

BLOW FILL SEAL: **TECHNOLOGY & PROCESS**

EFFICACY



The BFS process does not require any pre-formed containers, as it starts directly from the polymer granule that is fed to the machine, where it is melted and extruded, thus eliminating the need for complicated or costly upstream equipment or particular storage space.

ASEPTICITY



BFS process takes place under sterile air shower in grade A, so the final product is already aseptic. However, if regulations require the product to be terminally sterilized, it can easily withstand terminal sterilization at 121°C as per normal procedures.

VERSATILITY



BFS technology is nowadays the preferred primary packaging solution not only by pharmaceutical companies and healthcare providers, wherever there is the need to package products at minimal cost ensuring contamination free packaging.

Blowfillseal Technology

Michael C. Flickinger



Blowfillseal Technology:

Blow-fill-seal Technology R. Oschmann, Willmar Schwabe, O. E. Schubert, 1999 *Biotechnology and Biopharmaceutical Manufacturing, Processing, and Preservation* Kenneth E. Avis, Vincent L. Wu, 2020-08-13 In this unique book experts describe practices applicable to the large scale processing of biotechnological products Beginning with processing and bulk storage preservation techniques the book provides strategies for improving efficiency of process campaigns of multiple products and manufacturing facilities for such processing techniques Large scale chromatography for the purification of biomolecules in manufacturing and lyophilization of protein pharmaceuticals are discussed Includes a case study on blow fill seal processing technology and a chapter on economic and cost factors for bioprocess engineering

Formulation, Characterization, and Stability of Protein Drugs Rodney Pearlman, Y. John Wang, 1996-10-31 Leading scientists offer detailed profiles of ten protein drugs currently in development The case histories of these important new compounds are described from the perspective of their formulation characterization and stability This ready reference also features recent data and an abundance of previously unpublished information The in depth coverage includes a highly useful compendium of degradation sites occurring in over 70 proteins An invaluable aid in the rapid identification of potential hot spots in proteins this accessible compilation allows for inspection of the protein's primary structure and preparation of a hydroflex plot [The Manufacture of Sterile Pharmaceutical Products Using Blow-fill-seal Technology](#) Martin

Haerer, Kenneth Muhvich, 2017 **Sterilization of Medical Devices** Anne Booth, 2018-12-12 This book presents vital information on international sterilization standards and guidance on practical application of these standards in the manufacturing process It covers validation industrial sterilization methods emerging sterilization techniques laboratory testing manufacturing of sterile devices and device reuse Excerpted from *The Validator* edited by Anne F Booth more than fifty experts share their knowledge of current technologies in easy to understand articles that establish methods to ensure compliance Contents include reviews of ISO sterilization standards industrial sterilization methods and technologies and support testing methodologies **Validation of Pharmaceutical Processes** James P. Agalloco, Frederick J.

Carleton, 2007-09-25 Completely revised and updated to reflect the significant advances in pharmaceutical production and regulatory expectations this third edition of *Validation of Pharmaceutical Processes* examines and blueprints every step of the validation process needed to remain compliant and competitive The many chapters added to the prior compilation examine va *Advanced Aseptic Processing Technology* James Agalloco, James Akers, 2016-04-19 The preparation of sterile products using aseptic processing is considered perhaps the most critical process in the pharmaceutical industry and has witnessed continual improvement over the last half century New approaches that have transformed classical aseptic production methods are appearing almost daily This book reviews emerging technologies **Mucosal Delivery of Biopharmaceuticals** José das Neves, Bruno Sarmento, 2014-02-03 Biopharmaceutical medicines the newest class of

therapeutics are quite heterogeneous and include a range of molecules such as proteins peptides vaccines and nucleic acids with use in virtually all therapeutic fields e g cancer and infectious diseases vaccination metabolic dysfunctions and diagnostics This edited book gives a concise and up to date overview of the biological features justifying the use of different human mucosa as delivery routes for biopharmaceuticals the technological strategies that have been followed so far regarding the optimization of mucosal potentialities as well as the challenges that arise with the advent of new biopharmaceutical drugs and alternative means of administration Following a brief introduction the first section addresses general aspects of the biology of mucosal tissues and their unique aspects toward beneficial or deleterious interaction with biopharmaceuticals and their delivery systems The second part reviews the different delivery strategies that have recently been investigated for different mucosal sites The third section describes the development and clinical applications of drug delivery systems and products enclosing biopharmaceuticals for mucosal delivery with a focus on the most successful case studies of recent years The last section briefly centers on relevant aspects of the regulatory toxicological and market issues of mucosal delivery of biopharmaceuticals Scientists and researchers in the fields of drug delivery material science biomedical science and bioengineering as well as professionals regulators and policy makers in the pharmaceutical biotechnology and healthcare industries will find in this book an important compendium of fundamental concepts and practical tools for their daily research and activities

Handbook of Pharmaceutical Manufacturing Formulations Safaraz K. Niazi, 2016-04-19 No other area of regulatory compliance receives more attention and scrutiny by regulatory authorities than the regulation of sterile products for obvious reasons With the increasing number of potent products particularly the new line of small protein products joining the long list of proven sterile products the technology of manufacturing ster

Cell Culture Technology for Pharmaceutical and Cell-Based Therapies Sadettin Ozturk, Wei-Shou Hu, 2005-08-30 Edited by two of the most distinguished pioneers in genetic manipulation and bioprocess technology this bestselling reference presents a comprehensive overview of current cell culture technology used in the pharmaceutical industry Contributions from several leading researchers showcase the importance of gene discovery and genomic technology devel

H1N1 Preparedness United States. Congress. House. Committee on Energy and Commerce. Subcommittee on Health, 2012

Downstream Industrial Biotechnology Michael C. Flickinger, 2013-07-17 DOWNSTREAM INDUSTRIAL BIOTECHNOLOGY An affordable easily accessible desk reference on biomanufacturing focused on downstream recovery and purification Advances in the fundamental knowledge surrounding biotechnology novel materials and advanced engineering approaches continue to be translated into bioprocesses that bring new products to market at a significantly faster pace than most other industries Industrial scale biotechnology and new manufacturing methods are revolutionizing medicine environmental monitoring and remediation consumer products food production agriculture and forestry and continue to be a major area of research The downstream stage in industrial biotechnology refers to recovery isolation and purification of the microbial products from cell

debris processing medium and contaminating biomolecules from the upstream process into a finished product such as biopharmaceuticals and vaccines Downstream process design has the greatest impact on overall biomanufacturing cost because not only does the biochemistry of different products e g peptides proteins hormones antibiotics and complex antigens dictate different methods for the isolation and purification of these products but contaminating byproducts can also reduce overall process yield and may have serious consequences on clinical safety and efficacy Therefore downstream separation scientists and engineers are continually seeking to eliminate or combine unit operations to minimize the number of process steps in order to maximize product recovery at a specified concentration and purity Based on Wiley s Encyclopedia of Industrial Biotechnology Bioprocess Bioseparation and Cell Technology this volume features fifty articles that provide information on down stream recovery of cells and protein capture process development and facility design equipment PAT in downstream processes downstream cGMP operations and regulatory compliance It covers Cell wall disruption and lysis Cell recovery by centrifugation and filtration Large scale protein chromatography Scale down of biopharmaceutical purification operations Lipopolysaccharide removal Porous media in biotechnology Equipment used in industrial protein purification Affinity chromatography Antibody purification monoclonal and polyclonal Protein aggregation precipitation and crystallization Freeze drying of biopharmaceuticals Biopharmaceutical facility design and validation Pharmaceutical bioburden testing Regulatory requirements Ideal for graduate and advanced undergraduate courses on biomanufacturing biochemical engineering biopharmaceutical facility design biochemistry industrial microbiology gene expression technology and cell culture technology Downstream Industrial Biotechnology is also a highly recommended resource for industry professionals and libraries

Success Is Just Running Out of Mistakes Stephen R. Ash, MD, FACP, 2023-03-29 About the Book *Success is Just Running Out of Mistakes* is about a life long quest to improve the therapy of kidney failure especially with hemodialysis technology Dr Ash began to write this because of a lack of progress in dialysis therapy He is tired of physicians and politicians saying that there is a lack of innovation among nephrologists The problem isn t lack of innovation but rather a failure to commercialize radically better new technology In some ways the book is also a collection of 12 case studies of new technology and ideas and how a small technology driven firm can succeed or fail in efforts to bring their new product to become a widespread market success There are few textbooks that describe not only successes of R D companies in bringing products to the market but also failures What is surprising about the failures described in this book is that they occurred at many different steps of bringing a new product to market The answer to a physician who says I have a new idea and think it could help medical therapy What should I do next is very long and complicated The one trait *Success is Just Running Out of Mistakes* really demonstrates is the importance of persistence Not just in any one project but in a career trying to make just one small part of medical therapy better for patients with kidney failure Too many young physicians don t realize the tough road ahead to make medical therapy better and quit after the failure of their first good idea As Winston

Churchill said Success is not final failure is not fatal it is the courage to continue that counts About the Author Stephen R Ash MD FACP recently retired from clinical practice as a Nephrologist at Indiana University Health Arnett in Lafayette Indiana He is CEO of HemoCleanseTechnologies Chairman of the Board of AshAccess Technology and co founder of a number of spin off biotechnology firms He has a long history of research and product development in the field of sorbents resulting in devices for treatment of kidney failure Allient™ by Renal Solutions and for liver failure Liver Dialysis™ by HemoTherapies He was instrumental in development of an orally ingested sorbent for potassium now marketed by AstraZeneca as Lokelma Dr Ash has also invented a number of new catheters for dialysis access including the Ash Split Cath CentrosFLO and Advantage™ PD Catheter Dr Ash is a co founder and Past President of the American Society for Diagnostic and Interventional Nephrology ASDIN He is Past President of ASAO and until recently served as Secretary Treasurer of IFAO He is recipient of the Lifetime Achievement Award from ASDIN the Celebration of Life Honor by NKF of Indiana and the Lifetime Achievement Award from the Annual Dialysis Conference Dr Ash also has a dedicated and loving family including his wife Marianne and daughters Emily and Sarah Marianne and Dr Ash are long term members of Trinity United Methodist Church in Lafayette Indiana They live at and operate a retirement recovery farm for horses and his special interests are fixing things around the farm woodworking and flying fixed wing RC aircraft Official Gazette of the United States Patent and Trademark Office ,1998

Aseptic Pharmaceutical Manufacturing II Michael J. Groves,Ram Murty,1995-05-31 *Aseptic Pharmaceutical Manufacturing II* explores the sophisticated technology developments and applications that allow aseptic processing to approach the sterility levels achieved with terminal sterilization Written by experts in sterile manufacturing this book covers aseptic technology developments and applications and makes a valuable contribution to understanding the issues involved in aseptic manufacture Topics include the processing of biopharmaceuticals lyophilization personnel training radiopharmaceuticals hydrogen peroxide vapor sterilization regulatory requirements validation and quality systems

Quality Kathleen E. McCormick,Janet H. Sanders,2022-07-14 *Quality* second edition provides comprehensive application of regulatory guidelines and quality concepts and methodologies related to pharmaceutical manufacturing It is an excellent resource for practitioners those pursuing pharmaceutical related certifications and for students trying to learn more about pharmaceutical manufacturing This book provides the background theory applied descriptions of the guidelines and concepts plus questions and problems at the end of the chapters that will help provide practice for the reader to apply the concepts In this book the authors share their combined 60 years of extensive practical experience in the industry and in process improvement combined with detailed understanding of the needs of the industry and education system This book provides real life examples from industry and guidelines for practical application of tools that can be referenced by operators engineers and management This book is fully revised updated and expanded with new content in areas such as QbD Lean Six Sigma basic data analysis and CAPA tools Fully revised updated and expanded new edition Features new topics such as QbD

Lean Six Sigma basic data analysis and CAPA tools Includes end of chapter summaries and end of chapter question and or problems Provides detailed steps and examples for applying the guidelines and quality tools Written in an accessible style making the content easy to understand and apply *Integrated Pharmaceutics* Antoine Al-Achi, Mali Ram Gupta, William Craig Stagner, 2022-09-21 This work is an examination of all aspects of the science in developing effective dosage form for drug delivery Pharmaceutics refers to the subfield of pharmaceutical sciences that develops drug delivery products or devices to optimize the drug s performance once administered This multidisciplinary field draws on physical chemistry organic chemistry and biophysics to generate and refine these crucial elements of medical care Moreover incorporating such disparate dimensions of drug product design as material properties and legal regulation bridges the gap between effective chemicals and viable medical treatments *Integrated Pharmaceutics* provides a comprehensive introduction to the creation and manufacture of effective dosage forms for drug delivery It presents its subject following the principles of physical pharmacy product design and drug regulations This tripartite structure allows readers to move from theory to practice beginning from a firm foundation of physical pharmacy principles including drug solubility and stability estimation rheology and interfacial properties From there it proceeds to discussions of drug product design and of harmonizing pharmaceutical design with the regulatory regimens and technological standards of the United States European Union and Japan Readers of the second edition of *Integrated Pharmaceutics* will also find A glossary defining key terms extensive informative appendices and a list of references leading to the primary literature in the field for each chapter Earlier chapters are expanded with additional new chapters including one entitled Biotechnology Products Supplementary instructor guide with questions and solutions available online for registered professors Updated regulatory guidelines including quality by design design space analysis process analytical technology polymorphism characterization blend sample uniformity and stability protocols *Integrated Pharmaceutics* is a useful textbook for graduate students in pharmaceutical sciences drug formulation and design and biomedical engineering In addition professionals in the pharmaceutical industry including regulatory bodies will find it a helpful reference guide **The Future of Pharmaceutical Product Development and Research**, 2020-08-19 The Future of Pharmaceutical Product Development and Research examines the latest developments in the pharmaceutical sciences also highlighting key developments research and future opportunities Written by experts in the field this volume in the *Advances in Pharmaceutical Product Development and Research* series deepens our understanding of the product development phase of drug discovery and drug development Each chapter covers fundamental principles advanced methodologies and technologies employed by pharmaceutical scientists researchers and the pharmaceutical industry The book focuses on excipients radiopharmaceuticals and how manufacturing should be conducted in an environment that follows Good Manufacturing Practice GMP guidelines Researchers and students will find this book to be a comprehensive resource for those working in and studying pharmaceuticals cosmetics biotechnology foods and related industries **Handbook of**

Biogeneric Therapeutic Proteins Sarfaraz Niazi, 2024-04-15 Since 1972 which marks the invention of recombinant engineering more than 500 therapeutic proteins have been approved for clinical use Today biological drugs constitute almost 70% of all new drugs and have a biological origin The first edition of this book dealt with biosimilars and this edition i e the second edition focuses on new drugs yet limits to therapeutic proteins Newer technologies for drug development represent the updated topics in the book and include repurposing AI driven identification of newer designs novel expression systems manufacturing using these systems rapidly changing regulatory pathways and legal hurdles This edition discusses how to identify develop manufacture and take multibillion dollar products to market within the shortest possible time Features Complete and thorough coverage of the regulatory and technological challenges of developing generic therapeutic proteins Comprehensive discovery to market newer technologies regulatory planning and IP hurdles are included that are not found elsewhere Expanded volume that must be in the hands of every company interested in biological drugs including the mRNA based biopharmaceutical companies fast appearing on the market Discusses how to identify develop manufacture and take multibillion dollar products to market in the shortest possible time Renowned author and entrepreneur in the field of drug discovery and production *Pharmaceutical Quality Assurance* B.P. Nagori, Ajay Gaur, Renu Solanki, Vipin Mathur, 2018-01-01 The present state of art book has been written as per the new syllabus of B Pharmacy introduced by Pharmacy Council of India PCI This book has an inclusive content that covers the wider aspects of pharmaceutical quality assurance required by under graduates post graduates industry personnels researcher and students preparing for various competitive exams The distinguishing feature of this book is that the book is written in lucid simple and easy to understand language The book is accompanied with Multiple Choice Fill in the Blank True False Short Answer and Long Answer type of questions for the self evaluation of learning The answers of the Multiple Choice Fill in the Blank and True False questions have also been given Web links further reading are included to help the readers for keeping themselves abreast with the latest developments in the field of pharmaceutical quality assurance Academicians and instructors in universities colleges may use the book as primary or additional teaching material for under graduate and post graduate pharmacy courses

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