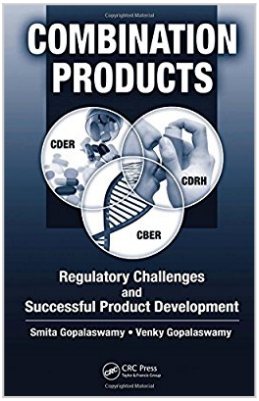


# Combination Products: Regulatory Challenges and Successful Product Development

*By Smita Gopalaswamy, Venky Gopalaswamy*



**Combination Products: Regulatory Challenges and Successful Product Development** By Smita Gopalaswamy, Venky Gopalaswamy

The field of combination product development (products born of the integration of medical devices, biologics, and drugs) is so new that, while literature abounds on each part individually, there are very few publications, including FDA documents, available concerning the unique challenges posed by this nascent but fast-growing area.
Providing the first in-depth look at this breakthrough field, **Combination Products** includes practical guidelines and a detailed step-by-step process for the development of these novel technologies. It addresses the technical, scientific, regulatory, and quality issues that arise when combining drugs, biologics, and medical devices into a single product. It takes a practical, readily applicable approach to discussing the challenges, victories, and pitfalls associated with merging technologies and systems and how to implement these products into the market successfully and in a timely manner.
Specifically, this text explores the process from start to finish, establishing a workable design and development plan complete with relevant definitions. It reviews FDA and other regulatory expectations and covers resource requirements, manufacturing pitfalls, post-launch compliance requirements, and agency audits and challenges.
Drawing on the experience and expertise of two leaders in their respective fields, **Combination Products** boasts the credentials of Dr. Smita Gopalaswamy, a 20 year veteran of technical consulting responsibilities in medical device, biologics, and pharmaceutical industries as well as combination products, along with the support of Dr. Venky Gopalaswamy, an expert in business improvement methodologies such as six sigma, lean, and change management, to provide a comprehensive assessment of the field and an efficient and effective approach to the creation and implementation of combination products.

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