



Formulation and Process Development Strategies for Manufacturing Biopharmaceuticals

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A real-world guide to the production and manufacturing of biopharmaceuticals

While much has been written about the science of biopharmaceuticals, there is a need for practical, up-to-date information on key issues at all stages of developing and manufacturing commercially viable biopharmaceutical drug products. This book helps fill the gap in the field, examining all areas of biopharmaceuticals manufacturing, from development and formulation to production and packaging.

Written by a group of experts from industry and academia, the book focuses on real-world methods for maintaining product integrity throughout the commercialization process, clearly explaining the fundamentals and essential pathways for all development stages. Coverage includes:

- Research and early development phase—appropriate approaches for ensuring product stability
- Development of commercially viable formulations for liquid and lyophilized dosage forms
- Optimal storage, packaging, and shipping methods
- Case studies relating to therapeutic monoclonal antibodies, recombinant proteins, and plasma fractions
- Useful analysis of successful and failed products

Formulation and Process Development Strategies for Manufacturing Biopharmaceuticals is an essential resource for scientists and engineers in the pharmaceutical and biotech industries, for government and regulatory agencies, and for anyone with an interest in the latest developments in the field.

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