Contents

Preface ix

Acknowledgment xiii

Abbreviations xv

Part I  Basics

1 Historical Perspective 3

2 Gene Transfer with Plasmid Biopharmaceuticals 35

3 Product and Process Development 69

4 Structure 85

5 Analytical Characterization 129

6 Delivery 167

Part II  Applications

7 Ethical and Safety Issues 213

8 Human and Veterinary Markets 243
9 Human Case Studies: Pandemic Influenza and Critical Limb Ischemia 273

10 Veterinary Case Studies: West Nile, Infectious Hematopoietic Necrosis, and Melanoma 301

Part III Manufacturing

11 Good Manufacturing Practice and Validation 329

12 Product Specifications and Quality Control 357

13 Cell Culture 391

14 An Overview of Downstream Processing 415

15 Primary Isolation 427

16 Intermediate Recovery 455

17 Final Purification 497

18 Process Synthesis 543

Part IV Concluding Remarks and Outlook

19 Concluding Remarks and Outlook 565

Index 579