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Foreword

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The field of combination products is relatively new and only a few publications concerning the unique challenges posed by this emerging but fast-growing area are available, particularly when it comes to respective regulatory challenges. It is a significant area with different regulatory environments in various geographical regions.

Unfortunately for the industry, there is an absence of clearly defined global harmonized regulations. Combination products bring together regulatory frameworks that are usually distinct from one another. A structured development process, using a risk-based approach and a sound quality system is required. Even though the terminology may be different in the two areas, a consistent framework helps bring them together and ensures a safe and effective use of a combination product.

This continues to be a remarkable time for regulatory science, very dynamic and changing frequently. However, while translating new discoveries into the real-world, combination products can make an enormous difference for individual and population health, both in hospitals but also in home-use. The process is complex and difficult. The painstaking work to develop, verify, validate, and receive approval of a new combination product requires a vast range of expertise, skills, and dedication. Complicating this challenge is the fact that, unlike drugs and devices by themselves, the degree of innovation in convergent technologies is a multiple of the innovation in either area alone. It demands coordinated work across disciplines, sectors, and, increasingly across nations. It addresses the technical, scientific, regulatory, and quality issues that arise when combining drugs, biologics, and medical devices into a single product.

Providing an in-depth look at this breakthrough field, *International Combination Products* includes background information and practical guidelines regarding regulatory challenges of these novel technologies. It takes a practical, readily applicable approach to discussing the relevant challenges, victories, and pitfalls associated with merging technologies. Specifically, this book explores the process from start to finish, establishing a workable regulatory strategy to bring the products to the market in a compliant and timely manner.

No matter how steeped one is in combination products and their various regulations in different geographical areas, this book provides both updated information and new insights. For those starting their career in regulatory, this book will serve as a vital source for knowledge and action.

This comprehensive publication with a wealth of invaluable information is based on the vast experience and expertise of **Jocelyn Jennings, MS, RAC (US, Drugs, Devices)**, a veteran in the combination product regulatory space. Although regulations are naturally ever-changing, this book is considered a landmark in this fascinating space.

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 products people so hope for and deserve. Every effort must be made to ensure the best possible products are delivered as swiftly as possible, but never forgetting the scientific rigor and regulatory oversight that ultimately determine failure or success.