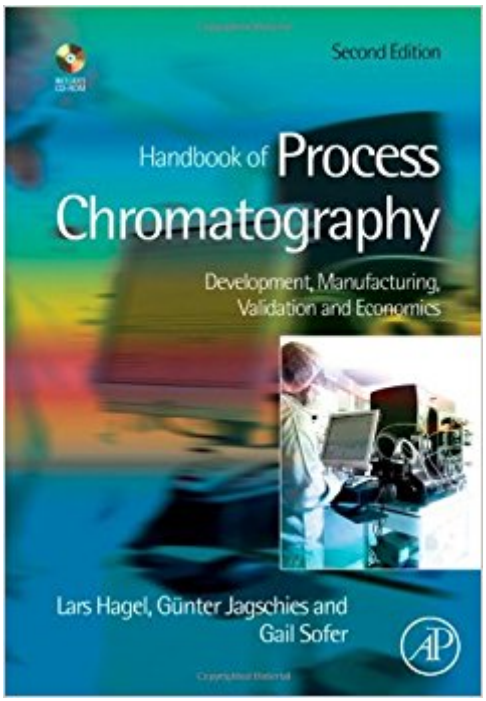
Handbook Of Process Chromatography, Second Edition: Development, Manufacturing, Validation And Economics



Synopsis

This book will update the original edition published in 1997. Since the publication of the first edition, the biotechnology and biologics industries have gained extensive knowledge and experience in downstream processing using chromatography and other technologies associated with recovery and purification unit operations. This book will tie that experience together for the next generation of readers. Updates include: - sources and productivity- types of products made today- experiences in clinical and licensed products - economics- current status of validation- illustrations and tables- automated column packing- automated systems New topics include: - the use of disposables- multiproduct versus dedicated production- design principles for chromatography media and filters- ultrafiltration principles and optimization- risk assessments- characterization studies- design space- platform technologies- process analytical technologies (PATs)- biogenerics - comparability assessments Key Features: - new approaches to process optimiaztion- use of patform technologies- applying risk assessment to process design

Book Information

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Customer Reviews

Dr. Jagschies is a 30-year employee of GE Healthcare and a widely recognized expert in the chemistry-manufacturing-control of pharmaceutical/biotherapeutic products. He has published numerous papers on the development, manufacturing and economics of biotherapeutics, and in 2012 he received the BioProcess International award, â œThought Leader of the Decade.”Gail Sofer has been consulting with biotechnology and pharmaceutical companies for the past five years through the Fast Trak Validation(r) group of PharmaciaBiotech as the Director

of International Validation Development. A series of publications on validation have provided guidance to many in this arena. She is active in organizations such as PDA and ASTM.Lars Hagel is a Ph.D. in analytical chemistry and also Associate Professor at the University of Uppsala. Dr. Hagel has held different management positions within the R&D department and is now a senior scientific consultant of Pharmacia Biotech. He is a member of the board for The Swedish Centre for Bioseparations, and he chairs the Centre for Bioprocess Technology. Dr. Hagel's research has focused upon practical implications of chromatography theory and he has published a vast number of papers and chapters, with special reference to gel filtration.

Good book, but if you are deep involved in this kind of process, it will help you in no more than two chapters, what is rather good and many times unusual. If you are related, but is not a daily matter, this is the perfect book.

This book bascially takes you through day 1 of drug manufacturing all the way to the end, when you have deal with regulatory. It also discusses analytical methods which was of great interest to me. Highly recommended for anyone who wants to learn more about this field.

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