



Process Validation in Manufacturing of Biopharmaceuticals, Third Edition (Biotechnology and Bioprocessing)

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Process Validation in Manufacturing of Biopharmaceuticals, Third Edition delves into the key aspects and current practices of process validation. It includes discussion on the final version of the *FDA 2011 Guidance for Industry on Process Validation Principles and Practices*, commonly referred to as the *Process Validation Guidance* or PVG, issued in final form on January 24, 2011. The book also provides guidelines and current practices, as well as industrial case studies illustrating the different approaches that can be taken for successful validation of biopharmaceutical processes.

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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