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Nota di contenuto	HANDBOOK OF PHARMACEUTICAL BIOTECHNOLOGY; CONTRIBUTORS; CONTENTS; Preface; 1.1 From Gene to Product: The Advantage of Integrative Biotechnology; 1.2 Sequencing the Human Genome: Was It Worth It?; 1.3 Overview: Differentiating Issues in the Development of Macromolecules Compared with Small Molecules; 1.4 Integrated Development of Glycobiologics: From Discovery to Applications in the Design of Nanoparticular Drug Delivery Systems; 1.5 R&D Paradigm Shift and Billion-Dollar Biologics 2 From Defining Bioinformatics and Pharmacogenomics to Developing Information-Based Medicine and Pharmacotyping in Health Care 3.1 Toxicogenomics; 3.2 Preclinical Pharmacokinetics; 3.3 Strategies for the Cytosolic Delivery of Macromolecules: An Overview; 4.1 Basic Issues in the Manufacture of Macromoleucles; 4.2 Process Validation for Biopharmaceuticals; 4.3 Stability Assessment and Formulation Characterization; 4.4 Protein Posttranslational Modification: A Potential Target in Pharmaceutical Development 4.5 PEGylation: Camouflage of Proteins, Cells, and Nanoparticles Against Recognition by the Body's Defense Mechanism 4.6 Unexpected

Benefits of a Formulation: Case Study with Erythropoetin; 5.1 Capillary Separation Techniques; 5.2 Pharmaceutical Bioassay; 5.3 Analytical Considerations for Immunoassays for Macromolecules; 5.4 Chromatography-Based Separation of Proteins, Peptides, and Amino Acids; 5.5 Bioanalytical Method Validation for Macromolecules; 5.6 Microarrays in Drug Discovery and Development; 5.7 Genetic Markers and Genotyping Analyses for Genetic Disease Studies
6.1 Proteins: Hormones, Enzymes, and Monoclonal\Antibodies-Background 6.2 Formulation and Delivery Issues of Therapeutic Proteins; 6.3 Pharmacokinetics; 6.4 Immunogenicity of Therapeutic Proteins; 6.5 Development and Characterization of High-Affinity Anti-Topotecan IgG and Fab Fragments; 6.6 Recombinant Antibodies for Pathogen Detection and Immunotherapy; 6.7 The Radiopharmaceutical Science of Monoclonal Antibodies and Peptides for Imaging and Targeted in situ Radiotherapy of Malignancies; 7.1 Gene Therapy-Basic Principles and the Road from Bench to Bedside
7.2 Plasmid DNA and Messenger RNA for Therapy 7.3 Formulations and Delivery Limitations of Nucleic-Acid-Based Therapies; 7.4 Pharmacokinetics of Nucleic-Acid-Based Therapeutics; 7.5 Case Studies-Development of Oligonucleotides; 7.6 RNA Interference: The Next Gene-Targeted Medicine; 7.7 Delivery Systems for Peptides/Oligonucleotides and Lipophilic Nucleoside Analogs; 8.1 Growth Factors and Cytokines; 8.2 Growth Factors, Cytokines, and Chemokines: Formulation, Delivery, and Pharmacokinetics; 9 Protein Engineering with Noncoded Amino Acids: Applications to Hirudin; 10.1 Production and Purification of Adenovirus Vectors for Gene Therapy

Sommario/riassunto

A practical overview of a full range of approaches to discovering, selecting, and producing biotechnology-derived drugs The Handbook of Pharmaceutical Biotechnology helps pharmaceutical scientists develop biotech drugs through a comprehensive framework that spans the process from discovery, development, and manufacturing through validation and registration. With chapters written by leading practitioners in their specialty areas, this reference: Provides an overview of biotechnology used in the drug development process Covers extensive applications, plus regulations and