



Handbook of Process Chromatography: Development, Manufacturing, Validation and Economics

By Gunter Jagschies, Gail K. Sofer, Lars Hagel

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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 optimization
- use of platform technologies

- applying risk assessment to process design

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Editorial Review

About the Author

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, "Thought 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.

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