Acknowledgments

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Foreword

This continues to be a remarkable time for science, medicine and public health. The rapid pace of scientific discovery—from the so-called "omics" revolution and synthetic biology, to newly evolving cellular and gene therapies, to advances in technology such as gene-editing, nanotechnology, 3-D printing and, of course, information technology and data science—holds the promise of truly revolutionary new therapies and interventions to prevent, treat and cure disease. Before us is the opportunity to advance human health and well-being in ways not previously understood or even imagined.

But, while translating new discoveries into real-world products can make an enormous difference for individual and population health, the process is a complex and difficult one. It is an activity fraught with challenges, requiring many steps and partners. The painstaking work to develop, test, manufacture and distribute a new medical product successfully requires a vast range of expertise, skills and dedication. Moreover, it demands coordinated work across disciplines, sectors and, increasingly, across nations.

The task is not easy, but this volume provides a wonderful roadmap for those who are part of this extraordinary enterprise seeking to realize the potential of modern medicine and public health through enhanced regulatory science and strategy. Organized around a set of thoughtful, authoritative and well-written chapters, the book lays out the essential elements of an integrated regulatory approach. Written by a group of distinguished authors, each chapter is a clear exposition of an important topic, ranging from the ABCs of regulatory strategy and the whys and wherefores of interacting with regulators, to more technical aspects of the medical product challenge such as preclinical and clinical development, expedited pathways, orphan designation, pediatric products and product formulation, manufacturing and control. Of note, this book takes a systematic approach, spanning the earliest stages of research and development to necessary assessments and modifications in the postmarket period, as well as embracing globalization's realities for regulatory strategy and systems.

No matter how steeped one is in drug development and regulation, this book can provide both updated information and new insights. And, for those still being initiated into this exciting and essential realm of professional activity, this book can serve as a vital handbook for knowledge and action.

Given the array of unmet medical care and public health needs before us, this is not an academic exercise. There is a pressing responsibility to make sure the opportunities in science and technology today will result in the safe, effective and high-quality medical therapeutics people so hope for and deserve. Every effort must be made to ensure the best possible products are delivered as swiftly and surely as possible, but never forgetting the scientific rigor and regulatory oversight that ultimately determine failure or success.

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