

TABLE OF CONTENTS

Preface vii
Acknowledgments ix
Introduction xi

1 Global regulatory agencies 1

1.1 Overview 1
1.2 The Global regulatory agencies 2
1.3 Global regulatory agency mission, scope, function and goals 5
1.4 Global regulatory agency interactions with industry 12
1.5 World Health Organization (WHO) 25
1.6 International Conference on Harmonization (ICH) 27
1.7 The Common Technical Document (CTD) 29
1.8 Conclusion 30

2 Global regulatory affairs—role in the biopharmaceutical industry 31

2.1 Overview 31
2.2 Global regulatory affairs organization 32
2.3 Role of global regulatory affairs 34
2.4 Key regulatory functions and activities 39
2.5 Global regulatory strategy 47
2.6 Global regulatory agency interactions 52

3 Global biopharmaceutical product development 55

3.1 Overview: Biopharmaceutical product development 55
3.2 Discovery research 56
3.3 Development research: pre-clinical and clinical testing 63
3.4 Product registration and maintenance 72

4 United States regulatory system 85

4.1 U.S. regulatory environment and FDA history 85
4.2 FDA organization, mission, scope and function 92
4.3 FDA process of review of applications and engagement 97
4.4 Product safety and post-approval activities 116
4.5 Post-approval activities 120

5	The European regulatory system	125
5.1	Chapter overview	125
5.2	European Medicines Agency (EMA)	131
5.3	European regulatory legislative incentives to industry for innovation	136
5.4	European regulatory agency systems and process of review of applications	139
5.5	EMA initiatives	159
5.6	Conclusion	159
6	Japan regulatory System	161
6.1	Japan regulatory environment—overview	161
6.2	Japan product development and registration process	166
6.3	Japan post-market surveillance system	174
7	Australia regulatory system	177
7.1	Overview—Australia regulatory environment and history of Therapeutic Goods Administration (TGA) organization and function	177
7.2	TGA process of review of applications and engagement and with industry	182
7.3	TGA product safety and post-approval activities	187
8	Canada regulatory system	189
8.1	Canada regulatory environment—overview	189
8.2	Health Canada—Health and Food Products Branch (HFPB)	193
8.3	Canada regulatory agency systems and process of review of applications	195
8.4	Canada post-marketing activities	200
9	Regulatory systems—Opportunity Market countries: Latin America, East and Central Europe	203
9.1	Opportunity markets overview	203
9.2	Latin America and the Caribbean	215
9.3	East and Central Europe	239
10	Regulatory systems in Opportunity Markets	249
10.1	Overview	249
10.2	Middle East	251
10.3	Africa	2554
10.4	East Asia	261
10.5	South East Asia	299
	Index	313
	About CenterWatch	319