



Process Validation in Manufacturing of Biopharmaceuticals: Guidelines, Current Practices, and Industrial Case Studies (Biotechnology and Bioprocessing Series)

Gail Sofer

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A study of biopharmaceutical process validation. It aims to enable developers and producers to ensure safe products, reduce the risk of adverse reactions in patients, and avoid recalls by outlining sophisticated validation approaches to characterize processes, process intermediates, and final product fully. The text emphasizes cost effectiveness while determining what level of validation is required for different phases of development, license application, and process improvements.

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