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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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