Preface

Our intention in putting together this volume, *A Practical Guide to Drug Development in Academia: The SPARK Approach*, was not to generate a comprehensive “how to” book; this topic cannot be taught in 150 pages. Rather, this volume is an answer to requests from our own SPARKees as well as from other academic institutions that have established or are planning to establish their own translational research programs. This book provides 4–5 pages on each topic that is part of the long process of drug development. The book is intended for novices who embark on this amazing path of translating basic research or clinical findings into new therapeutics to benefit patients. Ideally, you will read this book before you begin this translational effort, so that you will understand the path ahead, start planning what the final product will be (“target product profile” in the industry lingo), and then create a path back to where the project is today—doing it the industry way, with our own academic twist. This book should also be useful for students and postdoctoral fellows who plan a career in industry or who hope that their academic career will be translational in nature.

SPARK at Stanford is now in its seventh year. The program evolved slowly. We have found a certain formula that works well for our academician inventors and we hope that it will work for all. This book was written mainly by our SPARK mentors—the true engine for the success of the program. It is not a complete guide to what needs to be done but provides a general overview of the important topics in the development process.

Drug development is applied science with a concrete goal in mind. A successful program will require contributions from experts in multiple disciplines (chemistry, biology, pharmacology, toxicology, medicine, regulatory science, statistics, and many more). Since no single person can master all of these disciplines, we encourage you to seek advice liberally from experts in the field. By peppering the various chapters with lessons that surprised me since my initiation into biotechnology entrepreneurship 12 years ago, I hope to demonstrate how, at least for me, drug development is not necessarily intuitive. You will find these in boxed text throughout the chapters.
After working on my own translational research projects and now mentoring over 70 other academic projects, I can summarize the following key lessons that I have learned.

1. Check your ego at the door–drug discovery is not about any one person; it is a true team effort, requiring experts in multiple disciplines. The weakest link is standing between you and total failure.
2. Consult, consult, consult–there is always someone who knows much more than you about what is needed (preferably more than one person). Find these individuals and get their advice.
3. Always continue to apply your own judgment, as even experienced advisors can be wrong.

As the editors of this volume, Kevin Grimes and I hope that you will find it useful in your endeavor.

And now–Let’s SPARK

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