surgery, and co-director of the Stanford Biodesign Program at Stanford University. He has been a pioneer and consistent innovator throughout his career, and has served in leadership positions in many of the important surgical societies including the American College of Surgeons, the American Pediatric Surgical Association, the American Surgical Association, the American Board of Surgery, the American Board of Pediatric Surgery, and the American Board of Plastic Surgery. Over the last 14 years, Dr. Krummel has pioneered the application of technology to simulation-based surgical training and surgical robotics. For his work in this area, and developing a collaborative simulation-based surgical training system, he has received two Smithsonian Information Technology Innovation Awards.

Christine Kurihara is manager of special projects, Biodesign Program, Stanford University, where she oversees the development of new projects. She is currently developing the online companion to the biodesign textbook. Ms. Kurihara joined the Biodesign Program after an 11-year career with Stanford in media services. In her previous role she spearheaded media development efforts for an on-campus service unit, where her teams produced websites, online courseware, and video and broadcast products. Prior to running Media Solutions, she developed the first official Stanford University website and served as managing editor. In 1997, Ms. Kurihara co-chaired the Sixth International World Wide Web Conference.

Glossary

483 A form letter issued by the FDA if actionable problems are uncovered during an FDA audit.

510 (k) One of several pathways for medical devices through the regulatory process at the FDA. This pathway is used when similar devices are already in use.

Acquisition A transaction in which the seller of the property (technology, IP, company) completely relinquishes control of the property to the acquirer.

Administrative detention A temporary "cease and desist" order from the FDA.

AdvaMed Advanced Medical Technology Association. The advocacy group for medical device companies.

AHA American Hospital Association. An association that represents hospitals, healthcare networks, and their patients and communities.

AHRQ Agency for Healthcare Research and Quality. A US government agency responsible for collecting evidence-based data on healthcare outcomes. Longitudinal data are available through its website.

AIMDD Active Implantable Medical Device Directive 90/385/EEC. One of the key regulatory approval directives used in the European Union.

AMA American Medical Association. The primary association of physicians in the United States. The AMA controls the issuance of new CPT codes.

Angel investor Experienced individual investor who uses his or her own wealth to fund start-up companies. Angel investors may be organized in groups.

ANSI American National Standards Institute. The US standards organization that is representative to ISO.

APC Ambulatory Payment Classification. Codes for classifying hospital outpatient procedures.

Arm Any of the treatment groups in a randomized trial. Most randomized trials have two arms, but some have three or even more (see Randomized trial).

ASIC Application specific integrated circuit. One potential component of the electrical circuitry of a device.

ASQ American Society of Quality.

BATNA Best alternative to a negotiated agreement. The course of action that will be taken if a negotiation fails to lead to an agreement.

BCBS Blue Cross Blue Shield. Health plans that operate in various regions in the United States. There are 39 BCBS plans and the BCBS Association is a trade group that, among other things, helps establish guidelines for reimbursement.

Bench testing Testing prototypes (materials, methods, functionality) in a controlled laboratory environment (not in animals or humans).

Beneficence A basic principle of bioethics that all medical work is for the good of the patient; contrast to maleficence.

Bias When a point of view prevents impartial judgment on issues relating to the object of that point of view. In clinical studies, blinding and randomization control bias.

Bio-compatibility The property of a material that indicates that it is suitable to be placed in humans.

Blind trial A trial in which neither the members of the patient group nor any participating doctors, nurses, or data analysts, are aware of which treatment or control group the patients are in.

Blue-sky need A large-scale need that would require major new medical or scientific breakthroughs and/or significant changes in practice.

Bottom-up model A market model that uses a series of detailed sales factors, including sales cycle, adoption curve, hiring effort, commercial effort, etc. to predict future sales.

Breadboard A board that can be used to assemble electronic components and connect them for use in prototyping devices with computer parts.

Bridge loan An interim debt financing option available to individuals and companies that can be arranged relatively quickly and span the period of time before additional financing can be obtained.

Budget impact model A model for demonstrating product value that examines the cost and treatable population within a health plan, as well as the expected annual cost to the plan for covering a device.

Bundled pricing Setting a single price for a combination of products and/or services.

CAB Conformity Assessment Body. The body that determines compliance to ISO 13485.

CAC Carrier Advisory Committee. The committee that performs a review of all local coverage decisions through Medicare.

CAF Contracting administration fee. The fee that a global purchasing organization will charge for managing the purchasing contracts for many end users, paid by the manufacturer.

CAGR Compound annual growth rate. The annual growth rate for an investment.

CAPA Corrective and preventive actions. One subsystem of a quality management system. The system to implement corrections upon and to avoid future problems in quality control.

Capability-based advantages An advantage over competitors that is driven by a company's capabilities. This type of advantage is based on the ability to do something better or less expensively than the competition and/or customers.

Cash flow statement An accounting statement that shows the cash that flows in to the company in each period (typically quarter) minus the cash that flows out in the same period.

CBER Center for Biologics Evaluation & Research. The part of the FDA that approves biologics.

CDER Center for Drug Evaluation & Research. The part of the FDA that approves drugs.

CDRH The center within the FDA responsible for medical device regulation.

CE mark Resulting "mark" that is given to a device in the EU to indicate regulatory approval.

Citation A formal warning to a company from the FDA. Prosecution will follow if changes are not made.

Civil penalties Monetary penalties imposed on a company after a hearing for violations.

Class I Classification of a medical device by the FDA that indicates low risk to a person.

Class II Classification of a medical device by the FDA that indicates intermediate risk to a person. Class II devices are typically more complex than class I devices but are usually non-invasive.

Class III Classification of a medical device by the FDA that indicates the highest risk to a person. Class III devices are typically invasive or life sustaining.

Clinical investigator A medical researcher in charge of carrying out a clinical trial protocol.

Clinical protocol A study plan on which all clinical trials are based. The plan is carefully designed to safeguard the health of the participants, as well as to answer specific research questions. A protocol describes what types of people may participate in the trial; the schedule of tests, procedures, medications, and dosages; and the length of the study.

Clinical trial A research study performed to answer specific questions about diagnoses or therapies, including devices, or new ways of using known treatments. Clinical trials are used to determine whether new treatments are both safe and effective.

CME Continuing medical education. Additional training required to maintain a license for physicians and others in healthcare-related fields.

CMS Centers for Medicare and Medicaid Services. The primary government payer of healthcare charges for the elderly and disabled in the United States.

Coding The process of assigning a specific, identifiable code to a medical procedure or process.

COGS Cost of goods sold. Raw materials costs for a product.

Common stock Equity in a company that confers on shareholders' voting and pre-emptive rights (the right to keep a proportionate ownership of the company by buying additional shares when new stock is issued).

Comparables analysis Evaluating the pricing strategies (and associated reimbursement status) of similar offerings in the field.

Conditions precedent Section of a term sheet that outlines what steps must be taken before the financing deal proposed in the term sheet can be finalized.

Controlled trial A trial that uses two groups: one that receives treatment, and a second, control group, that does not, in order to compare outcomes.

Conversion, automatic conversion Section of a term sheet that describes how preferred shares will convert to common shares.

Convertible bonds A hybrid debt-equity alternative to companies seeking financing. A type of bond that can be converted into shares of stock of the issuing company, usually at some preannounced ratio.

Core laboratory Laboratories that analyze data from a clinical trial; these laboratories often have specialized equipment and expertise.

Corporate investment When corporations invest in new companies by: (1) the purchase of equity in support of a research and development or a licensing agreement, or (2) traditional venture investments.

Correction Repair or modification of a distributed product while it is still under the control of the manufacturer.

Cost-effectiveness model A model for determining product value where cost is expressed per unit of meaningful efficacy, usually used comparatively across interventions.

Cost-utility model A model for determining product value where cost is assigned for quality of life and years lived. It is based on clinical outcome measures related to quality of life and/or disability and mortality.

Cost/benefit analysis A model for determining product value that demonstrates that the money spent on the device is lower than the total cost of the outcomes of the disease or of current standard therapy.

CPT codes Common Procedural Terminology codes. Codes used to classify medical procedures in a standard way so that the same procedure is reimbursed in the same way across all facilities. Also known as HCPCS Level 1 codes.

CRO Contract (or Clinical) Research Organization. An independent organization that provides management services for clinical trials.

Cycle of care A description of how a patient interacts with the medical system.

Debt funding Funding that is repaid with interest. A loan.

Design controls One subsystem of a quality management system. Controls that ensure the device being designed will perform as intended when produced for commercial distribution.

Design creep Ongoing, minor changes in developing a device that can lead to significant delays and issues with intellectual property and regulatory clearance.

Design validation Ensuring that a design does what it is intended to do.

Design verification Ensuring that a design meets product specifications.

Determination meeting A formal meeting with the FDA to request approval of the design for a clinical study.

Differential pricing Pricing the same product or service differently for different customer segments, e.g., discounts for large buyers.

Dilution Section of a term sheet that stipulates how conversion prices will be calculated if future rounds of financing are dilutive to preferred shareholders' holdings (i.e., they reduce the total value of the shareholders' ownership stake in a company).

Direct sales model Hiring a sales force within a company to sell to customers directly.

Discounted cash flow analysis An analysis that uses cash flows discounted back to present at a discount rate that reflects the returns the shareholders expect from their investment in the company. The higher the risk in the investment, the higher the discount rate investors will use in this analysis.

Distribution play To focus on product breadth and channel relationships rather than on product superiority.

Dividend provisions Section of a term sheet that describes the conditions for which dividends will be paid. A dividend is a payment to the shareholder that is proportional to the shareholder's ownership of a company.

Divisional A type of patent application that claims a distinct or independent

invention based upon pertinent parts carved out of the specification in the original patent.

DRG Diagnosis related group. A set of codes that are grouped together by diagnosis; used specifically for coding hospital related billing for patient encounters. Replaced recently by MS-DRG (Medical Severity DRGs) that include adjustments based on comorbidities and complications.

DSMB Data Safety and Monitoring Board. An independent body that reviews results of clinical trials.

DSP Digital signal processor. One potential component of the electrical circuitry of a device.

DTC Direct-to-consumer. A type of marketing that targets the end user of a product, as opposed to the physician or other medical professional.

DTP Direct-to-patient. A type of marketing that targets patients directly, as opposed to physicians or other healthcare professionals.

Due diligence An iterative process of discovery, digging into detail about the various elements of a start-up company's business plan or licensing opportunities.

Earn-out An acquisition in which additional payments are made to the seller after the sale day if the acquired company reaches prespecified milestones.

Efficacy endpoints A result during an animal or clinical study that demonstrates efficacy (i.e., a therapeutic effect). Endpoints are what a study is designed to prove.

Epidemiology Study of factors affecting the health and illness of a population that are used as the basis of making interventions in the interest of public health.

EPO European Patent Office. The office that provides unified patent filing for 38 European countries.

Equity funding Funding in which the investor provides a cash infusion to a company and in exchange obtains equity in the company.

Ethnographic research Understanding a particular culture or way of life by studying the members of that culture or group.

Evergreening The process of introducing modifications to existing inventions and then applying for new patents to protect the original device beyond its original 20-year term.

Evidence-based Treatments, guidelines, and processes based on the results and outcomes generated from experiments and observation, which use specific evidence of outcomes and suggest treatment or processes based on such evidence.

Exclusion criteria Characteristics or contraindications that eliminate subjects from participating in a clinical study.

Exclusive rights The rights of the inventor or group of inventors, who has/ve been issued a patent on an invention, to be the sole person(s) creating and marketing that invention.

Exclusive license A license that grants only the licensee (and not even the licensor) the right to use a technology.

Exit When a company is either acquired or has an IPO.

Expansion funding Funding required to ensure completion of clinical trials, initiation of additional trials or initial product launch. Such funding is often acquired through VCs or corporate investment.

Facility and equipment controls One subsystem of a quality management system. It ensures, in part, that standard operating procedures have been designed and implemented for all equipment and facilities.

Fast follower A company that leverages its own corporate advantages to quickly capture market share from the first mover.

Field of use A licensing option that allows an existing patented device to be used within a restricted domain, such as one clinical area.

FPGA Field-programmable gate array. One potential component of the electrical circuitry of a device.

FIM First-in-man. The first time a device or technology is used in a human subject.

Financial model A detailed numerical articulation of a company's costs and revenue over time. It tracks both the cost of developing the innovation and bringing it to the market as well as market revenue, and it follows these costs and revenue over a period of five to seven years.

First mover strategy An attempt by a company to be first to market with any innovation.

Flow of money Analysis, aimed at identifying key stakeholders, that is focused on payments to providers of healthcare services.

Freedom to operate The ability to commercialize a product, without infringing on the intellectual property rights of others.

Fully burdened cost The total cost of an employee, including salary, benefits, associated overhead, and fees.

Gainsharing When hospitals negotiate reduced prices with certain manufacturers in exchange for increased volume.

GCP Good Clinical Practices. Guidelines from the FDA that outline specific standards for holding clinical trials.

GLP Good Laboratory Practices. A system of management controls for laboratories that assures consistent and reliable results.

GMP Good Manufacturing Practices. Formerly used by the FDA to promote quality; replaced by Quality Systems Regulation (QSR).

GPO Global purchasing organization. An organization that brings together multiple hospital groups, large clinics, and medical practices into buying cooperatives.

HCPCS Level II Health Care Financing Administration's Common Procedure Coding System Level II. Coding for supplies and services obtained outside the physician's office that are not covered by a CPT or APC code.

HDE Humanitarian Device Exemption. An exemption to the normal regulatory pathways for a medical device that is intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in fewer than 4,000 individuals in the United States per year.

HIPAA Health Insurance Portability and Accountability Act. Ensures comprehensive protection of patient health information (PHI).

HCUP net Healthcare Cost and Utilization Project. A website with data about healthcare cost and utilization statistics in the United States (e.g., hospital stays at the national, regional, and state levels).

Hypothesis A supposition or assumption advanced as a basis for reasoning or argument, or as a guide to experimental investigation.

IACUC Institutional Animal Care and Use Committee. A committee that institutions must establish in order to oversee and evaluate animals used for trials.

ICD-9-CM codes International Classification of Diseases, 9th edition, Clinical Modification codes. Codes for classifying morbidity data and describing patient diagnoses and procedures; variation on ICD-9 used by the United States.

ICD-9 codes International Classification of Diseases, 9th edition codes. Codes for classifying patient diagnoses.

IDE Investigational Device Exemption. An exemption to a hospital or doctor from the FDA that allows the hospital or doctor to use a device prior to its regulatory approval, usually as part of a trial.

IDN Integrated delivery network. An organization that aggregates hospitals, physicians, allied health professionals, clinics, outpatient facilities, home care providers, managed care, and suppliers into a single, closed network.

IFU Indications for use. Instructions on how to use a device. Mandated by the FDA. Typically a package insert.

Illiquid Not liquid (e.g., stock or other property that is not easily sold or converted to cash).

Inclusion criteria Characteristics or indications that subjects must have in order to participate in a clinical study.

Incubator Small companies that specifically serve to develop a need or concept at the early stages. An incubator may incubate multiple device concepts for a significant period of time. Successful products may result in the spin-out of a company from the incubator into a stand-alone entity.

Indirect sales model A sales and distribution agreement with an existing distributor, or forming a third-party partnership with another manufacturer.

Information rights Section of a term sheet that defines what and how much information about the company is shared with investors.

Informed consent Consent by a research subject that indicates they are fully aware of all aspects of the trial prior to participating, including both the risks and potential benefits.

Injunction An order issued by the courts that requires a medical device company to refrain from some action (manufacturing, selling, etc.).

Innovation notebook A notebook in which an innovator documents each aspect of the invention. This notebook may be used in infringement trials to prove inventorship.

Interference proceeding A proceeding held by the USPTO to determine who was first to invent a claimed invention.

IRB Institutional Review Board. A committee that monitors clinical trials to ensure the safety of human subjects.

Intrapreneur A person within a company who is tasked to develop new products or business models – an internal entrepreneur.

IPO Initial public offering. The first offering of a company's stock for public sale in a stock exchange such as the New York or London stock exchanges.

ISA International Searching Authority. The organization that performs patent searches as part of an international patent filing.

ISO International Organization for Standardization. A non-governmental network of national standards institutes that establishes standards of quality. The name ISO is not an acronym but rather based on the Greek word *isos* meaning equal.

ISO 13485 International Standards Organization Certification 13485. The European Union's Quality System (compare to QSR).

ISO 9001 International Standards Organization Certification 9001. A quality certification in use around the world between the 1980s and 1990s.

IVMDD In Vitro Diagnostic Medical Device Directive 98/79/EEC. One of three regulatory approval directives used in the EU.

KOL Key opinion leader. Physicians and others in the medical device arena who are often consulted when new devices are readying for the market.

LCD Local coverage determination. One of two types of reimbursement determinations made by Medicare that provides guidance on national reimbursement coverage. Typically applies to payments for outpatient services. LCDs are decisions made by one of 28 Medicare contractors and apply only to the contractors' area of coverage.

Lexicographer An inventor may use his/her own language and definitions in a patent application, thus becoming a lexicographer.

Licensing One option in getting a technology to market by transferring the rights to the technology from the innovator to a licensee in exchange for ongoing royalties and/or other payments.

Liquidity event The transaction that enables an investor to receive cash in exchange for its equity stake in a company. Also referred to as exit events.

LLC Limited Liability Company. A type of corporation that establishes a board and limits liability to the owners of the company.

Longitudinal data Data collected in studies that take place over several years, often decades or more.

Loss leader An item sold at a lower cost (often below the cost to the manufacturer) in order to stimulate additional sales of profitable items.

Management controls One subsystem of a quality management system. Controls that ensure adequate management support and participation in quality systems.

Manufacturing costs Costs for material (COGS), manufacturing labor, facilities, and equipment.

Market segmentation Using specific parameters to partition the market into identifiable, homogeneous segments in order to understand sales and marketing needs.

Market withdrawal A response to a minor violation that is not caused by legal action by the FDA.

Marquee physicians High-profile practitioners who are influential with their colleagues.

Material controls One subsystem of a quality management system; controls that ensure material quality and consistency.

MAUDE The FDA database of all significant adverse events due to medical devices.

MDD Medical Device Directives 93/42/EEC. One of three regulatory approval directives used in the European Union.

MDR Medical Device Reporting. The reporting vehicle through which the FDA receives information about significant medical device adverse events that was established by the Safe Medical Devices Act.

MDUFMA Medical Device User Fee and Modernization Act. The federal act that established user fees in the medtech industry.

Me-too products Products that are relatively undifferentiated from products already on the market.

Mechanism of action The specific biochemical or biomechanical interaction through which a drug or device produces its effect.

MEDLINE Medical Literature Analysis and Retrieval System Online. A literature database of biomedical research papers.

Medtech Medical device technology. A short form to allow comparisons to Biotech, for instance.

MEPS Medical Expenditures Panel Survey. The longitudinal data on health expenditures of 30,000 US households provided by AHRQ.

Mezzanine funding Funding that is required when some of the most significant risks have been resolved but the company has yet to generate sufficient revenue to be self-sustaining.

MHRA Medicines and Healthcare Products Regulatory Agency. The organization that approves devices and drugs for Europe (including the UK).

Mixed need A need with features that are easily achievable (more incremental to existing approaches) and other elements that introduce significant technical or clinical risk.

Morbidity When a human is harmed in some way (short of death) by infection, decreased quality of life, extended hospital stay, physical impairment, etc.

NAI No Action Indicated. A classification for an FDA audit that indicates no further action is required by the inventor or company in order to seek approval for a device.

NCD National coverage determination. One of two types of reimbursement determinations made by Medicare that provides guidance on national reimbursement coverage. Typically applies to payments for inpatient services.

NCHS National Center for Health Statistics. The US-based principal health statistics agency; they compile statistical information to guide actions and policies to improve health.

NDA Non-disclosure agreement. An agreement between two parties such that the party receiving confidential information from another party will not disclose the information to anyone for a fixed period of time.

Niche strategy A strategy whereby a company seeks to own the customer relationships in a specific, focused area of medicine.

Non-exclusive license A license that allows the licensee rights of use within a given field and within whatever other limitations are provided by the license, but allows the licensor to grant similar rights to other parties.

NGO Non-governmental organization. Non-profit organizations working for a cause. These organizations provide resources and assistance to parties when the governments will not or cannot provide them.

Notice of Allowance The notice from the USPTO to indicate the patent has been accepted.

NSE Not Substantially Equivalent. A determination by the FDA that a new device is not equivalent enough to a predicate device and therefore cannot use the 510k pathway.

OAI Official Action Indicated. A classification for an FDA audit indicating that action is required by the inventor or company in order to seek approval for a device.

Observational studies Studies that make conclusions about the efficacy of a treatment or device on a group of subjects where the assignment of subjects into the treated versus control groups is outside the control of the investigator.

OCP Office of Combination Products. The section of the FDA that reviews medical technology comprising a combination of drugs/device or drugs/biologics to determine which center of the FDA will regulate it.

OEM strategy Original equipment manufacturer strategy. When a company provides technology and/or components to another company that then assembles and sells the finished product.

Off-label use The use of a treatment for conditions other than those approved by the FDA.

Office action A document issued by the USPTO that outlines objections or necessary changes to an application or claim due to finding prior art.

OHRP Office for Human Research Protections. A federal agency that helps assure the protection of humans participating in clinical research.

OIPE Office of Initial Patent Examination. The first agency that examines patent applications for completeness.

Operating profit The difference between income and the expense incurred during operations.

OpEx Operating expenses. Costs considered not to be manufacturing costs, including R&D, sales staff, general and administrative functions, and non-production facilities costs.

Opportunity cost The opportunity forgone by choosing a different opportunity.

OPRR Office for Protection from Research Risks. Now called the Office for Human Research Protections.

Option pool The total number of stock options available for a company to grant, typically to employees.

OTC Over the counter. Drugs or devices that are sold directly to the end consumer.

OTL Office of Technology Licensing. The office within a university that manages its IP assets.

OUS Outside United States. Refers to clinical trials (or other activities) that are performed outside the United States. Often used in reference to obtaining regulatory approval.

P&PC Production and process controls. One subsystem of a quality management system. Requires that production processes be controlled and monitored to ensure product conforms to specifications.

Partnering strategy One option in getting an idea to market – joining with another company to help develop a device.

Pass-through code Also called a c-code. A code that is issued to cover the cost of a device that is incremental to the services provided under an existing APC code, or set of codes. The cost of the device may be bundled into this transitional APC code, or may still be billed separately under a temporary pass-through code.

Patho-physiology Study of the change of the normal mechanical, physical, and biochemical functions of a human