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## KEY=THE - DONAVAN ANIYA

## MICROPARTICULATE SYSTEMS FOR THE DELIVERY OF PROTEINS AND VACCINES

CRC Press **This practical guide offers concise coverage of the scientific and pharmaceutical aspects of protein delivery from controlled release microparticulate systems-emphasizing protein stability during encapsulation and release.**

## BIODEGRADABLE POLYMER MICRO- AND NANOPARTICLES AS PROTEIN DELIVERY SYSTEMS

## INFLUENCE OF MICROPARTICLE MORPHOLOGY AND IMPROVEMENT OF PROTEIN LOADING CAPACITY OF NANOPARTICLES

**In this work, microparticles and nanoparticles were investigated as protein delivery system. Chapter 1 firstly describes development and current status of degradable polymer microspheres as protein delivery systems. In Chapter 2 with the aim to establish the relationship of particles morphology, drug distribution and release profiles based on different polymer properties, relatively hydrophobic and hydrophilic PLGAs with different end functional groups were selected to prepare microspheres using W/O/W method with different porosity, pore size and drug loading. The results showed that morphology of particles play a different role in the release process depending on the property of polymer. For relative hydrophilic polymer, as RG503H, morphology influenced the burst release to the less extent relative to hydrophobic polymer RG502. Vice verse, at the slow release stage, morphology showed much less pronounced influence for hydrophobic polymer RG502. In Chapter 3 with the purpose to achieve high protein loading and to improve the release profiles, we supposed that protein can be effectively absorbed onto charged nanoparticles and can be released in the controlled manner. PLGA and PSS polymer blend were used to mimic negatively charged polymer and to prepare charged nanoparticles with variable surface charge density through adjusting the ratio of PSS to PLGA. Increased PSS led to the increment of size and high charge density of nanoparticles. Adsorption isotherm showed higher affinity of protein to the nanoparticles with increased PSS. Loading capacity of lysozyme closely related to charge density of nanoparticles. Adsorption process of protein and loading capacity investigations suggest that the electrostatic forces dominate the interaction between proteins and nanoparticles. Bioactivity determination showed protein remains intact during whole process and the release profiles were dependent on protein loading. This study proves our hypothesis that it is a feasible and mil.**

## UNIFORM BIODEGRADABLE MICROPARTICLE SYSTEMS FOR PROTEIN DELIVERY

## DEVELOPMENT AND EVALUATION OF ALBUMIN BASED MICROPARTICULATE SYSTEM AS A PLATFORM TECHNOLOGY FOR ORAL DELIVERY OF PROTEINS, VACCINES, AND DRUGS

## DEVELOPMENT AND EVALUATION OF MICROPARTICULATE CARRIER SYSTEMS AND THEIR APPLICATIONS FOR SUSTAINED DELIVERY OF INTERLEUKIN-2 FOR TUMOUR IMMUNOTHERAPY

**In conclusion, novel DS based microparticulate systems capable of high entrapment of peptides and proteins (insulin and IL-2) can be simply prepared by complex coacervation using a very mild ionic crosslinking technique. The physicochemical properties of the drug delivery systems (surface charge, encapsulation efficiencies and release rate) can be readily manipulated by varying the formulation variables including the polymer matrix composition, the amount of crosslinking agent and the pH of the formulation medium. The DS based microparticulate systems have the potential to be suitable carriers for the therapeutic bioactive macromolecules, including IL-2.**

## PROTEIN DELIVERY

## PHYSICAL SYSTEMS

Springer Science & Business Media **Thirteen chapters by industrial and academic authorities in this rapidly evolving field present detailed case histories and reviews of current sophisticated protein-drug delivery technologies. Highlights include a comprehensive overview of insulin delivery and a discussion of the use of biodegradable microspheres.**

## MICROPARTICULATE DELIVERY SYSTEMS FOR PROTEIN AND VACCINE THERAPY

## DRUG PRODUCT DEVELOPMENT FOR THE BACK OF THE EYE

Springer Science & Business Media **This comprehensive volume discusses approaches for a systematic selection of delivery systems for various classes of therapeutic agents including small molecule, protein, and nucleic acid drugs. Specific topics covered in this book include: Solution, suspension, gel, nanoparticle, microparticle, and implant dosage forms Refillable and microneedle devices Intravitreal, suprachoroidal, intrascleral, transscleral, systemic, and topical routes of delivery Physical methods including iontophoresis for drug delivery Rational selection of routes of administration and delivery systems Noninvasive and continuous drug monitoring Regulatory path to drug product development Clinical endpoints for drug product development Emerging and existing drugs and drug targets Drug Product Development for the Back of the Eye is authored by renowned ocular drug delivery experts, representing academic, clinical, and industrial organizations and serves as indispensable resource for ophthalmic researchers, drug formulation scientists, drug delivery and drug disposition scientists, as well as clinicians involved in designing and developing novel therapeutics for the back of the eye diseases. This book is also relevant for students in various disciplines including ophthalmology, pharmaceutical sciences, drug delivery, and biomedical engineering. Refillable and microneedle devices Intravitreal, suprachoroidal, intrascleral, transscleral, systemic, and topical routes of delivery Physical methods including iontophoresis for drug delivery Rational selection of routes of administration and delivery systems Noninvasive and continuous drug monitoring Regulatory path to drug product development Clinical endpoints for drug product development Emerging and existing drugs and drug targets Drug Product Development for the Back of the Eye is authored by renowned ocular drug delivery experts, representing academic, clinical, and industrial organizations and serves as indispensable resource for ophthalmic researchers, drug formulation scientists, drug delivery and drug disposition scientists, as well as clinicians involved in designing and developing novel therapeutics for the back of the eye diseases. This book is also relevant for students in various disciplines including ophthalmology, pharmaceutical sciences, drug delivery, and biomedical engineering. Refillable and microneedle devices Intravitreal, suprachoroidal, intrascleral, transscleral, systemic, and topical routes of delivery Physical methods including iontophoresis for drug delivery Rational selection of routes of administration and delivery systems Noninvasive and continuous drug monitoring Regulatory path to drug product development Clinical endpoints for drug product development Emerging and existing drugs and drug targets Drug Product Development for the Back of the Eye is authored by renowned ocular drug delivery experts, representing academic, clinical, and industrial organizations and serves as indispensable resource for ophthalmic researchers, drug formulation scientists, drug delivery and drug disposition scientists, as well as clinicians involved in designing and developing novel therapeutics for the back of the eye diseases. This book is also relevant for students in various disciplines including ophthalmology, pharmaceutical sciences, drug delivery, and biomedical engineering.**

## NANOPARTICLE- AND MICROPARTICLE-BASED DELIVERY SYSTEMS

## ENCAPSULATION, PROTECTION AND RELEASE OF ACTIVE COMPOUNDS

CRC Press **Recent developments in nanoparticle and microparticle delivery systems are revolutionizing delivery systems in the food industry. These developments have the potential to solve many of the technical challenges involved in creating encapsulation, protection, and delivery of active ingredients, such as colors, flavors, preservatives, vitamins, minerals, and nutraceuticals. Nanoparticle- and Microparticle-based Delivery Systems: Encapsulation, Protection and Release of Active Compounds explores various types of colloidal delivery systems available for encapsulating active ingredients, highlighting their relative advantages and limitations and their use. Written by an international authority known for his clear and rigorous technical writing style, this book discusses the numerous kinds of active ingredients available and the issues associated with their encapsulation, protection, and delivery. The author takes a traditional colloid science approach and emphasizes the practical aspects of formulation of particulate- and emulsion-based delivery systems with food applications. He then covers the physicochemical and mechanical methods available for manufacturing colloidal particles, highlighting the importance of designing particles for specific applications. The book includes chapters devoted specifically to the three major types of colloidal delivery systems available for encapsulating active ingredients in the food industry: surfactant-based, emulsion-based, and biopolymer-based. It then reviews the analytical tools available for characterizing the properties of colloidal delivery systems, presents the mathematical models for describing their properties, and highlights the factors to consider when selecting an appropriate delivery system for a particular application backed up by specific case studies. Based on insight from the author's own experience, the book describes why delivery systems are needed, the important factors to consider when designing them, methods of characterizing them, and specific examples of the range of food-grade delivery systems available. It gives you the necessary knowledge, understanding, and appreciation of developments within the current research literature in this rapidly growing field and the confidence to perform reliable experimental investigations according to modern international standards.**

## NOVEL PROTEIN THERAPEUTICS DELIVERY SYSTEMS BASED ON MULTIFUNCTIONAL NANOSTRUCTURES

**Delivery is a key challenge in novel protein therapeutic development. Even though numerous proteins are potential therapeutic candidates, a lack of delivery method limits the development of protein therapeutics. I have studied protein delivery and designed three novel delivery systems: gold nanoparticle based polymer particle system, multifunctional oligonucleotide, and nanostructured microparticles. Each of delivery system was designed to deliver CRISPR/Cas9 ribonucleoprotein, transcription factors, and oral protein drugs. First of all, CRISPR/Cas9 is a great tool in genome editing field. Moreover, CRISPR/Cas9-mediated genome editing has the potential to revolutionize the treatment of genetic diseases and the development of cell-based therapies. However, precise gene editing with Cas9 is still challenging in vivo because it requires simultaneous and efficient delivery of Cas9, guide RNA, and donor DNA into cells. We designed a gold nanoparticle-based delivery vehicle, CRISPR-Gold, which can directly deliver Cas9 protein, guide RNA (gRNA), and donor DNA in vitro and in vivo and efficiently induce homology directed repair (HDR). CRISPR-Gold is composed of gold nanoparticles assembled with the Cas9-gRNA ribonucleoprotein (RNP) complex, donor DNA, and an endosomal disruptive polymer. We demonstrate that CRISPR-Gold can induce HDR in human stem cells and mouse primary cells with an efficiency that is significantly higher than conventional transfection methods. Notably, we show that CRISPR-Gold can correct a nonsense mutation in the dystrophin gene that causes Duchenne muscular dystrophy in mdx mice, and restore dystrophin protein expression in mouse muscle after a single injection. Another potential protein therapeutic group is the transcription factor, which can have broad effects in gene regulation. We designed a novel multifunctional oligonucleotide, termed DARTs, which can deliver transcription factors with high efficiency in vivo. DARTs are composed of an oligonucleotide that contain a transcription factor binding sequence and hydrophobic membrane disruptive chains that are masked by acid cleavable galactose residues. DARTs have a unique molecular architecture, which allows them to bind transcription factors, trigger endocytosis in hepatocytes, and stimulate endosomal escape. The DARTs target hepatocytes as a result of the galactose residues and can disrupt endosomes efficiently with minimal toxicity because the unmasking of their hydrophobic domains selectively occurs in the acidic environment of the endosome. DARTs showed efficient delivery of the transcription factor Nrf2 to the liver, catalyzed the transcription of Nrf2 downstream genes, and rescued mice from acetaminophen induced liver injury. Another method of delivery that continues to be in the process of improvement is the oral drug delivery system for protein therapeutics. Oral drug delivery faces challenges including harsh acidic environment, rapid clearance of drug, and limited paracellular transport of therapeutic molecules. We studied a nanostructured microparticle system to overcome the challenges with an engineering approach. We showed that planar silica particles coated with silicon nanowires loaded proteins efficiently. The planar particles increased the transepithelial permeation of the protein drug as a result of a larger surface area in contact with the cell layer.**

## HANDBOOK OF POLYESTER DRUG DELIVERY SYSTEMS

CRC Press **In the quest for innovative drug delivery systems attempting to meet the unmet needs in pharmaceutical space, research has taken a much more complicated path that poses a significant challenge for translation. Despite the progress made with novel materials, polyesters still remain at the helm of drug delivery technologies. This book provides a single source of reference of polyester drug delivery systems that covers a broad spectrum of materials design, manufacturing techniques, and applications.**

## ADVANCES IN DRUG DELIVERY SYSTEMS, 5

## PROCEEDINGS OF THE FIFTH INTERNATIONAL SYMPOSIUM ON RECENT ADVANCES IN DRUG DELIVERY SYSTEMS, SALT LAKE CITY, UT, U.S.A., FEBRUARY 25-28, 1991

Elsevier Science Limited **Can improved delivery systems for vaccines be developed? Can oral delivery of peptides or proteins be achieved? Can clinically useful triggered drug delivery systems be developed? Can active drug targeting with microparticulates be achieved? Can cellular or viral delivery systems be designed? These questions stimulated discussion of recent advances and state of the art technology in drug delivery systems in this Fifth International Symposium. Significant advances have been made since the first meeting in 1983. Passive diffusion-based systems from before that time have evolved to dynamic interactive systems recognizing and responding to physiological and biochemical processes. The thirty papers in this volume represent recent research efforts considered to be important to the future development of drug delivery systems. Six major areas of the science and technology of drug delivery systems are covered: immunotherapeutic; oral delivery; triggered and modulated drug delivery systems; targeting and membrane recognition; new delivery systems; and clinical aspects of drug delivery systems. The interdisciplinary and multi-faceted nature of drug delivery systems is exemplified by representation in areas as diverse as physiology and pathology, chemical engineering and clinical science.**

## HANDBOOK OF PHARMACEUTICAL CONTROLLED RELEASE TECHNOLOGY

CRC Press **The Handbook of Pharmaceutical Controlled Release Technology reviews the design, fabrication, methodology, administration, and classifications of various drug delivery systems, including matrices, and membrane controlled reservoir, bioerodible, and pendant chain systems. Contains cutting-edge research on the controlled delivery of biomolecules! Discussing the advantages and limitations of controlled release systems, the Handbook of Pharmaceutical Controlled Release Technology covers oral, transdermal, parenteral, and implantable delivery of drugs discusses modification methods to achieve desired release kinetics highlights constraints of system design for practical clinical application analyzes diffusion equations and mathematical modeling considers environmental acceptance and tissue compatibility of biopolymeric systems for biologically active agents evaluates polymers as drug delivery carriers describes peptide, protein, micro-, and nanoparticulate release systems examines the cost, comfort, disease control, side effects, and patient compliance of numerous delivery systems and devices and more!**

## NANOPARTICULATES AS DRUG CARRIERS

Imperial College Press **Written by key experts in the field of nanomedicine, this book provides a broad introduction to the important field of nanomedicine and application of nanotechnology for drug delivery. It covers up-to-date information regarding various nanoparticulate drug delivery systems, describes the various opportunities for the application of nanoparticular drug carriers in different areas of clinical medicine, and analyzes already available information on their clinical applications. This book can be used as an advanced textbook by graduate students and young scientists and clinicians at the early stages of their career. It is also suitable for non-experts from related areas of chemistry, biochemistry, molecular biology, biomedical engineering, physiology, experimental and clinical medicine, and pharmaceutical sciences, who are interested in general problems of drug delivery and drug targeting, as well as in more specialized topics of using nanoparticulate-mediated drug delivery approaches in the individual areas of clinical medicine. Prof Torchilin is an expert in Nanomedicine and a recipient of numerous awards including the Lenin Prize in Science & Technology of the former USSR, membership in the European Academy of Sciences, and AAPS Research Achievement Award in Pharmaceutics and Drug Delivery. He served as an Associate Professor of Radiology at Harvard Medical School before joining Northeastern University as the Chairman of the Department of Pharmaceutical Sciences. Sample Chapter(s). Chapter 1: Introduction. Nanocarriers for Drug Delivery: Needs and Requirements (442 KB). Contents: Nanoparticle Flow: Implications for Drug Delivery (A T Florence); Polymer Micelles as Drug Carriers (E V Batrakova et al.); Lipoproteins as Pharmaceutical Carriers (S Liu et al.); Dendrimers as Nanoparticular Drug Carriers (S Svenson & D A Tomalia); Cells and Cell Ghosts as Drug Carriers (J M Lanao & M L Sayalero); Magnetic Nanoparticles as Drug Carriers (U O Hnfeli & M Chastellain); Liposomal Drug Carriers in Cancer Therapy (A A Gabizon); Delivery of Nanoparticles to the**

**Cardiovascular System (B-A Khaw); Nanoparticles for Targeting Lymphatics (W Phillips); Nanoparticular Carriers for Ocular Drug Delivery (A Sanchez & M J Alonso); and other papers. Readership: Graduate students, academics in nanomedicine, clinicians, pharmacologists, pharmacists, bioengineers, researchers in biotechnology and diagnostic imaging."**

## MICROENCAPSULACIÓN DE NANOPARTÍCULAS DE QUITOSANO PARA LA ADMINISTRACIÓN PULMONAR DE MACROMOLÉCULAS TERAPÉUTICAS

Univ Santiago de Compostela

## TISSUE ENGINEERING AND NOVEL DELIVERY SYSTEMS

CRC Press **Essential to anyone working in the field, this reference focuses on latest advancements in tissue construction, repair and regeneration focusing on developments in gene and drug therapy, the evolution of tissue-engineered products, and new technologies for the design of functional tissues and organ systems.**

## NANOPARTICLE- AND MICROPARTICLE-BASED DELIVERY SYSTEMS

## ENCAPSULATION, PROTECTION AND RELEASE OF ACTIVE COMPOUNDS

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## FORMULATION AND DELIVERY OF PROTEINS AND PEPTIDES

Amer Chemical Society **Developed from a symposium sponsored by the Division of Biochemical Technology at the 205th National Meeting of the American Chemical Society, Denver, Colorado, March 28-April 2, 1993.**

## TARGETING CHRONIC INFLAMMATORY LUNG DISEASES USING ADVANCED DRUG DELIVERY SYSTEMS

Academic Press **Targeting Chronic Inflammatory Lung Diseases Using Advanced Drug Delivery Systems explores the development of novel therapeutics and diagnostics to improve pulmonary disease management, looking down to the nanoscale level for an efficient system of targeting and managing respiratory disease. The book examines numerous nanoparticle-based drug systems such as nanocrystals, dendrimers, polymeric micelles, protein-based, carbon nanotube, and liposomes that can offer advantages over traditional drug delivery systems. Starting with a brief introduction on different types of nanoparticles in respiratory disease conditions, the book then focuses on current trends in disease pathology that use different in vitro and in vivo models. The comprehensive resource is designed for those new to the field and to specialized scientists and researchers involved in pulmonary research and drug development. Explores recent perspectives and challenges regarding the management and diagnosis of chronic respiratory diseases Provides insights into how advanced drug delivery systems can be effectively formulated and delivered for the management of various pulmonary diseases Includes the most recent information on diagnostic methods and treatment strategies using controlled drug delivery systems (including nanotechnology)**

## BIOPHARMACEUTICALS: ADVANCES IN RESEARCH AND APPLICATION: 2011 EDITION

ScholarlyEditions **Biopharmaceuticals: Advances in Research and Application: 2011 Edition is a ScholarlyEditions™ eBook that delivers timely, authoritative, and comprehensive information about Biopharmaceuticals. The editors have built Biopharmaceuticals: Advances in Research and Application: 2011 Edition on the vast information databases of ScholarlyNews.™ You can expect the information about Biopharmaceuticals in this eBook to be deeper than what you can access anywhere else, as well as consistently reliable, authoritative, informed, and relevant. The content of Biopharmaceuticals: Advances in Research and Application: 2011 Edition has been produced by the world's leading scientists, engineers, analysts, research institutions, and companies. All of the content is from peer-reviewed sources, and all of it is written, assembled, and edited by the editors at ScholarlyEditions™ and available exclusively from us. You now have a source you can cite with authority, confidence, and credibility. More information is available at http://www.ScholarlyEditions.com/.**

## NANOPARTICULATE VACCINE DELIVERY SYSTEMS

CRC Press **Recent years have seen the development of novel technologies that use nanoparticles and microparticles to deliver vaccines by the oral and microneedle-based transdermal route of administration. These new technologies enable the formulation of vaccine particles containing vaccine antigens, without loss of their biological activity during the formulation process. Also, multiple antigens, targeting ligands, and adjuvants can all be encapsulated within the same particle. When administered orally, these particles are designed to withstand the acidic environment of the stomach and are targeted to Peyer's patches and the gut-associated mucosal immune system. Since these vaccines are particulate in nature, they are readily taken up by phagocytic antigen-presenting cells, such as M cells, dendritic cells, and macrophages in Peyer's patches of the intestines, resulting in a strong immune response and antibody production. Since no needles are required for oral vaccines, this method of vaccine delivery is inexpensive and suitable for mass vaccination in the developing world as well as the developed world. This book discusses studies conducted on a wide array of vaccines, including vaccines for infectious diseases such as tuberculosis, typhoid, influenza, pneumonia, meningitis, human papillomavirus, and hepatitis B. It also discusses recent studies on vaccines for cancers such as melanoma and ovarian, breast, and prostate cancer.**

## DRUG DELIVERY IN ONCOLOGY

## FROM BASIC RESEARCH TO CANCER THERAPY

John Wiley & Sons **In this first authoritative overview on modern cancer chemotherapy 121 international specialists have contributed their experience and recent data for what is likely to become the gold standard in the field. The authors summarize knowledge gained over the past decade, from basic concepts to successful applications in the clinic, covering active and passive targeting strategies as well as tissue-specific approaches. All current and future targeted delivery systems are discussed, from ligand-based to antibody-based polymer-based systems, right up to micro- and nanoparticulate systems. A special section covers the delivery of nucleic acid therapeutics, such as siRNA, miRNA and antisense nucleotides. In each case, a description of the basic technique is followed by a discussion of the latest preclinical and clinical developments in the field. By virtue of its clear and didactic structure, rich illustrative material and summary chapters, this handbook and ready reference enables the efficient transfer of knowledge between different disciplines, from basic research to the clinician and vice versa. It is equally well suited for professionals, researchers and students in medical oncology and cancer biology, and is also excellent for teaching medical students the foundations of 21st century cancer chemotherapy.**

## DRUG PRODUCT DEVELOPMENT FOR THE BACK OF THE EYE

Springer **This comprehensive volume discusses approaches for a systematic selection of delivery systems for various classes of therapeutic agents including small molecule, protein, and nucleic acid drugs. Specific topics covered in this book include: Solution, suspension, gel, nanoparticle, microparticle, and implant dosage forms Refillable and microneedle devices Intravitreal, suprachoroidal, intrascleral, transscleral, systemic, and topical routes of delivery Physical methods including iontophoresis for drug delivery Rational selection of routes of administration and delivery systems Noninvasive and continuous drug monitoring Regulatory path to drug product development Clinical endpoints for drug product development Emerging and existing drugs and drug targets Drug Product Development for the Back of the Eye is authored by renowned ocular drug delivery experts, representing academic, clinical, and industrial organizations and serves as indispensable resource for ophthalmic researchers, drug formulation scientists, drug delivery and**

drug disposition scientists, as well as clinicians involved in designing and developing novel therapeutics for the back of the eye diseases. This book is also relevant for students in various disciplines including ophthalmology, pharmaceutical sciences, drug delivery, and biomedical engineering. Refillable and microneedle devices Intravitreal, suprachoroidal, intrascleral, transscleral, systemic, and topical routes of delivery Physical methods including iontophoresis for drug delivery Rational selection of routes of administration and delivery systems Noninvasive and continuous drug monitoring Regulatory path to drug product development Clinical endpoints for drug product development Emerging and existing drugs and drug targets Drug Product Development for the Back of the Eye is authored by renowned ocular drug delivery experts, representing academic, clinical, and industrial organizations and serves as indispensable resource for ophthalmic researchers, drug formulation scientists, drug delivery and drug disposition scientists, as well as clinicians involved in designing and developing novel therapeutics for the back of the eye diseases. This book is also relevant for students in various disciplines including ophthalmology, pharmaceutical sciences, drug delivery, and biomedical engineering. Refillable and microneedle devices Intravitreal, suprachoroidal, intrascleral, transscleral, systemic, and topical routes of delivery Physical methods including iontophoresis for drug delivery Rational selection of routes of administration and delivery systems Noninvasive and continuous drug monitoring Regulatory path to drug product development Clinical endpoints for drug product development Emerging and existing drugs and drug targets Drug Product Development for the Back of the Eye is authored by renowned ocular drug delivery experts, representing academic, clinical, and industrial organizations and serves as indispensable resource for ophthalmic researchers, drug formulation scientists, drug delivery and drug disposition scientists, as well as clinicians involved in designing and developing novel therapeutics for the back of the eye diseases. This book is also relevant for students in various disciplines including ophthalmology, pharmaceutical sciences, drug delivery, and biomedical engineering.

## POLYMERIC DRUGS AND DRUG DELIVERY SYSTEMS

CRC Press **Polymeric materials are now playing an increasingly important role in pharmaceuticals, as well as in sensing devices, in situ prostheses and probes, and microparticle diagnostic agents. This new volume consists of twenty-two recent research-based reports on the developments in these areas of pharmaceutical and biomaterials technology. The reports w**

## NANOPARTICULATE DRUG DELIVERY SYSTEMS

CRC Press **With the advent of analytical techniques and capabilities to measure particle sizes in nanometer ranges, there has been tremendous interest in the use of nanoparticles for more efficient methods of drug delivery. Nanoparticulate Drug Delivery Systems addresses the scientific methodologies, formulation, processing, applications, recent trends, and e**

## INNOVATIVE DOSAGE FORMS

## DESIGN AND DEVELOPMENT AT EARLY STAGE

John Wiley & Sons **Teaches future and current drug developers the latest innovations in drug formulation design and optimization This highly accessible, practice-oriented book examines current approaches in the development of drug formulations for preclinical and clinical studies, including the use of functional excipients to enhance solubility and stability. It covers oral, intravenous, topical, and parenteral administration routes. The book also discusses safety aspects of drugs and excipients, as well as regulatory issues relevant to formulation. Innovative Dosage Forms: Design and Development at Early Stage starts with a look at the impact of the polymorphic form of drugs on the preformulation and formulation development. It then offers readers reliable strategies for the formulation development of poorly soluble drugs. The book also studies the role of reactive impurities from the excipients on the formulation shelf life; preclinical formulation assessment of new chemical entities; and regulatory aspects for formulation design. Other chapters cover innovative formulations for special indications, including oncology injectables, delayed release and depot formulations; accessing pharmacokinetics of various dosage forms; physical characterization techniques to assess amorphous nature; novel formulations for protein oral dosage; and more. -Provides information that is essential for the drug development effort -Presents the latest advances in the field and describes in detail innovative formulations, such as nanosuspensions, micelles, and cocrystals -Describes current approaches in early pre-formulation to achieve the best in vivo results -Addresses regulatory and safety aspects, which are key considerations for pharmaceutical companies -Includes case studies from recent drug development programs to illustrate the practical challenges of preformulation design Innovative Dosage Forms: Design and Development at Early Stage provides valuable benefits to interdisciplinary drug discovery teams working in industry and academia and will appeal to medicinal chemists, pharmaceutical chemists, and pharmacologists.**

## PEPTIDE AND PROTEIN DRUG ANALYSIS

CRC Press **Furthering efforts to simulate the potency and specificity exhibited by peptides and proteins in healthy cells, this remarkable reference supplies pharmaceutical scientists with a wealth of techniques for tapping the enormous therapeutic potential of these molecules-providing a solid basis of knowledge for new drug design. Provides a broad, comprehensive overview of peptides and proteins as mediators of cell movement, proliferation, differentiation, and communication. Written by more than 50 leading international authorities, Peptides and Protein Drug Analysis discusses strategies for dealing with the complexity of peptides and proteins in conformational flexibility and amino acid sequence variability analyzes drug formulations facilitated by solid-phase peptide synthesis and recombinant DNA technology examines chemical purity analysis by high-pressure chromatographic, capillary electrophoretic, gel electrophoretic, and isoelectric focusing methods highlights drug design elements derived from protein folding, bioinformatics, and computational chemistry demonstrates uses of unnatural mutagenesis and combinatorial chemistry explores mass spectrometry, protein sequence, and carbohydrate analysis illustrates bioassays and other new functional analysis methods surveys spectroscopic techniques such as ultraviolet, fluorescence, Fourier transform infrared, and nuclear magnetic resonance (NMR) addresses ways of distinguishing between levels of therapeutic and endogenous agents in cells reviews structural analysis tools such as ultracentrifugation and light, X-ray, and neutron scattering and more! Featuring over 3400 bibliographic citations and more than 500 tables, equations, and illustrations, Peptide and Protein Drug Analysis is a must-read resource for pharmacists; pharmacologists; analytical, organic, and pharmaceutical chemists; cell and molecular biologists; biochemists; and upper-level undergraduate and graduate students in these disciplines.**

## APPLICATIONS OF ENCAPSULATION AND CONTROLLED RELEASE

CRC Press **The field of encapsulation, especially microencapsulation, is a rapidly growing area of research and product development. Applications of Encapsulation and Controlled Release offers a broad perspective on a variety of applications and processes, including, up-to-date research, figures, tables, illustrations, and references. Written at a level comprehensible to non-experts, it is a rich source of technical information and current practices in research and industry.**

## BIOMEDICAL SCIENCE AND TECHNOLOGY

## RECENT DEVELOPMENTS IN THE PHARMACEUTICAL AND MEDICAL SCIENCES

Springer Science & Business Media **Advancing with Biomedical Engineering Today, in most developed countries, modem hospitals have become centers of sophis ticated health care delivery using advanced technological methods. These have come from the emergence of a new interdisciplinary field and profession, commonly referred to as "Bio medical Engineering." Although what is included in the field of biomedical engineering is quite clear, there are some disagreements about its definition. In its most comprehensive meaning, biomedical engineering is the application of the principles and methods of engi neering and basic sciences to the understanding of the structure-function relationships in normal and pathological mammalian tissues, as well as the design and manufacture of prod ucts to maintain, restore, or improve tissue functions, thus assisting in the diagnosis and treat ment of patients. In this very broad definition, the field of biomedical engineering now includes: • System analysis (modeling, simulation, and control of the biological system) • Biomedical instrumentation (detection, measurement, and monitoring of physio logic signals) • Medical imaging (display of anatomic details or physiologic functions for diag nosis) • Biomaterials (development of materials used in prostheses or in medical devices) • Artificial organs (design and manufacture of devices for replacement or augmen tation of tissues or organs) • Rehabilitation (development oftherapeutic and rehabilitation procedures and de vices) • Diagnostics (development of expert systems for diagnosis of diseases) • Controlled drug delivery (development of systems for administration of drugs and other active agents in a controlled manner, preferably to the target area)**

## PHARMACEUTICAL MANUFACTURING HANDBOOK

### PRODUCTION AND PROCESSES

John Wiley & Sons **This handbook features contributions from a team of expert authors representing the many disciplines within science, engineering, and technology that are involved in pharmaceutical manufacturing. They provide the information and tools you need to design, implement, operate, and troubleshoot a pharmaceutical manufacturing system. The editor, with more than thirty years' experience working with pharmaceutical and biotechnology companies, carefully reviewed all the chapters to ensure that each one is thorough, accurate, and clear.**

## BIOENGINEERING IN WOUND HEALING: A SYSTEMS APPROACH

World Scientific **What is a wound, how does it heal, and how can we prevent scarring? The concept of wound healing has puzzled humans even before the advent of modern medicine. In recent years, bioengineering has tackled the problems of cancer, tissue engineering and molecular manufacturing. The broad spectrum of technologies developed in these fields could potentially transform the wound care practice. However, entering the world of wound healing research is challenging — a broad spectrum of knowledge is required to understand wounds and improve healing. This book provides an essential introduction of the field of wound healing to bioengineers and scientists outside the field of medicine. Written by leading researchers from various fields, this book is a comprehensive primer that gives readers a holistic understanding of the field of wound biology, diagnostics and treatment technologies. Contents:Scarless Tissue Regeneration (Alexander Golberg)Anatomy of the Human Skin and Wound Healing (Amit Sharma, Labib R Zakka and Martin C Mihm Jr)Deprived and Enriched Environments: How Sensory Stimulation Affects Wound Healing (Jonathan G Fricchione and John B Levine)Models of Ischemic and Vascular Wounds (Michael T Watkins and Hassan Albadawi)Developmental Biology of Skin Wound Healing: On Pathways and Genes Controlling Regeneration Versus Scarring (Sarah Susan Kelangi and Marianna Bei)Nutrition, Metabolism, and Wound Healing Process (Yong-Ming Yu and Alan J Fischman)Polarization Sensitive Optical Coherence Tomography for Imaging of Wound Repair (Martin Villiger and Brett E Bouma)Functional Imaging of Wound Metabolism (Jake Jones, Vasily Belov and Kyle P Quinn)Functional Skin Substitutes — The Intersection of Tissue Engineering and Biomaterials (Kevin Dooley, Julie Devalliere and Basak Uygun)Biomaterial-Based Systems for Pharmacologic Treatment of Wound Repair (Mara A Pop, Julia B Sun and Benjamin D Almquist)Laser Tissue Welding in Wound Healing and Surgical Repair (Russell Urie, Tanner Flake and Kaushal Rege)Bioprinting for Wound Healing Applications (Aleksander Skardal, Sean Murphy, Anthony Atala and Shay Soker)Electroporation Applications in Wound Healing (Laure Gibot, Tadej Kotnik and Alexander Golberg) Readership: Bioengineers, scientists, researchers and graduate students outside the field of medicine.**

## ADVANCES IN PROTEIN CHEMISTRY AND STRUCTURAL BIOLOGY

Academic Press **Structural genomics is the systematic determination of 3-D structures of proteins representative of the range of protein structure and function found in nature. The goal is to build a body of structural information that will predict the structure and potential function for almost any protein from knowledge of its coding sequence. This is essential information for understanding the functioning of the human proteome, the ensemble of tens of thousands of proteins specified by the human genome. While most structural biologists pursue structures of individual proteins or protein groups, specialists in structural genomics pursue structures of proteins on a genome wide scale. This implies large-scale cloning, expression and purification. One main advantage of this approach is economy of scale. Examines the three dimensional structure of all proteins of a given organism, by experimental methods such as X-ray crystallography and NMR spectroscopy Looks at structural genomics as a foundation of drug discovery as discovering new medicines is becoming more challenging and the pharmaceutical industry is looking to new technologies to help in this mission**

## STIMULUS-RESPONSIVE DELIVERY SYSTEMS FOR ENABLING THE ORAL DELIVERY OF PROTEIN THERAPEUTICS EXHIBITING HIGH ISOELECTRIC POINT

**Protein therapeutics offer numerous advantages over small molecule drugs and are rapidly becoming one of the most prominent classes of therapeutics. Unfortunately, they are delivered almost exclusively by injection due to biological obstacles preventing high bioavailability via the oral route. In this work, numerous approaches to overcoming these barriers are explored. PH-Responsive poly(itaconic acid-co-N-vinylpyrrolidone) (P(IA-co-NVP)) hydrogels were synthesized, and the effects of monomer ratios, crosslinking density, microparticle size, protein size, and loading conditions were systematically evaluated using in vitro tests. P(IA-co-NVP) hydrogels demonstrated up to 69% greater equilibrium swelling at neutral conditions than previously-studied poly(methacrylic acid-co-N-vinylpyrrolidone) hydrogels and a 10-fold improvement in time-sensitive swelling experiments. Furthermore, P(IA-co-NVP) hydrogel microparticles demonstrated up to a 2.7-fold improvement in delivery of salmon calcitonin (sCT) compared to methacrylic acid-based systems, with a formulation comprised of a 1:2 ratio of itaconic acid to N-vinylpyrrolidone demonstrating the greatest delivery capability. Vast improvement in delivery capability was achieved using reduced ionic strength conditions during drug loading. Use of a 1.50 mM PBS buffer during loading yielded an 83-fold improvement in delivery of sCT compared to a standard 150 mM buffer. With this improvement, a daily dose of sCT could be provided using P(IA-co-NVP) microparticles in one standard-sized gel capsule. P(IA-co-NVP) was also tested with larger proteins urokinase and Rituxan. Crosslinking density provided a facile method for tuning hydrogels to accommodate a wide range of protein sizes. The effects of protein PEGylation were also explored. PEGylated sCT displayed lower release from P(IA-co-NVP) microparticles, but displayed increased apparent permeability across a Caco-2 monolayer by two orders of magnitude. Therefore, PEG-containing systems could yield high bioavailability of orally delivered proteins. Finally, a modified SELEX protocol for cellular selection of transcellular transport-initiating aptamers was developed and used to identify aptamer sequences showing enhanced intestinal perfusion. Over three selection cycles, the selected aptamer library showed significant increases in absorption, and from an initial library of 1.1 trillion sequences, 5-10 sequences were selected that demonstrated up to 10-fold amplification compared to the naïve library. These sequences could provide a means of overcoming the significant final barrier of intestinal absorption.**

## LYOPHILIZATION OF BIOPHARMACEUTICALS

Springer Science & Business Media **Humans have been experimenting with lyophilization, or freeze-drying, as a method to preserve biological structures for over a thousand years. This comprehensive volume, intended for scientists in both academia and industry, covers a wide range of topics relevant to the formulation of peptide and protein drugs in the freeze-dried state.**

## HANDBOOK OF NANOBIOMEDICAL RESEARCH: FUNDAMENTALS, APPLICATIONS AND RECENT DEVELOPMENTS (IN 4 VOLUMES)

World Scientific **This book consists of 4 volumes containing about 70 chapters covering all the major aspects of the growing area of nanomedicine. Leading scientists from 15 countries cover all major areas of nanobiomedical research — materials for nanomedicine, application of nanomedicine in therapy of various diseases, use of nanomedicines for diagnostic purposes, technology of nanomedicines, and new trends in nanobiomedical research.This is the first detailed handbook specifically addressing various aspects of nanobiomedicine. Readers are treated to cutting-edge research and the newest data from leading researchers in this area.**

## STIMULI-RESPONSIVE DRUG DELIVERY SYSTEMS

Royal Society of Chemistry **The increased understanding of molecular aspects associated with chronic diseases, such as cancer and the role of tumor microenvironment, has led to the identification of endogenous and exogenous stimuli that can be exploited to devise "stimuli-responsive" materials for site-specific drug delivery applications. This book provides a comprehensive account on the design, materials chemistry, and application aspects behind these novel stimuli-responsive materials. Setting the scene, the editors open with a chapter addressing the need for smart materials in delivery applications for therapy, imaging and disease diagnosis. The following chapter describes the key physical and chemical aspects of smart materials, from lipids to polymers to hybrid materials, providing the reader with a springboard to delve into the more application oriented chapters that follow. With in-depth coverage of key drug delivery systems such as pH-responsive, temperature responsive, enzyme-responsive and light responsive systems, this book provides a rigorous foundation to the field. A perfect resource for graduate students and newcomers, the closing chapter on regulatory and commercialization challenges also makes the book ideal for those wanting to take the next step towards clinical translation. responsive systems, this book provides a rigorous foundation to the field. A perfect resource for graduate students and newcomers, the closing chapter on regulatory and commercialization challenges also makes the book ideal for those wanting to take the next step towards clinical translation.responsive systems, this book provides a rigorous foundation to the field. A perfect resource for graduate students and newcomers, the closing chapter on regulatory and commercialization challenges also makes the book ideal for those wanting to take the next step towards clinical translation.responsive systems, this book provides a rigorous foundation to the field. A perfect resource for graduate students and newcomers, the closing chapter on regulatory and commercialization challenges also makes the book**

**ideal for those wanting to take the next step towards clinical translation.**

## IMMUNOMIC DISCOVERY OF ADJUVANTS AND CANDIDATE SUBUNIT VACCINES

Springer Science & Business Media **This volume will address an important emergent area within the field of immunomics: the discovery of antigens and adjuvants within the context of reverse vaccinology. Conventional approaches to vaccine design and development requires pathogens to be cultivated in the laboratory and the immunogenic molecules within them to be identifiable. Conventional vaccinology is no longer universally successful, particularly for recalcitrant pathogens. By using genomic information we can study vaccine development in silico: 'reverse vaccinology', can identify candidate subunits vaccines by identifying antigenic proteins and by using equally rational approaches to identify novel immune response-enhancing adjuvants.**

## PEPTIDE AND PROTEIN DELIVERY

Academic Press **The growing area of peptide and protein therapeutics research is of paramount importance to medical application and advancement. A needed reference for entry level researchers and researchers working in interdisciplinary / collaborative projects, Peptide and Protein Delivery addresses the current and emerging routes for delivery of therapeutics. Covering cerebral delivery, pulmonary delivery, transdermal delivery, intestinal delivery, ocular delivery, parenteral delivery, and nasal delivery, this resource offers an overview of the main routes in therapeutics. Researchers across biochemistry, pharmaceutical, molecular biology, cell biology, immunology, chemistry and biotechnology fields will find this publication invaluable for peptide and protein laboratory research. Discusses the most recent data, ideas and concepts Presents case studies and an industrial perspective Details information from the molecular level to bioprocessing Thought provoking, for the novice to the specialist Timely, for today's biopharmaceuticals market**

## HANDBOOK OF NANOPHYSICS

## NANOMEDICINE AND NANOROBOTICS

CRC Press **The tools of nanodiagnostics, nanotherapy, and nanorobotics are expected to revolutionize the future of medicine, leading to presymptomatic diagnosis of disease, highly effective targeted treatment therapy, and minimum side effects. Handbook of Nanophysics: Nanomedicine and Nanorobotics presents an up-to-date overview of the application of nanotechnology to molecular and biological processes, medical imaging, targeted drug delivery, and cancer treatment. Each peer-reviewed chapter contains a broad-based introduction and enhances understanding of the state-of-the-art scientific content through fundamental equations and illustrations, some in color. This volume shows how the materials, tools, and techniques of nanotechnology, such as enzymatic nanolithography, biomimetic approaches, and force spectroscopy, are currently used in biological applications, including living cell biochips, biosensors, protein recognition, and the analysis of biomolecules. Drawing on emerging toxicology research, it examines the impact and risks of nanomaterials on human health and the environment. Researchers at the forefront of the field cover tissue engineering, diagnostic, drug delivery, and therapeutic applications, including organs derived from nanomaterials, quantum dots and magnetic nanoparticles for imaging, pharmaceutical nanocarriers, targeted magnetic particles and biodegradable nanoparticles for drug delivery, and cancer treatment using gold nanoparticles. They also explain how cells and skin respond to these nanomaterials. In addition, the book investigates the next generation of nanotechnology research that is focused on nanorobotics and its potential in detecting and destroying cancer cells and detecting and measuring toxic chemicals. It considers the roles nanoheaters, nanomotors, and nanobatteries can play in this new technology. Nanophysics brings together multiple disciplines to determine the structural, electronic, optical, and thermal behavior of nanomaterials; electrical and thermal conductivity; the forces between nanoscale objects; and the transition between classical and quantum behavior. Facilitating communication across many disciplines, this landmark publication encourages scientists with disparate interests to collaborate on interdisciplinary projects and incorporate the theory and methodology of other areas into their work.**

## NANOPARTICULATE DRUG DELIVERY

## PERSPECTIVES ON THE TRANSITION FROM LABORATORY TO MARKET

Elsevier **Nanotechnology-based therapeutics, operating at scales of billionths of a metre, have great potential for future expansion in altering the scale and methods of drug delivery. The availability of these novel formulations to once-inaccessible areas of the body has greatly expanded the therapeutic window of existing drug molecules. Nanoparticulate drug delivery highlights and examines the transition of nanoparticulate drug delivery systems from the laboratory into a commercially viable sector. The first chapters of the book provide an overview of the use and characterization of nanoparticulate systems as drug carriers, including the assessment of their morphology, sterility and potential toxicity. In the latter part of the book, chapters cover nanotoxicology, regulatory aspect and clinical trials, ending with an overview of several case studies and a look towards future developments. Discusses the issues surrounding nanoparticulate products, based on personal experience of their formulation Provides an overview of new application areas, including RNA interference Outlines the pros and cons of nanoparticulate products, and discusses how these may influence their route into the commercial sector**