Foreword

Since the enactment of the Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act, medical technology has evolved at an unprecedented rate. Innovation is being fueled by new concepts and ideas derived from virtually all fields of science and medicine. Simultaneously, legislation has expanded the roles and responsibilities of regulatory agencies to meet the challenges created by the imagination-stretching medical device industry. While the U.S. regulatory construct for medical devices has remained relatively constant, the expectations of our society, coupled with the complexities of an overburdened healthcare system, have resulted in a number of amendments to the statute, as well as new laws, regulations, and guidance documents. It is a constant challenge for individuals working in the field to keep pace with these changing, and sometimes divergent, regulatory requirements. Until now, there has been no single source of answers to the many common questions that surface when working within a complex system of somewhat overlapping and competing regulatory requirements for medical devices.

The contents of this book reflect that, while specialization is necessary to survive a complex regulatory environment, integration is essential if tomorrow's leaders are to have a clear understanding of the challenges and opportunities before them. Application of this integrated knowledge is the basis for successful growth and survival of a medical device company. There is simply no better time to ensure that the proverbial forest is not obscured by the trees. To this end, this book brings together insights from the world's leading experts in medical device law and regulation for the purpose of compiling a comprehensive overview of topics and questions of interest to virtually everyone doing business in the medical device sector.

Readers will find a compilation of far-ranging topics, from an overview of the U.S. legal framework for FDA device regulation to in-depth coverage of individual FDA programs that cover everything from conducting clinical trials, preparing successful premarket submissions, adhering to quality system requirements, and fulfilling post-market

obligations. For those facing complexities related to *in vitro* diagnostics and devices incorporating drugs, biologics, cell therapies, and software, experts familiar with these areas provide insight into what it takes to make these advances a reality. Perhaps even more importantly, other critical topics that are often overlooked in textbooks devoted to medical device issues are integrated to provide the reader a more global view of the realities that are encountered when operating in this heavily regulated environment. In this regard, the editors include chapters on specialized topics that have a marked impact on the medical device industry, such as intellectual property, product liability, and reimbursement. Nowhere is such a breadth of information presented in one answer book.

I suggest that this text be maintained for easy reference by all lawyers, consultants, and companies operating in the medical device sector, as well as all companies contemplating entry into the heavily regulated world of medical devices. After becoming familiar with its contents, readers will find it to be a ready source for valuable information on the topics that they will inevitably face, with answers to the most frequently encountered questions.

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