

Table of Contents

Preface

About the Editors

About the Authors

Section 1—Protecting Your Idea for Your New Pharmaceutical Product

Chapter 1-1:	The Basics About Patents	3
Chapter 1-2:	How to Get a Patent.....	7
Chapter 1-3:	Trademarks	13
Chapter 1-4:	Copyright Protection	25
Chapter 1-5:	An Overview of Pharmaceutical Data Protection in the United States, Canada, and the European Union	31
Chapter 1-6:	Licensing	45

Section 2—Establishing Your Business

Chapter 2-1:	Form the Appropriate Legal Entity and Manage Important Tax Issues	83
Chapter 2-2:	Develop Contracts for Your Employees, Including Executive Compensation/Incentives and Employee Benefits Packages.....	97
Chapter 2-3:	Develop Company's Employee and Related Policies and Procedures	129
Chapter 2-4:	Risk Management and Insurance Considerations for Your Business	165
Chapter 2-5:	Best Practices for Corporate Governance.....	179

Section 3—Development and Approval of Your Pharmaceutical Product

Chapter 3-1:	FDA Regulatory Scheme	191
Chapter 3-2:	Research and Development	205
Chapter 3-3:	Naming Your Pharmaceutical	219
Chapter 3-4:	Investigational New Drug Application (IND)	235
Chapter 3-5:	Clinical Trial Compliance Issues Affecting Data Integrity	267
Chapter 3-6:	What Pharmaceutical Manufacturers Should Know About Combination Products	289
Chapter 3-7:	Orphan Drugs	303
Chapter 3-8:	Generics	321

Chapter 3-9:	Good Manufacturing and Laboratory Practices for Pharmaceutical Development	339
Chapter 3-10:	Labeling	365
Chapter 3-11:	Submitting a New Drug Application (NDA)	401
Chapter 3-12:	Timing of Application Review, Approval, or Complete Response Letters	417
Chapter 3-13:	Postmarketing Obligations & REMS (Risk Evaluation and Mitigation Strategies) Programs	445

Section 4—Legal Issues in Marketing Your Pharmaceutical Product

Chapter 4-1:	FDA Regulatory Framework for Marketing Your Product	469
Chapter 4-2:	Promoting Your Product	505
Chapter 4-3:	Developing and Implementing a Corporate Compliance Program.....	543
Chapter 4-4:	Maturing a Corporate Compliance Program	569
Chapter 4-5:	Working with Healthcare Professionals	591
Chapter 4-6:	Avoiding Pitfalls: Government Investigations and Enforcement	609
Chapter 4-7:	Ensuring the Integrity of the Drug Product Supply and Distribution Chain.....	645
Chapter 4-8:	Selling to and Negotiating with Payors	683
Chapter 4-9:	Avoiding Product Liability Problems and Confronting Product Liability Litigation	703
Chapter 4-10:	Pharmacovigilance	729
Chapter 4-11:	Understanding, Anticipating, and Preventing Pharmaceutical Recalls	737
Chapter 4-12:	Communications Preparedness for Times of Crisis	753
Index.....	769	