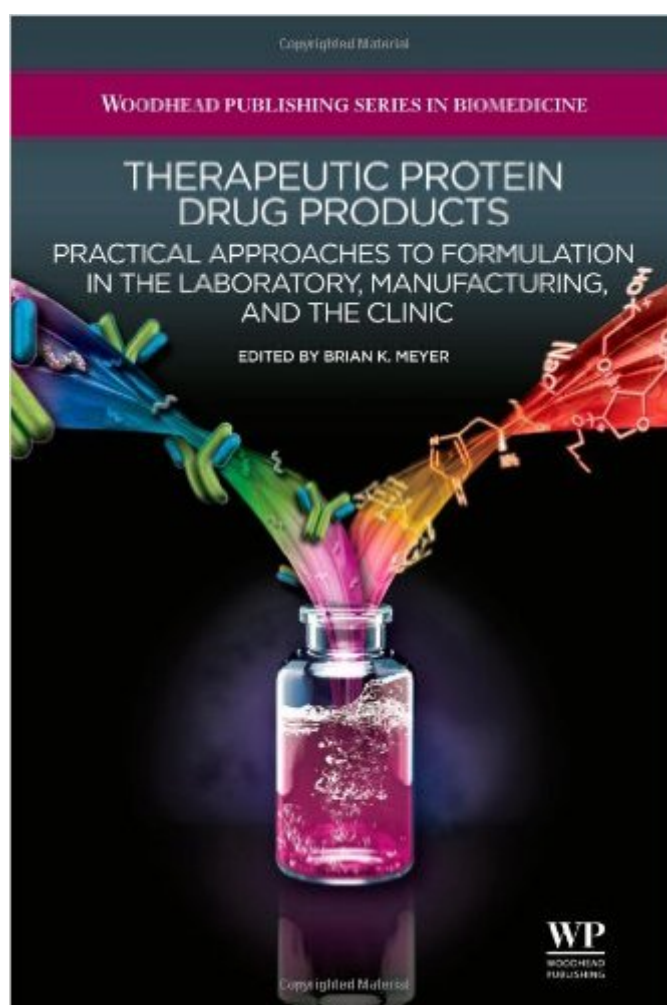


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Therapeutic Protein Drug Products: Practical Approaches To Formulation In The Laboratory, Manufacturing, And The Clinic (Woodhead Publishing Series In Biomedicine)



Synopsis

Therapeutic protein drug products provides a comprehensive overview of therapeutic protein drug products, with an emphasis on formulation beginning in the laboratory, followed by manufacturing and administration in the clinic. A list of many commercial therapeutic drug products are described and include the product name, dosages, active concentration, buffer, excipients, Ph, container type and route of administration. The laboratory formulation sections focus on the most common buffers, excipients, and Ph ranges that are commonly tested in addition to systematic approaches. A brief section on biophysical and analytical analysis is also provided. Properties of therapeutic protein formulations are described and include opalescence, phase separation, color, and subvisible particles. An emphasis is placed on material and process testing to ensure success during manufacturing. The drug product manufacturing process, which includes the process of compounding to filling, is also covered. Methods of delivery in the clinic are addressed, as well as delivery strategies. Finally, a perspective on the regulatory requirements for therapeutic protein formulations is discussed. Provides a list and description of commercially available therapeutic drug products and their formulations A comprehensive and practical overview of protein formulation in the laboratory, manufacturing, and the clinic Discusses recent topics including high protein concentration, phase separation, opalescence, and subvisible particles

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