



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

Günter 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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