



Development of FDA-Regulated Medical Products: A Translational Approach, Second Edition

Elaine Whitmore

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Translating promising discoveries and innovations into useful, marketable medical products demands a robust process to guide nascent products through a tangle of scientific, clinical, regulatory, economic, social, and legal challenges. There are so many human and environmental elements involved in shepherding medical advances from lab to launch that the field of medical product development has been referred to as an ecosystem. The purpose of this book is to help provide a shared foundation from which cross-functional participants in that ecosystem can negotiate the product development labyrinth and accomplish the goal of providing both groundbreaking and iterative new medical products. The book is intended for anyone in industry, the public sector, or academia regardless of functional specialty, workplace, or seniority who is interested in medical product development. The years since the publication of the previous edition of this book have seen profound changes in the actions and attitudes of patients, insurers, manufacturers, and the Food and Drug Administration regarding the streamlining of medical product development and approval. What those years have not seen is a concomitant increase in innovative treatments with profound benefits to patients. Despite enormous investments in research by both private and public sources and a surge in scientific and technological advances, new medical products barely trickle into the marketplace. For a variety of reasons, applied sciences necessary for medical product development are not keeping pace with the tremendous advances in basic sciences. Not surprisingly, industry and academia are under substantial pressure to transform discoveries and innovations from the laboratory into safe and effective medical products to benefit patients and improve health. This evolution from bench to bedside has become known as translational research and development, and this approach is what this book illuminates.

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