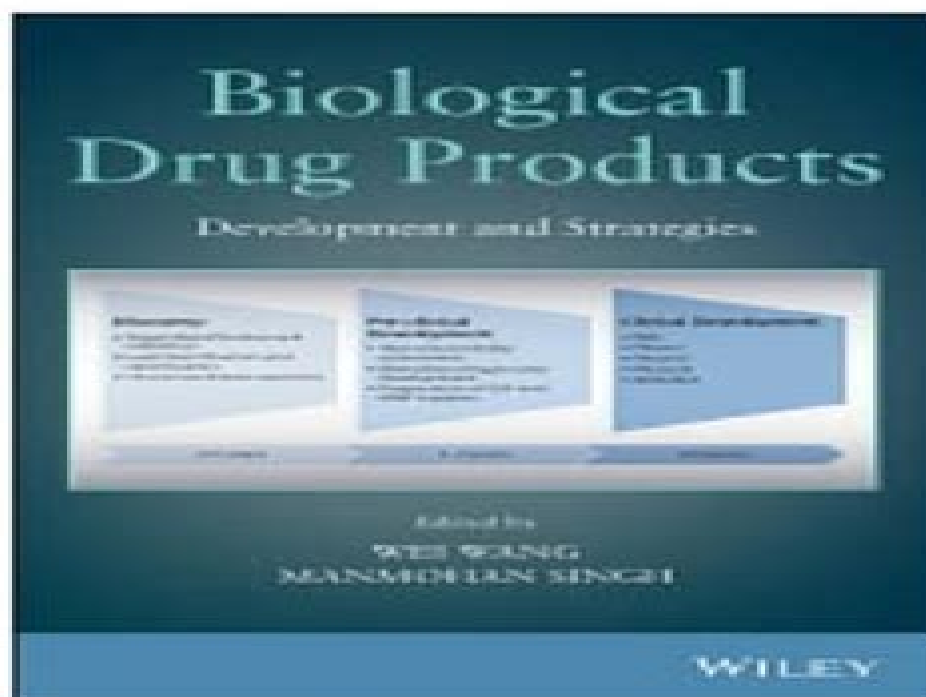


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Instability at Interfaces During Drug Product Development Jinjiang Li, Mary E. Krause, Raymond Tu, 2021-02-12

Proteins are exposed to various interfacial stresses during drug product development. They are subjected to air-liquid, liquid-solid, and sometimes liquid-liquid interfaces throughout the development cycle from manufacturing of drug substances to storage and drug delivery. Unlike small molecule drugs, proteins are typically unstable at interfaces where, on adsorption, they often denature and form aggregates resulting in loss of efficacy and potential immunogenicity. This book covers both the fundamental aspects of proteins at interfaces and the quantification of interfacial behaviors of proteins. Importantly, this book introduces the industrial aspects of protein instabilities at interfaces, including the processes that introduce new interfaces, evaluation of interfacial instabilities, and mitigation strategies. The audience that this book targets encompasses scientists in the pharmaceutical and biotech industry as well as faculty and students from academia in the surface science, pharmaceutical, and medicinal chemistry areas.

Immunomodulators and Biologics in Dermatologic Treatment Neal Bhatia, 2024-09-21. This title provides a practically applicable guide to the use of immunomodulators and biologics to treat cutaneous diseases. Chapters cover the mechanisms, applications, and safety concerns pertaining to the latest systemic therapies. Extensive guidance is provided on how to design lab monitoring schedules, manage patient follow-up visits, develop tapering plans, and assess adverse outcomes. The book also reviews how to initiate off-label applications and establish methods of matching mechanisms for a range of diseases to the mechanisms of the available therapies. The latest updates in the development and utility of systemic immunomodulators, biologics, and JAK inhibitors from clinical trials and updated guidelines are also discussed. *Immunomodulators and Biologics in Dermatologic Treatment* comprehensively describes the use of a range of systemic therapies for immunomodulation in dermatology and how best to incorporate these into practice. It therefore represents a valuable resource for novice readers and experienced dermatologists involved in the management of these patients.

Good Design Practices for GMP Pharmaceutical Facilities Terry Jacobs, Andrew A. Signore, 2016-08-19. This revised publication serves as a handy and current reference for professionals engaged in planning, designing, building, validating, and maintaining modern cGMP pharmaceutical manufacturing facilities in the U.S. and internationally. The new edition expands on facility planning with a focus on the ever-growing need to modify existing legacy facilities and on current trends in pharmaceutical manufacturing, which include strategies for sustainability and LEED building ratings. All chapters have been re-examined with a fresh outlook on current good design practices.

Safety of Biologics Therapy Brian A. Baldo, 2016-08-12. This long-overdue title provides a comprehensive up-to-date state-of-the-art review of approved biologic therapies with coverage of mechanisms of action, indications for therapy, immunogenicity, and a detailed examination of adverse effects and safety of the many and diverse therapeutic agents presented in a total of 13 chapters. It is predicted that by 2016, biologics will make up half of the world's 20 top-selling drugs, and by 2018, biologic medicine sales will account for almost half of the world's 100 biggest-selling drugs. Recombinant proteins dominate the growing list of the more than 200

approved biotherapeutic agents with targeted antibodies fusion proteins and receptors cytokines hormones enzymes proteins involved in blood clotting homeostasis and thrombosis vaccines botulinum neurotoxins and more recently biosimilar preparations comprising the majority of approved biologics Written with clinicians other health care professionals and researchers in mind *Safety of Biologics Therapy* examines in a single volume the full range of issues surrounding the safety of approved biologic therapies A good understanding of the risks and safety issues of modern biologics therapy is increasingly being demanded of all those connected with their development handling prescribing administration and subsequent patient management In addition to being of great value to clinicians in all branches of medicine and to nurses pharmacists and researchers this book will prove invaluable for students taking undergraduate and graduate courses in the above disciplines and in the biomedical sciences

The Combination Products Handbook Susan Neadle, 2023-05-16 Combination products are therapeutic and diagnostic products that combine drugs devices and or biological products According to the US Food and Drug Administration FDA a combination product is one composed of any combination of a drug and a device a biological product and a device a drug and a biological product or a drug device and a biological product Examples include prefilled syringes pen injectors autoinjectors inhalers transdermal delivery systems drug eluting stents and kits containing drug administration devices co packaged with drugs and or biological products This handbook provides the most up to date information on the development of combination products from the technology involved to successful delivery to market The authors present important and up to the minute pre and post market reviews of international combination product regulations guidance considerations and best practices This handbook Brings clarity of understanding for global combination products guidance and regulations Reviews the current state of the art considerations and best practices spanning the combination product lifecycle pre market through post market Reviews medical product classification and assignment issues faced by global regulatory authorities and industry The editor is a recognized international Combination Products and Medical Device expert with over 35 years of industry experience and has an outstanding team of contributors Endorsed by AAMI Association for the Advancement of Medical Instrumentation

The Future of Pharmaceuticals Sarfaraz K. Niazi, 2022-02-28 Before now biological systems could only be expressed in terms of linear relationships however as knowledge grows and new techniques of analysis on biological systems is made available we are realizing the non linearity of these systems The concepts and techniques of nonlinear analysis allow for more realistic and accurate models in science The *Future of Pharmaceuticals A Nonlinear Analysis* provides an opportunity to understand the non linearity of biological systems and its application in various areas of science primarily pharmaceutical sciences This book will benefit professionals in pharmaceutical industries academia and policy who are interested in an entirely new approach to how we will treat disease in the future Key Features Addresses a new approach of nonlinear analysis Applies a theory of projection to chalk out the future instead of basing on linear evolution Provides an opportunity to better understand the non linearity in biological

systems and its applications in various areas of science primarily pharmaceutical sciences Helps change the thought process for those looking for answers to their questions which they do not find in the linear relationship approach Encourages a broader perspective for the creative process of drug development

Development of Biopharmaceutical Drug-Device Products Feroz Jameel, John W. Skoug, Robert R. Nesbitt, 2020-03-13 The biotechnology biopharmaceutical sector has tremendously grown which led to the invention of engineered antibodies such as Antibody Drug Conjugates ADCs Bispecific T cell engager BITEs Dual Variable Domain DVD antibodies and fusion proteins that are currently being used as therapeutic agents for immunology oncology and other disease conditions Regulatory agencies have raised the bar for the development and manufacture of antibody based products expecting to see the use of Quality by Design QbD elements demonstrating an in depth understanding of product and process based on sound science Drug delivery systems have become an increasingly important part of the therapy and most biopharmaceuticals for self administration are being marketed as combination products A survey of the market indicates that there is a strong need for a new book that will provide one stop shopping for the latest information and knowledge of the scientific and engineering advances made over the last few years in the area of biopharmaceutical product development The new book entitled Development of Biopharmaceutical Drug Device Products is a reference text for scientists and engineers in the biopharmaceutical industry academia or regulatory agencies With insightful chapters from experts in the field this new book reviews first principles covers recent technological advancements and provides case studies and regulatory strategies relating to the development and manufacture of antibody based products It covers topics such as the importance of early preformulation studies during drug discovery to influence molecular selection for development formulation strategies for new modalities and the analytical techniques used to characterize them It also addresses important considerations for later stage development such as the development of robust formulations and processes including process engineering and modeling of manufacturing unit operations the design of analytical comparability studies and characterization of primary containers pre filled syringes and vials Finally the latter half of the book reviews key considerations to ensure the development and approval of a patient centered delivery system design This involves the evolving regulatory framework with perspectives from both the US and EU industry experts the role of international standards design control risk management human factors and its importance in the product development and regulatory approval process as well as review of the risk based approach to bridging between devices used in clinical trials and the to be marketed device Finally case studies are provided throughout The typical readership would have biology and or engineering degrees and would include researchers scientific leaders industry specialists and technology developers working in the biopharmaceutical field

An Introduction to Ethical, Safety and Intellectual Property Rights Issues in Biotechnology Padma Nambisan, 2017-06-21 An Introduction to Ethical Safety and Intellectual Property Rights Issues in Biotechnology provides a comprehensive look at the biggest technologies that have revolutionized biology since the early 20th century also

discussing their impact on society The book focuses on issues related to bioethics biosafety and intellectual property rights and is written in an easy to understand manner for graduate students and early career researchers interested in the opportunities and challenges associated with advances in biotechnology Important topics covered include the Human Genome Project human cloning rDNA technology the 3Rs and animal welfare bioterrorism human rights and genetic discrimination good laboratory practices good manufacturing practices the protection of biological material and much more Full of relevant case studies practical examples weblinks and resources for further reading this book offers an essential and holistic look at the ways in which biotechnology has affected our global society Provides a comprehensive look at the ethical legal and social implications of biotechnology Discusses the global efforts made to resolve issues Incorporates numerous case studies to more clearly convey concepts and chart the development of guidelines and legislation regulating issues in biotechnology Takes a straightforward approach to highlight and discuss both the benefits and risks associated with the latest biotechnologies

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