



Re-inventing Drug Development



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The biopharmaceutical industry has entered an era of unprecedented change and challenge, characterized by increasing pricing pressures, rising rates of attrition in the product development lifecycle, and decreasing scientific innovation. The most successful products are losing patent protection, and pipelines have been unable to fill the gap. This book explores the evolving definition of innovation in therapeutic product development and begins to examine its effects on the life sciences R&D industry.

Historically, scientific innovation alone was sufficient to maintain ROI and deliver on unmet medical needs. However, with many forces now conspiring to increase pressures on the commoditization of drug development, industry support for truly novel, often high-risk development has eroded. This calls for a drastic redefinition of what "innovation" is. While innovation in the pharmaceutical R&D industry has historically been applied to major advances in therapy and unmet medical needs, we now need to see innovation increasingly defined in terms of financial, marketing (e.g. branded generics and emerging markets), pharmacoeconomic, and operational innovation.

In this book, contributors drawn from the executive ranks of clinical development practitioners and stakeholders—from biopharmaceutical companies, clinical research organizations, academia, the financial community, and the patient perspective—have all come together to provide their expertise and visions. Their goal is to start a dialogue about ways to radically improve therapeutics development and get more and better medicines to the patients who need them, as fast as possible, in the most cost-efficient manner.

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