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Nota di contenuto	Part I: Manufacturing of Recombinant Therapeutic Proteins -- Chapter 1. Single-Use Systems in Biopharmaceutical Manufacture: State of the Art and Recent Trends (Jossen et al.) -- Chapter 2. Recent Developments in Bioprocess Monitoring Systems (Rahmatnejad et al.) -- Chapter 3. Advances in Characterization of Industrial Bioreactors for Cell Culture Process (Fitschen et al.) -- Chapter 4. Continuous Bioprocessing for Upstream Process - Perfusion Process (Chotteau et al.) -- Chapter 5. Continuous Bioprocessing for Downstream (Gerstweiler) -- Chapter 6. Towards Digital Twin for Biopharmaceutical Processes: Concept and Progress (Ding et al.) -- Chapter 7. Integrated

Process and Supply Chain Design and Optimization (Triantafyllou et al.) -- Chapter 8. Production of Complex Proteins in Plants – From Farming to Manufacturing (Nausch et al.) -- Chapter 9. Manufacturing of Recombinant Proteins Using Quality by Design (QbD) Methodology: Current Trend and Challenges (Shin and Landauer) -- Chapter 10. Biopharma 4.0 for Biologics Manufacturing Under Pandemic Constraints (Schmidt et al.) -- Chapter 11. Biopharma 4.0: Digital Technologies Driving Smart Manufacturing (Nargund et al.) -- Part II: Manufacturing Aspects of Cell and Gene Therapy -- Chapter 12. Essential Aspects of Mesenchymal Stem Cell Manufacturing (Fleischhammer et al.) -- Chapter 13. Towards a Continuous Production of Human Mesenchymal Stromal Cells in a Chemically Defined Medium: Opportunities and Challenges for a Robust and Scalable Expansion Process (Tasto and Salzig) -- Chapter 14. Biomanufacturing Aspects of Gene Therapy (Warnock) -- Chapter 15. Manufacturing and Quality of Advanced Therapeutics: Cellular Therapies, CAR-T and Gene Therapies (van den Bos et al.).

Sommario/riassunto

This volume “Cell Engineerring 11 - Biopharmaceutical Manufacturing: Progress, Trends and Challenges” is a source of the latest innovative research and technical development in biomanufacturing systems. It is organised into 2 parts: 1) Manufacturing of recombinant therapeutic proteins (e.g. therapeutic antibodies, biosimilars/biogenerics) and 2) Manufacturing aspects of cell and gene therapy. Each with selected chapters on the following topics for both up- and downstream, such as: Advanced process strategies, especially continuous manufacturing, Advanced culture techniques, especially single-use systems, Process transfer, scale-up/scale-down models, Processing advances/Manufacturing productivity/efficiency, Model-assisted process understanding and development/Digital Twins, Process controls and analytics, Quality control, Quality by design, Facility design and full-scale commercial systems, manufacturing technology innovation. The book comprises contributions of experts from academia and industry active in the field of cell culture development for the production of recombinant proteins, cell therapy and gene therapy, with consideration of Digital Twin´s and facility design. The knowledge and expertise of the authors cover disciplines like cell biology, engineering, biotechnology and biomedical sciences. Inevitably, some omissions will occur in the test, but the authors have sought to avoid duplications by extensive cross-referencing to chapters in other volumes of this series and elsewhere. We hope the volume provides a useful compendium of techniques for scientists in industrial and research laboratories active in this field.