

Nancy J. Alexander Anne Colston Wentz Editors

## Idea to Product

The Process

With 11 Figures





## Contents

	facetributors	vi Xii
	Part I. Introduction	
1.	The Preclinical Research Process  James S. Hutchison	3
2.	The Commercial Development Process	5
	Part II. Getting Started	
3.	What's Involved in Clinical Research?	ç
4.	Product Development Partnership: Role of Academia and the NIH	17
5.	Identifying Funding Opportunities at the NIH: A Grants Perspective	21
6.	Identifying Funding Opportunities at the NIH: A Contract Perspective	25

7.	Role of the Institution in Furthering the Young Investigator	33
	Part III. Details of Drug Development	
8.	Role of Toxicology in Drug Discovery and Development ROBIN S. GOLDSTEIN	47
9.	Pharmacokinetics Study	49
10.	Formulation of Dosage Forms	51
11.	Polymeric Drug Delivery Systems	53
12.	What Is a Drug, a Device, a Biological?	69
	Part IV. Negotiating the System	
13.	Part IV. Negotiating the System  Understanding the Organization and Function of the FDA	75 .
13. 14.	Understanding the Organization and Function of the FDA	75 · 81
	Understanding the Organization and Function of the FDA	
14. 15.	Understanding the Organization and Function of the FDA	81
14. 15.	Understanding the Organization and Function of the FDA	81

	Contents	_ xi
18.	FDA Recommendations for Drug Safety Testing	115
19.	Decision Strategies in Assessment of Reproductive and Developmental Toxicology: A Paradigm for Safety Evaluation	119
20.	What Is Involved in a New Drug Application? LISA D. RARICK	133
21.	Institutional Review Boards and Informed Consent  GARY B. ELLIS	141
22.	Postmarketing Surveillance: A Brief Synopsis of Its History and Current Direction	147
	Part VI. Business Issues	
23.	I Had an Idea, and I Made It Work: Here's How Elie S. Nuwayser	159
24.	Working with Companies to Market Your Discoveries ELIZABETH G. POSILLICO	165
25.	Developing Information for Health-Care Decision Makers	167
26.	Getting a Medical Products Business Started	169
27.	From Start-Up to Initial Public Offering	179
Aut	hor Index	189
Sub	ject Index	191