

Downstream Process Technology A New Horizon In Biotechnology

This is the most comprehensive treatise of this topic available, providing invaluable information on the technological and economic benefits to be gained from implementing continuous processes in the biopharmaceutical industry. Top experts from industry and academia cover the latest technical developments in the field, describing the use of single-use technologies alongside perfusion production platforms and downstream operations. Special emphasis is given to process control and monitoring, including such topics as 'quality by design' and automation. The book is supplemented by case studies that highlight the enormous potential of continuous manufacturing for biopharmaceutical production facilities.

Downstream processing is an essential practice in the production and purification of biosynthetic materials, which is especially important in the production of pharmaceutical products. This book covers the fundamentals and the design concepts of various downstream recovery and purification steps (unit operations) involved in biochemical and chemical processes. The book describes cell breakage and recovery of intracellular material, isolation of solids, product recovery, product enrichment, and product polishing and finishing. It also covers basic chemical engineering purification techniques such as distillation, absorption, adsorption, etc. Described in the book are several case studies that discuss the various unit operation in each of the processes. An important point to consider is the economics of the downstream operation, and this book provides practical information on capital costs and operating expenses in addition to other operating cost factors with respect to downstream processing. Green chemistry and safety issues are also addressed. Practicing chemical engineers in biotechnology and pharmaceutical chemistry and other areas will find this book valuable as a reference on downstream techniques used in biological processes. Students in chemical engineering would benefit from this book as well.

This book provides an extensive overview of the latest research in environmentally benign integrated bioprocess technology. The cutting edge bioprocess technologies highlighted in the book include bioenergy from lignocellulose materials, biomass gasification, ethanol, butanol, biodiesel from agro waste, enzymatic bioprocess technology, food fermentation with starter cultures, and intellectual property rights for bioprocesses. This book further addresses niche technologies in bioprocesses that broadens readers' understanding of downstream processing for bio products and membrane technology for bioprocesses. The latest developments in biomass and bioenergy technology are reviewed exhaustively, including IPR rights, nanotechnology for bioenergy products, biomass gasification, and biomass combustion. This is an ideal book for scientists, engineers, students, as well as members of industry and policy-makers. This book also: Addresses cutting-edge technologies in bioprocesses Broadens readers' understanding of metabolic engineering, downstream processing for bioproducts, and membrane technology for bioprocesses Reviews exhaustively the latest developments in biomass and bioenergy technology, including nanotechnology for bioenergy products, biomass gasification, biomass combustion, and more

This book provides fundamental principles, terminology, mechanisms, methods, types and applications of unit operation in downstream processing of various fields, ranging from engineering, technology, pure sciences and applied sciences. The discussion revolves around the principle of unit operations such as filtration, coagulation and flocculation, centrifugation, cell disruption, adsorption, chromatography, distillation, crystallization and drying. This book is designed to serve as a reference book for students, researchers, professionals and others who work in the processing industries.

Presents comprehensive coverage of process intensification and integration for sustainable design, along with fundamental techniques and experiences from the industry Drawing from fundamental techniques and recent industrial experiences, this book discusses the many developments in process intensification and integration and focuses on increasing sustainability via several overarching topics such as Sustainable Manufacturing, Energy Saving Technologies, and Resource Conservation and Pollution Prevention Techniques. Process Intensification and Integration for Sustainable Design starts discussions on: shale gas as an option for the production of chemicals and challenges for process intensification; the design and techno-economic analysis of separation units to handle feedstock variability in shale gas treatment; RO-PRO desalination; and techno-economic and environmental assessment of ultrathin polysulfone membranes for oxygen-enriched combustion. Next, it looks at process intensification of membrane-based systems for water, energy, and environment applications; the design of internally heat-integrated distillation column (HIDiC); and graphical analysis and integration of heat exchanger networks with heat pumps.

Decomposition and implementation of large-scale interplant heat integration is covered, as is the synthesis of combined heat and mass exchange networks (CHAMENs) with renewables. The book also covers optimization strategies for integrating and intensifying housing complexes; a sustainable biomass conversion process assessment; and more. Covers the many advances and changes in process intensification and integration Provides side-by-side discussions of fundamental techniques and recent industrial experiences to guide practitioners in their own processes Presents comprehensive coverage of topics relevant, among others, to the process industry, biorefineries, and plant energy management Offers insightful analysis and integration of reactor and heat exchanger network Looks at optimization of integrated water and multi-regenerator membrane systems involving multi-contaminants Process Intensification and Integration for Sustainable Design is an ideal book for process engineers, chemical engineers, engineering scientists, engineering consultants, and chemists.

On July 30-31, 2018, the National Academies of Sciences, Engineering, and Medicine held a workshop titled Continuous Manufacturing for the Modernization of Pharmaceutical Production. This workshop discussed the business and regulatory concerns associated with adopting continuous manufacturing techniques to produce biologics such as enzymes, monoclonal antibodies, and vaccines. The participants also discussed specific challenges for integration across the manufacturing system, including upstream and downstream processes, analytical techniques, and drug product development. The workshop addressed these challenges broadly across the biologics domain but focused particularly on drug categories of greatest FDA and industrial interest such as monoclonal antibodies and vaccines. This publication summarizes the presentations and discussions from the workshop.

Microorganisms have been exploited for many centuries for the production of fermented foods and beverages and for bread-making. The production of alcoholic beverages using microbes was the first major industrialized process. The technology developed for large-scale brewing was adapted for other anaerobic processes such as acetone and butanol in the early 1900s. With the discovery of penicillins, rapid developments were made in the technology of submerged culture fermentation of aerobic microorganisms under controlled conditions. The advancements in microbiology and process biochemistry improved our ability to harness the potential of microorganisms through improved bioprocessing methods to manufacture new products with economic

viability. Microbial derived bioproducts have been gaining importance in the food, pharmaceutical, textile, leather, cosmetic and chemical industries, and most important among them are therapeutic proteins and peptides, enzymes, antigens, vaccines, antibiotics, drugs, etc. Not all microbial production processes involve culture of the organism in liquid medium. Instead, the organism can be grown on the surface of a solid substrate. Solid substrate (or solid state) fermentation (SSF) is an established traditional technology in many countries, producing edible mushrooms, fungal-fermented foods and soy sauce. Before the development of processes in liquid culture, citric acid and some microbial enzymes were produced by SSF. Carbon composting is also a form of SSF.

Enzymes are currently used in various industries, most commonly in food, detergents, and pharmaceuticals production. Lipases are hydrolytic enzymes that demonstrate great potential as an alternative to conventional catalysts in a number of industrial applications. A complete understanding of enzymes, and their proteins structure and environmental behavior, can greatly aid in the further development of industrial applications. *Supercritical Fluids Technology in Lipase Catalyzed Processes* provides basic information about enzymes, their sources, reaction kinetics, and main industrial applications. The book focuses in lipases. their main sources, structure, and features, with an emphasis on their specificity and interfacial activity, and presents proven techniques for isolating, extracting, and purifying. Comprised of six compact chapters, this comprehensive guide introduces: Immobilization techniques and immobilized lipases that allow repeated use (which is essential from an economic point of view) Different bioreactor configurations using immobilized lipases The latest information on the available technologies in lipolytic reactions The advantages of nonaqueous media in biochemical synthesis over aqueous and solvent-free systems Material on the use of lipases in nonaqueous media to overcome the drawbacks usually encountered with the use of conventional chemical catalysts The use of supercritical fluids (SCFs) as a green alternative reaction medium Factors affecting the physical properties of lipases in this medium and, hence, their activity and stability A case study using supercritical carbon dioxide (SC-CO₂) for biodiesel production Novel, cutting-edge technology, using immobilized enzymes to reduce the overall production cost *Supercritical Fluids Technology in Lipase Catalyzed Processes* outlines the main industrial applications of common enzymes and discusses relevant challenges and innovations emerging in the field.

Authoritative guide to the principles, characteristics, engineering aspects, economics, and applications of disposables in the manufacture of biopharmaceuticals The revised and updated second edition of *Single-Use Technology in Biopharmaceutical Manufacture* offers a comprehensive examination of the most-commonly used disposables in the manufacture of biopharmaceuticals. The authors—noted experts on the topic—provide the essential information on the principles, characteristics, engineering aspects, economics, and applications. This authoritative guide contains the basic knowledge and information about disposable equipment. The author also discusses biopharmaceuticals' applications through the lens of case studies that clearly illustrate the role of manufacturing, quality assurance, and environmental influences. This updated second edition revises existing information with recent developments that have taken place since the first edition was published. The book also presents the latest advances in the field of single-use technology and explores topics including applying single-use devices for microorganisms, human mesenchymal stem cells, and T-cells. This important book: • Contains an updated and end-to-end view of the development and manufacturing of single-use biologics • Helps in the identification of appropriate disposables and relevant vendors • Offers illustrative case studies that examine manufacturing, quality assurance, and environmental influences • Includes updated coverage on cross-functional/transversal dependencies, significant improvements made by suppliers, and the successful application of the single-use technologies Written for biopharmaceutical manufacturers, process developers, and biological and chemical engineers, *Single-Use Technology in Biopharmaceutical Manufacture, 2nd Edition* provides the information needed for professionals to come to an easier decision for or against disposable alternatives and to choose the appropriate system. *Approaches to the Purification, Analysis and Characterization of Antibody-Based Therapeutics* provides the interested and informed reader with an overview of current approaches, strategies and considerations relating to the purification, analytics and characterization of therapeutic antibodies and related molecules. While there are obviously other books published in and around this subject area, they seem to be either older (c.a. year 2000 publication date) or are more limited in scope. The book will include an extensive bibliography of the published literature in the respective areas covered. It is not, however, intended to be a how-to methods book. Covers the vital new area of R&D on therapeutic antibodies Written by leading scientists and researchers Up-to-date coverage and includes a detailed bibliography This book describes how microbes can be used as effective and sustainable resources to meet the current challenge of finding suitable and economical solutions for biopharmaceuticals, enzymes, food additives, nutraceuticals, value added biochemicals and microbial fuels, and discusses various aspects of microbial regulatory activity and its applications. It particularly focuses on the design, layout and other relevant issues in industrial microbe applications. Moreover, it discusses the entire microbial-product supply chain, from manufacturing sites to end users, both in domestic and international markets, providing insights into the global marketing of microbes and microbial biomass-derived products. Further, it includes topics concerning the effective production and utilization of eco-friendly biotechnology industries. It offers a valuable, ready-to-use guide for technologists and policymakers developing new biotechnologies.

Proteins are the most diverse group of biologically important substances. With the recent technological advances in the genomics area and the efforts in proteomics research, the rate of discovery for new proteins with unknown structure and function has increased. These proteins generated from genomic approaches present enormous opportunities for research and industrial application. *Protein Downstream Processing: Design, Development and Application of High and Low-Resolution Methods* is a compilation of chapters within the exciting area of protein purification designed to give the laboratory worker the information needed to design and implement a successful purification strategy. It presents reliable and robust protocols in a concise form, emphasizing the critical aspects on practical problems and questions

encountered at the lab bench. Written in the successful Methods in Molecular Biology series format, chapters include introductions to their respective topics, lists of the necessary materials and reagents, step-by-step, readily reproducible protocols and notes on troubleshooting and avoiding known pitfalls. Authoritative and easily accessible, Protein Downstream Processing: Design, Development and Application of High and Low-Resolution Methods will be an ideal source of scientific information to advanced students, junior researchers, and scientists involved in health sciences, cellular and molecular biology, biochemistry, and biotechnology and other related areas in both academia and industry. ? A comprehensive review of the current status and challenges for natural gas and shale gas production, treatment and monetization technologies Natural Gas Processing from Midstream to Downstream presents an international perspective on the production and monetization of shale gas and natural gas. The authors review techno-economic assessments of the midstream and downstream natural gas processing technologies. Comprehensive in scope, the text offers insight into the current status and the challenges facing the advancement of the midstream natural gas treatments. Treatments covered include gas sweetening processes, sulfur recovery units, gas dehydration and natural gas pipeline transportation. The authors highlight the downstream processes including physical treatment and chemical conversion of both direct and indirect conversion. The book also contains an important overview of natural gas monetization processes and the potential for shale gas to play a role in the future of the energy market, specifically for the production of ultra-clean fuels and value-added chemicals. This vital resource: Provides fundamental chemical engineering aspects of natural gas technologies Covers topics related to upstream, midstream and downstream natural gas treatment and processing Contains well-integrated coverage of several technologies and processes for treatment and production of natural gas Highlights the economic factors and risks facing the monetization technologies Discusses supply chain, environmental and safety issues associated with the emerging shale gas industry Identifies future trends in educational and research opportunities, directions and emerging opportunities in natural gas monetization Includes contributions from leading researchers in academia and industry Written for Industrial scientists, academic researchers and government agencies working on developing and sustaining state-of-the-art technologies in gas and fuels production and processing, Natural Gas Processing from Midstream to Downstream provides a broad overview of the current status and challenges for natural gas production, treatment and monetization technologies.

The current book gives an excellent insight into downstream processing technology and explains how to establish a successful strategy for an efficient recovery, isolation and purification of biosynthetic products. In addition to the overview of purification steps and unit operations, the authors provide practical information on capital and operating costs related to downstream processing.

Microalgae can be future resource for industrial biotechnology In current energy crisis era, microalgae are under tremendous research focus for the production of biodiesel due to their high photosynthetic efficiency, growth rate and high lipid content compared to territorial plants. However, the large-scale production of algal biomass and downstream processing of harvested algae towards bio-fuels are facing several challenges from economic viability perspective. Apart from bio-fuels, the microalgae synthesize number of bio-molecules such as pigments (e.g., chlorophyll, carotenoid), protein (e.g., lectin, phycobiliprotein), and carbohydrates (e.g., agar, carrageenan, alginate, fucodian) which are available in the various forms of microalgal products. Therefore, developing a strategy for large-scale production and use of algal biomass for the co-production of these value-added macromolecules is thus imperative for the improvement of the economics of algal biorefinery. In the above context, this book covers three major areas (i) commercial-scale production of bio-molecules from microalgae, (ii) sustainable approach for industrial-scale operation, and (iii) optimization of downstream processes. Each of these sections is composed of several chapters written by the renowned academicians/industry experts. Furthermore, in this book, a significant weightage is given to the industry experts (around 50%) to enrich the industrial perspectives. We hope that amalgamate of fundamental knowledge from academicians and applied research information from industry experts will be useful for forthcoming implementation of a sustainable integrated microalgal biorefinery. This book highlights following. Explores biomolecules from microalgae and their applications Discusses microalgae cultivations and harvesting Examines downstream processing of biomolecules Explores sustainable integrated approaches for industrial scale operations Examines purification techniques specific for microalgal proteins, Omega 3 fatty Acids, carbohydrates, and pigments

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Providing a critical and extensive compilation of the downstream processes of natural gas that involve the principle of gas processing, transmission and distribution, gas flow and network analysis, instrumentation and measurement systems and its utilisation, this book also serves to enrich readers understanding of the business and management aspects of natural gas and highlights some of the recent research and innovations in the field. Featuring extensive coverage of the design and pipeline failures and safety challenges in terms of fire and explosions relating to the downstream of natural gas technology, the book covers the needs of practising engineers from different disciplines, who may include project and operations managers, planning and design engineers as well as undergraduate and postgraduate students in the field of gas, petroleum and chemical engineering. This book also includes several case studies to illustrate the analysis of the downstream process in the gas and oil industry. Of interest to researchers is the field of flame and mitigation of explosion: the fundamental processes involved are also discussed, including outlines of contemporary and possible future research and challenges in the different fields.

This book review series presents current trends in modern biotechnology. The aim is to cover all aspects of this interdisciplinary technology where knowledge, methods and expertise are required from chemistry, biochemistry, microbiology, genetics, chemical engineering and computer science. Volumes are organized topically and provide a

comprehensive discussion of developments in the respective field over the past 3-5 years. The series also discusses new discoveries and applications. Special volumes are dedicated to selected topics which focus on new biotechnological products and new processes for their synthesis and purification. In general, special volumes are edited by well-known guest editors. The series editor and publisher will however always be pleased to receive suggestions and supplementary information. Manuscripts are accepted in English.

Biopharmaceutical Processing: Development, Design, and Implementation of Manufacturing Processes covers bioprocessing from cell line development to bulk drug substances. The methods and strategies described are essential learning for every scientist, engineer or manager in the biopharmaceutical and vaccines industry. The integrity of the bioprocess ultimately determines the quality of the product in the biotherapeutics arena, and this book covers every stage including all technologies related to downstream purification and upstream processing fields. Economic considerations are included throughout, with recommendations for lowering costs and improving efficiencies. Designed for quick reference and easy accessibility of facts, calculations and guidelines, this book is an essential tool for industrial scientists and managers in the biopharmaceutical industry. Offers a comprehensive, go-to reference for daily work decisions
Covers both upstream and downstream processes Includes case studies that emphasize financial outcomes Presents summaries, decision grids, graphs and overviews for quick reference

Promoting a continued and much-needed renaissance in biopharmaceutical manufacturing, this book covers the different strategies and assembles top-tier technology experts to address the challenges of antibody purification. • Updates existing topics and adds new ones that include purification of antibodies produced in novel production systems, novel separation technologies, novel antibody formats and alternative scaffolds, and strategies for ton-scale manufacturing • Presents new and updated discussions of different purification technologies, focusing on how they can address the capacity crunch in antibody purification • Emphasizes antibodies and innovative chromatography methods for processing
An all-in-one practical guide on how to efficiently use chromatographic separation methods Based on a training course that teaches the theoretical as well as practical aspects of protein bioseparation to bioprocess professionals, this fully updated and revised new edition offers comprehensive coverage of continuous chromatography and provides readers with many relevant examples from the biopharmaceutical industry. Divided into two large parts, **Protein Chromatography: Process Development and Scale-Up, Second Edition** presents all the necessary knowledge for effective process development in chromatographic bioseparation, both on small and large scale. The first part introduces chromatographic theory, including process design principles, to enable the reader to rationalize the set-up of a bioseparation process. The second part illustrates by way of case studies and sample protocols how the theory learned in the first part may be applied to real-life problems. Chapters look at: Downstream Processing of Biotechnology Products; Chromatography Media; Laboratory and Process Columns and Equipment; Adsorption Equilibrium; Rate Processes; and Dynamics of Chromatography Columns. The book closes with chapters on: Effects of Dispersion and Rate Processes on Column Performance; Gradient Elution Chromatography; and Chromatographic Column Design and Optimization. -Presents the most pertinent examples from the biopharmaceutical industry, including monoclonal antibodies -Provides an overview of the field along with design tools and examples illustrating the advantages of continuous processing in biopharmaceutical productions -Focuses on process development and large-scale bioseparation tasks, making it an ideal guide for the professional bioengineer in the biotech and pharma industries -Offers field-tested information based on decades of training courses for biotech and chemical engineers in Europe and the U.S. **Protein Chromatography: Process Development and Scale-Up, Second Edition** will appeal to biotechnologists, analytical chemists, chromatographers, chemical engineers, pharmaceutical industry, biotechnological industry, and biochemists.

This edited work presents studies that clarify the basics of producing recombinant enzymes that finally lead to commercialization. It enables researchers to see what is crucial to the commercialization process, from examining the cloning method, using analytical techniques such as calculating the total protein content and enzyme activity, through considering upstream and downstream processes, to the final product. Readers will discover the importance of the cloning method as it influences the upstream and downstream processes and determines the level of success of the recombinant enzyme commercialization processes. We see that the two main factors that are particularly sensitive during the cloning process are the vector and the host. A discussion of analytical techniques is presented followed by studies on important stages during the upstream processes including the process of optimizing the media to get results and high enzyme activity. Downstream processes such as the cell disruption technique, purification and formulation of the final product are then considered. The reader is introduced to software that helps streamline recombinant enzyme production from the upstream to downstream processes, to facilitate the process of up-scaling production. This work includes a case study as tool, to guide understanding of the commercialization process. The work is written for researchers in the field and is especially suited to those who are under pressure to embark on the tough process of commercialization.

Edited to avoid duplication and favor comprehensiveness, 20 contributors detail the recovery, separation, and purification operations of bioprocess technology. Individual chapters in this classic yet still highly relevant work emphasize concepts that are becoming more and more important when applied to the large scale versions of techniques that are considered well established. Aside from fully discussing processes, **Separation Processes in Biotechnology** includes sections on concentration separation and operation, purification operations, and product release and recovery. It also discusses plant operation and equipment and delves into economic considerations

The emergence and refinement of techniques in molecular biology has changed our perceptions of medicine, agriculture and environmental management. Scientific breakthroughs in gene expression, protein engineering and cell fusion are being translated by a strengthening biotechnology industry into revolutionary new products and services. Many a student has been enticed by the promise of biotechnology and the excitement of being near the cutting edge of scientific

advancement. However, graduates trained in molecular biology and cell manipulation soon realise that these techniques are only part of the picture. Reaping the full benefits of biotechnology requires manufacturing capability involving the large-scale processing of biological material. Increasingly, biotechnologists are being employed by companies to work in co-operation with chemical engineers to achieve pragmatic commercial goals. For many years aspects of biochemistry and molecular genetics have been included in chemical engineering curricula, yet there has been little attempt until recently to teach aspects of engineering applicable to process design to biotechnologists. This textbook is the first to present the principles of bioprocess engineering in a way that is accessible to biological scientists. Other texts on bioprocess engineering currently available assume that the reader already has engineering training. On the other hand, chemical engineering textbooks do not consider examples from bioprocessing, and are written almost exclusively with the petroleum and chemical industries in mind. This publication explains process analysis from an engineering point of view, but refers exclusively to the treatment of biological systems. Over 170 problems and worked examples encompass a wide range of applications, including recombinant cells, plant and animal cell cultures, immobilised catalysts as well as traditional fermentation systems.

- * * First book to present the principles of bioprocess engineering in a way that is accessible to biological scientists
- * Explains process analysis from an engineering point of view, but uses worked examples relating to biological systems
- * Comprehensive, single-authored
- * 170 problems and worked examples encompass a wide range of applications, involving recombinant plant and animal cell cultures, immobilized catalysts, and traditional fermentation systems
- * 13 chapters, organized according to engineering sub-disciplines, are grouped in four sections - Introduction, Material and Energy Balances, Physical Processes, and Reactions and Reactors
- * Each chapter includes a set of problems and exercises for the student, key references, and a list of suggestions for further reading
- * Includes useful appendices, detailing conversion factors, physical and chemical property data, steam tables, mathematical rules, and a list of symbols used
- * Suitable for course adoption - follows closely curricula used on most bioprocessing and process biotechnology courses at senior undergraduate and graduate levels.

In *Downstream Processing of Proteins: Methods and Protocols*, Mohamed A. Desai and a team of experienced biotechnologists review both conventional and novel isolation techniques used in industrial applications for the downstream processing of protein molecules. These techniques include primary and secondary separations during the isolation of biomolecules, as well as unique laboratory-scale research methods with a potential for scale-up. Also treated are the various strands of the downstream biological process essential for a successful product license application, including both the validation of DSP stages, and the design and validation of viral clearance stages during the purification process. *Downstream Processing of Proteins: Methods and Protocols* provides scientists everywhere, but particularly in the biopharmaceutical and biotechnology industry, with a much-needed introduction to this critical technology. Every bioprocess scientist and engineer working to design and validate biological processes for novel proteins-and successfully apply for their new product licenses-will find this important book an eminently practical resource.

Step by step simulation procedure including key technical parameters and neutral layout to be implemented in any available flowsheet simulator, thermo package recommendation and design tips specific for each type of presented unit/process. Starting from Upstream processes like FPSO/GOSP, then passing to Midstream with NGL recovery and complete fractionation train, mercury removal, glycol & molecular sieve dehydration, amine unit, then arriving Downstream to Refinery where crude, vacuum & condensate distillation units are touch, various strippers like: NHT, distillate, VGO, reformat splitter and stripper are presented, FCC & hydrocracking separation sections, saturated gas plant, sour water stripping unit plus sulfur recovery & TGT and finally to Petrochemical sector where PP Splitter with heat pump, BT fractionation and aromatic separation are presented. Also four special chapters are part of the book, MDMT rigorous calculation including tensile stress of wall expose to fire with practical examples (one vessel and multiple equipment protected by the same depressurization valve), HIPPS implementation for FPSO and toluene separation (dynamic simulation layout with integrator settings and various scenarios), CPA validation against experimental data with extensive graphs showing equilibrium for various available experimental data and DWC Opex & Capex quick tips and simulation / optimization tricks. At the end of each chapter the reader shall find "take away" section with useful information to be discovered.

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.

This book will update the original edition published in 1997. Since the publication of the first edition, the biotechnology and biologics industries have gained extensive knowledge and experience in downstream processing using chromatography and other technologies associated with recovery and purification unit operations. This book will tie that experience together for the next generation of readers. Updates include: - sources and productivity - types of products made today - experiences in clinical and licensed products - economics - current status of validation - illustrations and tables - automated column packing - automated systems New topics include: - the use of disposables - multiproduct versus dedicated production - design principles for chromatography media and filters - ultrafiltration principles and optimization - risk assessments - characterization studies - design space - platform technologies - process analytical technologies (PATs) - biogenerics - comparability assessments Key Features: - new approaches to process optimization - use of platform technologies - applying risk assessment to process design

This book will help you become a better product leader. Benefitting from Roman Pichler's extensive experience, you will learn how to align stakeholders and guide development teams even in challenging circumstances, avoid common leadership mistakes, and grow as a leader. Written in an engaging and easily accessible style, How to Lead in Product Management offers a wealth of practical tips and strategies. Through helpful examples, the book illustrates how you can directly apply the techniques to your work. Coverage includes: * Choosing the right leadership style * Cultivating empathy, building trust, and influencing others * Increasing your authority and empowering others * Directing stakeholders and development teams through common goals * Making decisions that people will support and follow through * Successfully resolving disputes and conflicts even with senior stakeholders * Listening deeply to discover and address hidden needs and interests * Practising mindfulness and embracing a growth mindset to develop as a leader Praise for How to Lead in Product Management: "Roman has done it again, delivering a practical book for the product management community that appeals to both heart and mind. How to Lead in Product Management is packed with concise, direct, and practical advice that addresses the deeper, personal aspects of the product leadership. Roman's book shares wisdom on topics including goals, healthy interactions with stakeholders, handling conflict, effective conversations, decision-making, having a growth mindset, and self-care. It is a must read for both new and experienced product people." ~Ellen Gottesdiener, Product Coach at EBG Consulting "Being a great product manager is tough. It requires domain knowledge, industry knowledge, technical skills, but also the skills to lead and inspire a team. Roman Pichler's How to Lead in Product Management is the best book I've read for equipping product managers to lead their teams." ~Mike Cohn, Author of Succeeding with Agile, Agile Estimating and Planning, and User Stories Applied "This is the book that has been missing for product people. Roman has created another masterpiece, a fast read with lots of value. It's a must read for every aspiring product manager." ~Magnus Billgren, CEO of Tolpagorni Product Management "How Lead in Product Management is for everyone who manages a product or drives important business decisions. Roman lays out the key challenges of product leadership and shows us ways of thoughtfully working with team members, stakeholders, partners, and the inevitable conflicts." ~Rich Mironov, CEO of Mironov Consulting and "Smokejumper" Head of Product

Biochemical Engineering and Biotechnology, 2nd Edition, outlines the principles of biochemical processes and explains their use in the manufacturing of every day products. The author uses a direct approach that should be very useful for students in following the concepts and practical applications. This book is unique in having many solved problems, case studies, examples and demonstrations of detailed experiments, with simple design equations and required calculations. Covers major concepts of biochemical engineering and biotechnology, including applications in bioprocesses, fermentation technologies, enzymatic processes, and membrane separations, amongst others Accessible to chemical engineering students who need to both learn, and apply, biological knowledge in engineering principals Includes solved problems, examples, and demonstrations of detailed experiments with simple design equations and all required calculations Offers many graphs that present actual experimental data, figures, and tables, along with explanations

This is the first book to present the idea of Industry 5.0 in biomanufacturing and bioprocess engineering, both upstream and downstream. The Prospect of Industry 5.0 in Biomanufacturing details the latest technologies and how they can be used efficiently and explains process analysis from an engineering point of view. In addition, it covers applications and challenges. FEATURES Describes the previous Industrial Revolution, current Industry 4.0, and how new technologies will transition toward Industry 5.0 Explains how Industry 5.0 can be applied in biomanufacturing Demonstrates new technologies catered to Industry 5.0 Uses worked examples related to biological systems This book enables readers in industry and academia working in the biomanufacturing engineering sector to understand current trends and future directions in this field.

Bioprocess Engineering: Downstream Processing is the first book to present the principles of bioprocess engineering, focusing on downstream bioprocessing. It aims to provide the latest bioprocess technology and explain process analysis from an engineering point of view, using worked examples related to biological systems. This book introduces the commonly used technologies for downstream processing of biobased products. The covered topics include centrifugation, filtration, membrane separation, reverse osmosis, chromatography, biosorption, liquid-liquid separation, and drying. The basic principles and mechanism of separation are covered in each of the topics, wherein the engineering concept and design are emphasized. This book is aimed at bioprocess engineers and professionals who wish to perform downstream processing for their feedstock, as well as students.

In recent years bioprocessing has increased in popularity and importance, however, bioprocessing still poses various important techno-economic and environmental challenges, such as product yields, excessive energy consumption for separations in highly watery systems, batch operation or the downstream processing bottlenecks in the production of biopharmaceutical products. Many

of those challenges can be addressed by application of different process intensification technologies discussed in the present book. The first book dedicated entirely to this area, *Intensification of Biobased Processes* provides a comprehensive overview of modern process intensification technologies used in bioprocessing. The book focusses on four different categories of biobased products: bio-fuels and platform chemicals; cosmeceuticals; food products; and polymers and advanced materials. It will cover various intensification aspects of the processes concerned, including (bio)reactor intensification; intensification of separation, recovery and formulation operations; and process integration. This is an invaluable source of information for researchers and industrialists working in chemical engineering, biotechnology and process engineering.

The last two decades have seen a phenomenal growth of the field of genetic or biochemical engineering and have witnessed the development and ultimately marketing of a variety of products-typically through the manipulation and growth of different types of microorganisms, followed by the recovery and purification of the associated products. The engineers and biotechnologists who are involved in the full-scale process design of such facilities must be familiar with the variety of unit operations and equipment and the applicable regulatory requirements. This book describes current commercial practice and will be useful to those engineers working in this field in the design, construction and operation of pharmaceutical and biotechnology plants. It will be of help to the chemical or pharmaceutical engineer who is developing a plant design and who faces issues such as: Should the process be batch or continuous or a combination of batch and continuous? How should the optimum process design be developed? Should one employ a new revolutionary separation which could be potentially difficult to validate or use accepted technology which involves less risk? Should the process be run with ingredients formulated from water for injection, deionized water, or even filtered tap water? Should any of the separations be run in cold rooms or in glycol jacketed lines to minimize microbial growth where sterilization is not possible? Should the process equipment and lines be designed to be sterilized in-place, cleaned-in-place, or should every piece be broken down, cleaned and autoclaved after every turn?

Expanded bed adsorption chromatography is a novel processing technique for the purification of biomolecules, combining clarification, concentration and initial purification in one step. By such an integration it is possible to reduce the number of steps in the purification process, to shorten the processing time and to improve the yields. The technology is new, and interesting developments have taken place concerning the adsorbents, the processing technology and potential applications. Both small-scale laboratory processes and larger industrial processes are being developed. Expanded bed chromatography is one of the most exciting new developments in downstream processing in recent years. The technology will be a standard procedure when new biotechnological processes are being developed.

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