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Nota di contenuto	Cover; Contents; Preface; Preface to First Edition; List of Abbreviations; Part I: Introduction; Chapter 1 Biopharmaceutical Production: Value Creation, Product Types, and Biological Basics Introduction; 1.1 Role of Production in Pharmaceutical Biotechnology; 1.1.1 Relationship Between Production and Development; 1.1.2 Relationship Between Production and Marketing; 1.2 Product Groups; 1.2.1 Vaccines; 1.2.2 Pharmaceuticals from Blood and Organs; 1.2.3 Recombinant Therapeutic Proteins; 1.2.4 Cell and Gene Therapeutics; 1.2.5 Antibiotics; 1.3 Basics of Biology; 1.3.1 Cells and Microorganisms 1.3.1.1 Structure and Types of Cells1.3.1.2 Metabolism; 1.3.1.3 Reproduction and Aging; 1.3.1.4 Viruses and Bacteriophages; 1.3.1.5 Protein Biosynthesis; 1.3.2 The Four Molecular Building Blocks of Biochemistry; 1.3.2.1 Proteins; 1.3.2.2 Nucleic Acids; 1.3.2.3 Polysaccharides; 1.3.2.4 Lipids; Part II: Technology; Chapter 2 Manufacturing Process; 2.1 Role of the Manufacturing Process in Biotechnology; 2.2 Process Schematic and Evaluation; 2.2.1 Drug Substance Manufacturing; 2.2.2 Drug Product Manufacturing; 2.2.3 Key Factors for Process Evaluation; 2.3 Cell Bank; 2.3.1 Expression Systems 2.3.2 Microbial Systems2.3.2.1 Mammalian Systems; 2.3.2.2 Transgenic

Systems; 2.3.3 Manufacturing and Storage of the Cell Bank; 2.4 Fermentation; 2.4.1 Basic Principles; 2.4.1.1 Cell Growth and Product Expression; 2.4.1.2 Comparison of Batch and Continuous Processes; 2.4.1.3 Sterility and Sterile Technology; 2.4.1.4 Comparison of Fermentation with Mammalian Cells and Microorganisms; 2.4.2 Technologies and Equipment; 2.4.2.1 Fermentation in Suspension Culture; 2.4.2.2 Adherent Cell Cultures; 2.4.2.3 Transgenic Systems; 2.4.3 Raw Materials and Processing Aids; 2.4.3.1 Nutrient Media 2.4.3.2 Water, Gases, and Other Processing Aids 2.4.4 Overview of Fermentation; 2.5 Purification; 2.5.1 Basic Principles; 2.5.1.1 Basic Pattern of Purification; 2.5.1.2 Types of Impurities; 2.5.1.3 Principles of Separation Technologies; 2.5.2 Technologies for Cell Separation and Product Isolation; 2.5.2.1 Cell Separation; 2.5.2.2 Cell Disruption, Solubilization, and Refolding; 2.5.2.3 Concentration and Stabilization; 2.5.3 Technologies for Final Purification; 2.5.3.1 Chromatographic Processes; 2.5.3.2 Precipitation and Extraction; 2.5.3.3 Sterile Filtration and Virus Removal 2.5.4 Raw Materials and Processing Aids 2.5.4.1 Gels for Chromatography; 2.5.4.2 Membranes for TFF; 2.5.5 Overview of Purification; 2.6 Formulation and Filling; 2.6.1 Basic Principles; 2.6.2 Freeze-Drying; 2.7 Labeling and Packaging; Chapter 3 Analytics; 3.1 Role of Analytics in Biotechnology; 3.2 Product Analytics; 3.2.1 Identity; 3.2.2 Content; 3.2.3 Purity; 3.2.4 Activity; 3.2.5 Appearance; 3.2.6 Stability; 3.2.7 Quality Criteria of Analytical Methods; 3.2.8 Analytical Methods; 3.2.8.1 Amino Acid Analysis; 3.2.8.2 Protein Sequencing; 3.2.8.3 Peptide Mapping; 3.2.8.4 Protein Content 3.2.8.5 Electrophoresis

Sommario/riassunto

Structured like a textbook, the second edition of this reference covers all aspects of biopharmaceutical manufacturing, including legal and regulatory issues, production facility design, and quality assurance, with a focus on supply chain management and regulations in emerging markets and cost control.
The author has longstanding industrial expertise in biopharmaceutical production and years of experience teaching at universities. As such, this practical book is ideal for use in academia as well as for internal training within companies.
