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3.7 Expanded-Bed Chromatography; 3.8 Comparison of Harvest and Clarification Unit Operations; 3.9 Acknowledgments; 3.10 References; 4 Protein A-Based Affinity Chromatography; 4.1 Introduction; 4.2 Properties of Protein A and Commercially Available Protein A Resins; 4.2.1 Protein A Structure; 4.2.2 Protein A-Immunoglobulin G (IgG) Interaction; 4.2.3 Stoichiometry of Protein A-IgG Binding; 4.2.4 Protein A Stability; 4.2.5 Commercial Protein A Resins; 4.2.6 Static Capacity; 4.2.7 DBC; 4.2.8 Leaching; 4.2.9 Production Rates; 4.3 Protein A Chromatography Step Development; 4.3.1 Loading/Binding; 4.3.2 Wash Development; 4.3.3 Elution; 4.3.4 Stripping; 4.3.5 Regeneration and CIP; 4.4 Additional Considerations During Development and Scale-Up; 4.4.1 Controlling HMW Formation; 4.4.2 Removal of Soluble HMW Contaminants; 4.4.3 Turbidity; 4.5 Virus Removal/Inactivation; 4.5.1 Virus Removal; 4.5.2 Low-pH Inactivation; 4.5.3 Bovine/Transmissible Spongiform Encephalopathy (BSE/TSE) Clearance; 4.6 Validation and Robustness; 4.6.1 Validation; 4.6.2 Robustness; 4.7 Conclusions; 4.8 Acknowledgments; 4.9 References; 5 Purification of Human Monoclonal Antibodies: Non-Protein A Strategies; 5.1 Introduction; 5.2 Integrated Process Designs for Human Monoclonal Antibody (HuMab) Production; 5.3 Purification Process Designs for HuMabs; 5.3.1 Protein A Purification Schemes; 5.3.2 Non-Protein A Purification Schemes; 5.3.3 Host Cell Protein (HCP) Exclusion Approach for Ion-Exchange Purification Schemes; 5.4 Conclusions; 5.5 Acknowledgments; 5.6 References; 6 Purification of Monoclonal Antibodies by Mixed-Mode Chromatography; 6.1 Introduction; 6.2 A Brief History; 6.3 Prerequisites for Industrial Implementation; 6.4 Mechanisms, Screening, and Method Development; 6.5 Capture Applications; 6.6 Polishing Applications

Sommario/riassunto

Traditional column chromatography dominates current purification technology, and many of the productivity gains that have been achieved have relied on upscaling such devices. However, this comes with a cost penalty and the pharmaceutical industry has reached the point at which further upscaling becomes economically unsupportable. This book offers a broad-based reassessment of old and new purification methods, incorporating an analysis of innovative new trends in purification. The book has wide coverage of different antibody purification strategies and brings together top-tier experts to address
