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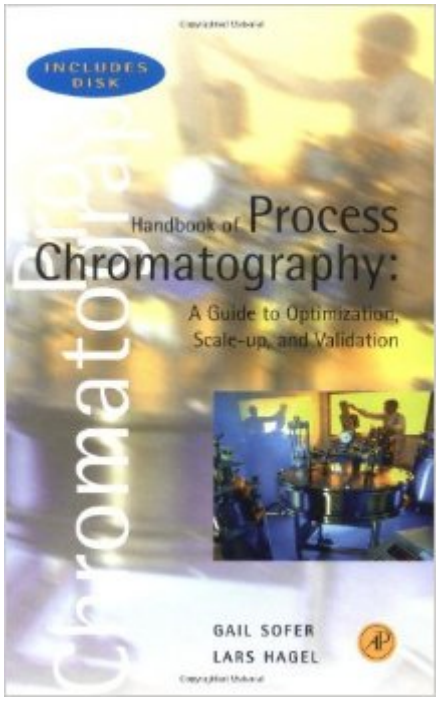
Handbook Of Process Chromatography: A Guide To Optimization, Scale Up, And Validation



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Synopsis

This handbook is an excellent reference for graduates and researchers in biotechnology and practitioners in the pharmaceutical industry who wish to develop a commercial chromatographic purification process. The authors guide readers through each step of the development process, beginning with basic chromatography theory and practice and incorporating examples from companies with established processes and approved biotherapeutics. They also cover properties of biological molecules, and reveal pitfalls often encountered in the process. Design strategies are discussed in depth, considering common starting materials and their impact on purification design, scale-up concerns, and validation. The authors use their extensive consulting and teaching experience to present a practical approach to developing an optimal chromatographic process, scaling it up, and meeting requirements set forth by regulatory agencies. The included diskette contains modeling exercises providing valuable insights into the influence of chromatographic parameters on separation results and the impact of process design on production costs, making the Handbook an excellent hands-on teaching tool. Key Features* Considers the entire scope of process chromatography, including scale up, regulatory issues, equipment, evaluation studies, scheduling, and cost-effectiveness* Provides examples from companies with established processes and approved biotherapeutics* Includes an appendix which lists the most pertinent regulatory documents, allowing the user to gather necessary information to comply with global regulatory expectations for process chromatography* Contains a modeling program on the included disk

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Perfect for someone wanting to learn about IQ/OQ/PQ for chromatography. Easy to read. Good presentation. Useful examples. Software is great addition. Very practical approach. Plenty of useful up-to-date references. Great buy!

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