



# Biological Drug Products: Development and Strategies

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### Tested and proven solutions to the challenges of biological drug product development

Biological drug products play a central role in combating human diseases; however, developing new successful biological drugs presents many challenges, including labor intensive production processes, tighter regulatory controls, and increased market competition. This book reviews the current state of the science, offering readers a single resource that sets forth the fundamentals as well as tested and proven development strategies for biological drugs. Moreover, the book prepares readers for the challenges that typically arise during drug development, offering straightforward solutions to improve their ability to pass through all the regulatory hurdles and deliver new drug products to the market.

*Biological Drug Products* begins with general considerations for the development of any biological drug product and then explores the strategies and challenges involved in the development of specific types of biologics. Divided into five parts, the book examines:

- **Part 1:** General Aspects
- **Part 2:** Proteins and Peptides
- **Part 3:** Vaccines
- **Part 4:** Novel Biologics
- **Part 5:** Product Administration/Delivery

Each chapter has been prepared by one or more leading experts in biological drug development.

Contributions are based on a comprehensive review and analysis of the current literature as well as the authors' first-hand experience developing and testing new drugs. References at the end of each chapter serve as a gateway to original research papers and reviews in the field.

By incorporating lessons learned and future directions for research, *Biological Drug Products* enables pharmaceutical scientists and students to improve their success rate in developing new biologics to treat a broad range of human diseases.

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