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This title is intended to assist pharmaceutical scientists in the development of stable protein formulations during the early stages of the product development process, providing a comprehensive review of mechanisms and causes of protein instability in formulation development, coverage of accelerated stability testing methods and relevant analytical methods, and an overview of the drug substance manufacturing process. Preformulation and the development of traditional solutions and lyophilized formulations frequently used for intravenous delivery and non-traditional formulations are also addressed. Because many developments in the field have emerged since the publication of the First Edition, this Second Edition addresses important new patient-friendly developments in the field, such as formulation for implantable devices, needle-free formulation and delivery approaches, and oral delivery of proteins.

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Editorial Review

Review

...written to assist the pharmaceutical scientist involved in the protein formulation and delivery processes...also...of use to students doing thesis research in these areas. Of particular value...are numerous insights into critical practical issues that impact the development of protein therapeutic products.

-Pharmaceutical Research (for previous edition)

...concerns very timely topics...well written and organized.

-Pharmaceutical Research (for previous edition)

...concise and informative...the authors have wisely chosen to illustrate their information with real-life examples and case studies.

-Pharmaceutical Development and Technology (for previous edition)

...the most pertinent and readable summary of the familial ataxias that has been written to date...an excellent summary of all the knowledge an interested clinician in this area needs to know.

-European Journal of Paediatric Neurology (for previous edition)

...a 'must read'...exceptionally well written...Highly recommended.

-Journal of Controlled Release (for previous edition)

About the Author

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