

1. Record Nr.	UNINA9910819255503321
Titolo	Process scale purification of antibodies [[electronic resource] /] / edited by Uwe Gottschalk
Pubbl/distr/stampa	Hoboken, N.J., : John Wiley & Sons, c2009
ISBN	1-118-21074-3 1-282-00919-2 9786612009198 0-470-44489-4 0-470-44488-6
Edizione	[1st ed.]
Descrizione fisica	1 online resource (458 p.)
Altri autori (Persone)	GottschalkUwe
Disciplina	615/.19
Soggetti	Monoclonal antibodies - Purification Biochemical engineering
Lingua di pubblicazione	Inglese
Formato	Materiale a stampa
Livello bibliografico	Monografia
Note generali	Errata slip inserted.
Nota di bibliografia	Includes bibliographical references and index.
Nota di contenuto	PROCESS SCALE PURIFICATION OF ANTIBODIES; CONTENTS; Preface; About the Author; Contributors; 1 Downstream Processing of Monoclonal Antibodies: Current Practices and Future Opportunities; 1.1 Introduction; 1.2 A Brief History of cGMP mAb and Intravenous Immunoglobulin (IgIV) Purification; 1.3 Current Approaches in Purification Process Development: Impact of Platform Processes; 1.4 Typical Unit Operations and Processing Alternatives; 1.5 VLS Processes: Ton-Scale Production and Beyond; 1.6 Process Validation; 1.7 Product Life Cycle Management; 1.8 Future Opportunities; 1.9 Conclusions 1.10 Acknowledgments 1.11 References; 2 The Development of Antibody Purification Technologies; 2.1 Introduction; 2.2 Chromatographic Purification of Antibodies before Protein A; 2.3 Antibody Purification after 1975; 2.4 Additional Technologies for Antibody Purification; 2.5 Purification of mAbS Approved in North America and in Europe; 2.6 Acknowledgments; 2.7 References; 3 Harvest and Recovery of Monoclonal Antibodies: Cell Removal and Clarification; 3.1 Introduction; 3.2 Centrifugation; 3.3 Microfiltration; 3.4 Depth Filtration; 3.5 Flocculation; 3.6 Absolute Filtration

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
