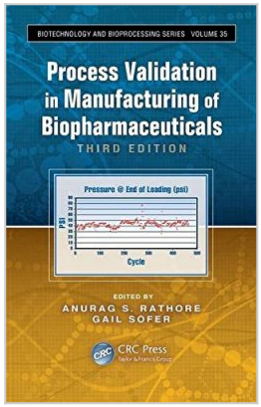

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Case studies include

- Process validation for membrane chromatography
- Leveraging multivariate analysis tools to qualify scale-down models
- A matrix approach for process validation of a multivalent bacterial vaccine
- Purification validation for a therapeutic monoclonal antibody expressed and secreted by Chinese Hamster Ovary (CHO) cells
- Viral clearance validation studies for a product produced in a human cell line

A much-needed resource, this book presents process characterization techniques for scaling down unit operations in biopharmaceutical manufacturing, including chromatography, chemical modification reactions, ultrafiltration, and microfiltration. It also provides practical methods to test raw materials and in-process samples. Stressing the importance of taking a risk-based approach towards computerized system compliance, this book will help you and your team ascertain process validation is carried out and exceeds expectations.

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