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Altri autori (Persone)	NarhiLinda O
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Nota di contenuto	Introduction -- High Throughput Biophysical Approaches to Therapeutic Protein Development -- Techniques for Higher Order Structure Determination -- Biophysical Techniques for Protein Size Distribution Analysis -- Qualification of biophysical methods for the analysis of protein therapeutics -- Application of Biophysics to the Early Developability Assessment of Therapeutic Candidates and its Application to Enhance Developability Properties -- Application of Biophysics in Formulation, Process and Product Characterization: Selected Case Studies -- Biophysical Analysis in Support of Development of Protein Pharmaceuticals -- Case Studies Applying Biophysical Techniques to Better Characterize Protein Aggregates and Particulates of Varying Size -- Investigation of Non Conformance During Protein Therapeutic Manufacturing -- Higher order structure and protein aggregate characterization of protein therapeutics: perspectives from good manufacturing practices and regulatory guidance -- Index.
Sommario/riassunto	The last few decades have seen the genesis of protein therapeutics, such that these large molecule based drugs comprise an increasingly

larger part of the commercial market. The conformation (overall global fold or three-dimensional structure) of these molecules is important for maintaining biological activity, stability during long term storage, and can impact the safety profile and biological consequences of administration. For this reason at every stage of product discovery and development biophysical methods play a key analytical role in product development, as they are applied for the determination of protein higher order structure. In addition to helping define binding kinetics and other parameters important for target validation, they are the only techniques available to determine if a potential protein product is folded properly, and can maintain this active conformation during manufacturing, storage, and delivery. Thus the biophysical techniques play a key role during the development of protein therapeutics. This volume is organized to mimic the product lifecycle. The initial chapters describe the underlying theory, and strengths and weaknesses of the different techniques commonly used during therapeutic development. The majority of the chapters discuss the applications of these techniques, including case studies, across the product lifecycle from early discovery, where the focus is on identifying targets, and screening for potential drug product candidates, through expression and purification, large scale production, formulation development, lot-to-lot comparability studies, and commercial support including investigations. There is also a chapter from the perspective of the regulatory agencies. This book can be used to provide insight into this important application of biophysics for those who are planning a career in protein therapeutic development, and for those outside this area who are interested in understanding it better. y>.