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Biosystems, Biomedical & Drug Delivery Systems

Characterization, Restoration and Optimization

Springer

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ISBN 978-981-97-2595-3 ISBN 978-981-97-2596-0 (eBook)
https://doi.org/10.1007/978-981-97-2596-0

This Springer imprint is published by the registered company Springer Nature Singapore Pte Ltd.
The registered company address is: 152 Beach Road, #21-01/04 Gateway East, Singapore 189721, Singapore

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Preface

The book *Biosystems, Biomedical, and Drug Delivery Systems: Characterization, Restoration and Optimization* is a value addition to the subject domain of Biosystems and Biomedicine. In this volume, we embark on a journey through cutting-edge advancements in the realms of biosystems, biomedical, and drug delivery, exploring innovative technologies that redefine the landscape of medical science.

The landscape of health care is undergoing a profound transformation, fueled by groundbreaking discoveries, technological innovations, and a relentless pursuit of understanding the intricate complexities of biosystems. This book serves as a comprehensive guide to the latest developments in the field, offering insights into the characterization, restoration, and optimization of biological processes and drug delivery systems. The book delves into the detailed exploration of biosystems at various levels, from molecular structures to complex organisms. Understand how advanced analytical techniques and imaging modalities are revolutionizing our understanding of biological entities. The volume explores the innovative approaches and interventions that aim to restore normal physiological functions. From regenerative medicine to targeted therapies, discover how researchers are unlocking the potential to heal and rejuvenate the human body. Further, the book witnesses the optimization of drug delivery systems for enhanced efficacy and reduced side effects. Uncover the engineering marvels that enable precise and targeted drug administration, paving the way for personalized medicine.

This compilation brings together contributions from esteemed experts in the fields of biology, medicine, and engineering, providing a multidisciplinary perspective on the symbiotic relationship between technology and life sciences. Whether you are a seasoned researcher, a medical professional, or an enthusiast eager to grasp the forefront of scientific progress, this book offers a comprehensive overview of the transformative technologies shaping the future of health care.

As we navigate this exploration of novel technologies, may the pages ahead inspire curiosity, spark dialogue, and contribute to the collective endeavour of advancing biosystems, biomedical, and drug delivery.

The book starts with an editorial shedding light on the future of Novel Technologies in Biosystems, Biomedical, and Drug Delivery. The volume is divided into three

parts. Part I is devoted to the characterization of Biosystems, Biomedical, and Drug Delivery, Part II deals with the optimization of Biosystems, Biomedical, and Drug Delivery, Part III is aimed at covering a host of applications of Biosystems, Biomedical, and Drug Delivery, while Part IV aims to discuss applications of Biosystems, Biomedical, and Drug Delivery.

Part I consists of four chapters. Chapter 1 sheds light on the future of Biosystems, Biomedical, and Drug Delivery systems. Chapter 2 deals with the characterization tools employed for drug delivery systems. Chapter 3 delves into the retrospect, prospects, and characterization of transdermal drug delivery systems. Chapter 4 explains with requisite details about the analytical tools in characterizing nasal spray drug products.

Part II contains three chapters. Chapter 5 deals with AI-enabled models in the restoration of drug efficacy, and drug design. Chapter 6 discusses the potential, challenges, and limitations in the restoration, and sustenance of nano-drug delivery systems. Chapter 7 is devoted to artificial intelligence and machine learning in restoring and promoting health care.

Part III consists of four chapters. Chapter 8 aims to optimize oncology tools for organ-on-a-clip alternatives to the animal model. Chapter 9 presents the optimization of drug formulations: by undertaking an AI-powered kinetics study in pharmaceutical research. Chapter 10 offers in silico toxicological protocols for optimizing, and predicting the toxicity of drugs. Chapter 11 dwells upon the importance of machine learning and data analytics in optimizing healthcare throughput.

Part IV consists of five chapters. Chapter 12 gives an overview of applications of AI-based models in the field of Biomedicine. Chapter 13 takes a review of the application of new biological entities (NBEs) as therapeutical agents. Chapter 14 gives an account of the applications of computational tools in the prediction of toxicity. Chapter 15 discusses at length the application of peptides derived from plants as a bioactive material for the treatment of diabetes: The concluding Chap. 16 deals with the application of regenerative medicines in curing degenerative diseases and disorders.

Overall, the volume is a meaningful resource not only adding value to the subject domain of Biomedicine but also providing research directions for the researchers, further enriching the knowledge base of academicians and students. The book will also be of immense help to professionals and practitioners.

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Abbreviations

ADME	Absorption, Distribution, Metabolism, and Excretion
ADMET	Absorption, Distribution, Metabolism, Excretion, and Toxicology
ADR	Adverse Drug Reaction
AE	Adverse Effects
AF	Actuation Force
AI	Artificial Intelligence
AN	Analog Approach
ANDA	Abbreviated New Drug Application
ANN	Artificial Neural Network
ANNs	Artificial Neural Networks
API	Active Pharmaceutical Ingredient
AUC-ROC	Area Under Curve-Receiver Operating Characteristic Curve
AV	Actuation Velocity
BBDR	Biologically Based Dose-Response Model
BBPD	Biologically Based Pharmacodynamic Model
BMDL	Benchmark Dose Level
CA	Category Approach
CA	Concentration Addition
CAR-T	Chimeric Antigen Receptor (CAR) T-Cell Therapy
CARTs	Classification and Regression Trees
CASE	Computer Assisted Structure Elucidation
Cat-QSAR	Categorical Quantitative Structure-Activity Relationship
CDSS	Clinical Decision Support Systems
CLSM	Confocal Laser Scanning Microscopy
cm	Centimetre
CNNs	Convolutional Neural Networks
CoVID	Covid Vaccine Intelligence Network
cp	Centipoise
CP	Plasma Concentration
CRISPR	Clustered Regularly Interspaced Short Palindromic Repeats technology

CRISPR-Cas9	Clustered Regularly Interspaced Short Palindromic Repeats and CRISPR-associated protein 9
CTC	Circulating Tumour Cell
CTS	Computed Tomography Scans
CVD	Cardiovascular Disease
D10	10% of the Droplet Size
D50	50% of the Droplet Size
D90	90% of the Droplet Size
DDS	Drug Delivery Systems
DEPT	Directed Enzyme Prodrug Therapy
DL	Data Learning
DLD	Deterministic lateral displacement
DLS	Dynamic Light Scattering
Dmax	Maximum Diameter
Dmin	Minimum Diameter
DNA	Deoxy-Ribose Nucleic Acid
DSC	Differential Scanning Calorimetry
DSD	Droplet Size Distribution
DTs	Decision Tree
ECHA	The European Chemicals Agency
ECM	Extracellular Matrix
ECOSAR	Ecological Structure-Activity Relationships
ED	Emergency Department
EHRs	Electronic Health Records
EMA	European Medicines Agency
EMT	Epithelial-Mesenchymal Transition
EPA	Environmental Protection Agency
EPR	Enhanced Permeability and Retention
ERA	Environmental Risk Assessment
ERICA	Environmental Risk from Ionizing Contaminants Assessment
ESEM	Environmental Scanning Electron Microscopy
FDA	Food and Drug Administration
FDA-FAERS	Food and Drug Administration Adverse Event Reporting System
FESEM	Field Emission Scanning Electron Microscopy
FFSM	Fast Frequent Subgraph Mining
FTIR	Fourier Transform Infrared Spectroscopy
g	Gram
GANs	Adversarial Networks
GMP	Good Manufacturing Practices
GSEA	Gene Set Enrichment Analysis
gSPAN	Graph-dependent Substructure Patterns Extraction
HBRs	Human-Based Rules
HER	Electronic Health Records
HIPAA	Health Insurance Portability and Accountability Act
HMFs	Human Mammary Fibroblasts

hPSCs	Human Pluripotent Stem Cells
HSC	Hematopoietic Stem Cells
HTS	High-Throughput Screening
HUVECs	Human Umbilical Vein Endothelial Cells
IA	Independent Action
IBRs	Induction-Based Rules
ICH	International Council for Harmonisation
ICPerMed	International Consortium for Personalized Medicine
ICP-MS	Single-Particle Inductively Coupled Plasma-Mass Spectrometry
IL	Interleukin
IM	Intramuscular
IND	Investigational New Drug
IPR	Increased Permeability and Retention
iPSC	Induced Pluripotent Stem Cells
ISO	International Organization for Standardization
iTSC	Induced Tissue-Specific Stem Cells
IV	Intravenous
kg	Kilogram
KNN	K-Nearest Neighbour
LCA	Life Cycle Assessment
LD50	Lethal Dose for 50% of Population
LIME	Local Interpretable Model-Agnostic Explanations
LOAEL	Least Observed Adverse Effect Level
LR	Logistic Regression
mAbs	Monoclonal Antibodies
MCL	Markov Cluster Algorithm
MF	Modifying Factors
ML	Machine Learning
mL	Milliliter
mm	Millimeter
mm/s 2	Millimeter per sec square
mm/s	Millimeter per sec
MPS	Micro-Physiological Systems
MRIs	Magnetic Resonance Images
mRNA	Messenger Ribonucleic Acid
ms	Millisecond
MSCs	Mesenchymal Stem Cells
mtk	Multitasking
NB	Naive Bayes
NBEs	New Biological Entities
NDA	New Drug Application
NFT	Neurofibrillary Tangles
NLC	Nanostructure Lipid Carriers
NLP	Natural Language Processing
NOAEL	No Observed Adverse Effect Level

NPs	Nanoparticles
NTP	National Toxicology Program (United States)
OCES	Oncologic Cancer Expert System
OCR	Optical Character Recognition
OECD	Organization for Economic Cooperation and Development
OoC	Organ-on-a-chip
osmol/kg	Osmoles per kilogram
PASS	Prediction of Activity Spectra for Substances
PCA	Principal Component Analysis
PCL	Poly(caprolactone)
PCL	Polycaprolactone
PD	Pharmacodynamics
PDMS	Polydimethylsiloxane
PDPK	Pharmacodynamics and Pharmacokinetics
PEC	Predicted Environmental Concentrations
PEG	Polyethylene Glycol
PET	Polyethylene Terephthalate
PG	Plume Geometry
PI	Polyimide
PK	Pharmacokinetics
PK/PD	Pharmacokinetics and Pharmacodynamics
PLA	Polylactic Acid
PLDLA	Poly (l-co-d, l-lactide)
PLGA	Polylactic Glycolic Acid
PMC	PubMed Central
PMMA	Polymethyl Methacrylate
PNEC	Predicted No-Effect Concentrations
PS	Polystyrene
psd files	Particle Size Distribution File
psh file	Particle Size History File
PTX	Paclitaxel
PVA	Polyvinyl Alcohol
QDs	Quantum Dots
QSAR	Quantitative Structure-Activity Relationship
QSNR	Quantitative Structure Nanomaterial Relationship
QSTR	Quantitative Structure-Toxicity Relationship
QSTR/QSPR	Quantitative Structure Toxicity/Property Relationship
R&D	Research and Development
RD	Relevancy Domain
REACH	Registration, Evaluation, Authorization and Restriction of Chemical
RF	Return force
RFA	Random Forest Algorithm
RfC	Reference Concentration
RfD	Reference Dose

RNNs	Recurrent Neural Networks
RNSC	Restricted neighbourhood search cluster
RPM	Revolution Per Minutes
RSD	Relative Standard Deviation
RV	Return Velocity
SA	Structural Alert
SaMD	Software as a Medical Device
SAR	Structure-Activity Relationship
SBRT	Stereotactic Body Radiotherapy
SC	Subcutaneous
SeDeC	Structure Editor in a Distributed Computing Environment
SEM	Scanning Electron Microscopy
SF	Safety Factors
SHAP	SHapley Additive Explanations
siRNA	Small Interfering RNA
SL	Stroke length
SLN	Solid Lipid Nanoparticles
SP	Spray Pattern
SPC	Super-Paramagnetic Clustering
SRS	Stereotactic Radiosurgery
TALEN	Transcription Activator-Like Effector Nucleases
TDDS	Transdermal Drug Delivery Systems
TGF-β1	Transforming Growth Factor-beta
TGFH	Transforming Growth Factor-H
TME	Tumour Microenvironment
TPU	Thermoplastic Polyurethane
UF	Unpredictable Factors
US FDA	United State Food and Drug Administration
US	United States
US-FDA	United States Food and Drug Administration
v/s	Versus
VEGF	Vascular Endothelial Growth Factor
WGS	Whole Genome Sequencing
XRPD	X-ray Powder Diffraction
ZFN	Zinc-Finger Nucleases
μm	Micrometre
%	Percentage
°	Degree
2D	Two-Dimensional
3D	Three-Dimensional

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Chapter 1
Editorial: Future of Novel Technologies in Biosystems, Biomedical, and Drug Delivery

Shrikaant Kulkarni

In the ever-evolving landscape of biosystems, biomedical, and drug delivery, a wave of innovative technologies is revolutionizing our approach to understanding, restoring, and optimizing biological processes. This editorial explores the remarkable progress in these fields, highlighting breakthroughs in characterization, restoration, and optimization that promise to reshape the future of healthcare and beyond.

1.1 Nature and Characterization of Biosystems

The advent of advanced characterization techniques has ushered in a new era of precision medicine. High-throughput technologies, namely, genomics, proteomics, and metabolomics, are unraveling the intricacies of biological systems at unprecedented scales. The ability to decode the genome, scrutinize the proteome, and analyze the metabolome provides a comprehensive understanding of cellular functions, paving the way for personalized diagnostics and treatment strategies.

Characterization of biosystems involves the comprehensive study and understanding of biological entities, such as cells, tissues, and organisms, at various levels of complexity. This process employs a range of advanced techniques and technologies to unravel the intricate mechanisms that govern biological functions. Here are some key aspects and methodologies in the characterization of biosystems:

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S. Kulkarni et al. (eds.), *Biosystems, Biomedical & Drug Delivery Systems*,
https://doi.org/10.1007/978-981-97-2596-0_1

Genomics:

Definition:

Genomics involves the study of an organism's entire set of DNA, including genes and non-coding regions.

Methods: Next-generation sequencing (NGS) technologies help fast and cheap ways to sequence entire genomes. Comparative genomics helps identify genetic variations across different species or individuals.

Proteomics:

Definition:

Proteomics focuses on the large-scale study of proteins expressed by an organism.

Methods: Mass spectrometry and two-dimensional gel electrophoresis are common techniques for protein identification and quantification. Proteomic analyses provide insights into protein interactions, post-translational modifications, and functional pathways.

Metabolomics:

Definition:

Metabolomics aims to analyze the complete set of small molecules (metabolites) within a biological system.

Methods: Nuclear magnetic resonance (NMR) spectroscopy and mass spectrometry are utilized to identify and quantify metabolites. Metabolomics helps in understanding metabolic pathways, cellular responses, and disease biomarkers.

Transcriptomics:

Definition:

Transcriptomics studies the complete set of RNA transcripts produced by a cell or tissue.

Methods: RNA sequencing (RNA-Seq) explores gene expression patterns, splicing events, and non-coding RNA molecules. Transcriptomic data aids in understanding cellular responses to various stimuli.

Imaging Techniques:

Definition:

Imaging technologies allow the visualization of biological structures and processes.

Methods: Fluorescence microscopy, confocal microscopy, and electron microscopy provide detailed images of cellular and subcellular structures. In vivo imaging tools, like positron emission tomography (PET) and magnetic resonance imaging (MRI), shed light on living organisms.

Bioinformatics:

Definition:

Bioinformatics refers to the application of computational tools in analyzing and interpreting biological data.

Methods: Computational algorithms and statistical analyses are applied to genomic, proteomic, and other -omic data to extract meaningful information. Bioinformatics aids in identifying patterns, pathways, and potential relationships within large datasets.

Functional Genomics:

Definition:

Functional genomics studies how genes function and interact within a biological system.

Methods: Techniques such as CRISPR-Cas9 gene editing, RNA interference (RNAi), and functional screens are used to manipulate gene expression and study the resulting phenotypic changes. This helps in understanding the roles of specific genes in cellular processes.

Systems Biology:

Definition:

Systems biology integrates data from various -omics disciplines to understand the holistic behavior of biological systems.

Methods: Mathematical modeling and simulation are employed to represent complex biological networks and predict system-level responses. Systems biology aims to capture the dynamic interactions within a biological system.

Characterizing biosystems using these techniques provides a foundation for advancing our understanding of normal physiological processes, as well as the underlying mechanisms of diseases. This knowledge is crucial for the development of targeted therapies, personalized medicine, and the optimization of healthcare interventions.

1.2 Restoration of Biological Functions

One of the most promising frontiers is the restoration of biological functions through synthetic biology and gene therapy. The ability to edit genomes with unprecedented precision, exemplified by CRISPR-Cas9, opens doors to correcting genetic anomalies responsible for a myriad of diseases. Synthetic genomes and gene circuits are enabling the design of biological systems with tailored functionalities, offering novel solutions for previously untreatable conditions.

Optogenetics, another groundbreaking technology, allows the precise control of cellular activities using light. This not only enhances our understanding of complex neural networks but also holds tremendous potential for developing therapies to modulate cellular behaviors spatially and temporally.

The restoration of biological functions involves the application of various technologies and approaches to correct or compensate for dysfunctional processes within living organisms. This can encompass a wide range of interventions, from targeted gene therapies to the modulation of cellular activities. Here are key aspects and methodologies related to the restoration of biological functions:

Gene Therapy:

Definition:

Gene therapy involves the introduction, alteration, or deletion of genetic material to treat or prevent diseases caused by genetic mutations.

Methods: Technologies such as CRISPR-Cas9, zinc finger nucleases (ZFNs), and transcription activator-like effector nucleases (TALENs) enable precise editing of the genome. Viral vectors, like adeno-associated viruses (AAVs) or lentiviruses, find use in delivering therapeutic genes into target cells.

Synthetic Biology:

Definition:

Synthetic biology is an interdisciplinary field that involves designing and constructing biological components or systems with novel functionalities.

Methods: Constructing synthetic genomes, gene circuits, and biological modules allow researchers to engineer cells with specific functions. This can include the creation of synthetic organisms with customized capabilities or the modification of existing organisms for therapeutic purposes.

Optogenetics:

Definition:

Optogenetics involves the use of light-sensitive proteins to control cellular activities with high spatial and temporal precision.

Methods: Light-activated ion channels and pumps, such as channelrhodopsin and halorhodopsin, are introduced into target cells. By exposing these cells to light, researchers can modulate neuronal or cellular activities. Optogenetics has applications in neuroscience, as well as potential therapeutic uses.

Stem Cell Therapy:

Definition:

Stem cell therapy refers to the application of stem cells to repair, replace, or regenerate tissues or organs that are damaged.

Methods: Differentiation of pluripotent stem cells into specific cell types allows for the generation of cells needed for tissue repair. Mesenchymal stem cells, for example, possess regenerative properties and can be used to treat conditions such as tissue damage or inflammatory disorders.

RNA Therapeutics:

Definition:

RNA therapeutics involve the use of RNA molecules, such as messenger RNA (mRNA) or small interfering RNA (siRNA), to modulate gene expression.

Methods: mRNA-based vaccines, RNA interference for gene silencing, and antisense oligonucleotides are examples of RNA therapeutics. These approaches can be used to correct aberrant gene expression or inhibit the expression of specific genes associated with diseases.

Tissue Engineering and 3D Bioprinting:

Definition:

Tissue engineering and 3D bioprinting aim to create functional tissues and organs for transplantation or regenerative medicine.

Methods: Using biocompatible materials and cells, researchers can construct three-dimensional structures that mimic native tissues. 3D bioprinting allows precise placement of cells and biomaterials to recreate complex tissue architectures.

Regenerative Medicine:

Definition:

Regenerative medicine focuses on harnessing the body's natural ability to repair and replace damaged tissues.

Methods: This includes the use of growth factors, stem cells, and biomaterials to stimulate tissue regeneration. Approaches like platelet-rich plasma (PRP) injections or autologous cell transplantation are used in various medical fields.

CRISPR-Based Therapeutics:

Definition:

Beyond gene editing, CRISPR-based therapeutics include applications for gene regulation and modulation.

Methods: CRISPR technologies can be adapted for controlling gene expression without permanently modifying the genome. This includes CRISPR interference (CRISPRi) and CRISPR activation (CRISPRa), which enable targeted gene silencing or activation.

The restoration of biological functions through these approaches holds an incredible potential for curing a wide range of diseases, from genetic disorders to degenerative conditions. As these technologies continue to advance, they bring new possibilities for personalized and precise interventions in the field of medicine.

1.3 Optimization of Drug Delivery

In the realm of drug delivery, optimization has become a focal point for enhancing therapeutic efficacy and containing ill effects. Nanotechnology has emerged as a powerful tool, with nano biosensors monitoring drug concentrations in real-time and responses within the body. 3D bioprinting is pushing the boundaries of drug testing by allowing the creation of physiologically relevant tissue models for more accurate preclinical assessments.

Advancements in AI have revolutionized drug discovery by analyzing huge databases and predicting potential drug leads. Machine learning algorithms are uncovering hidden patterns in biological data, expediting the identification of novel drug targets, and accelerating the drug development pipeline.

Microbiome engineering represents another avenue for optimizing health. Understanding the complex interactions within microbial communities and leveraging this knowledge to manipulate the microbiome offers new possibilities for treating various diseases and promoting overall well-being.

Nanotechnology in Drug Delivery:

Definition:

Nanoparticles and nanocarriers are designed to transport drugs with precision, improving bioavailability and targeted delivery.

Methods: Liposomes, micelles, and polymeric nanoparticles can encapsulate drugs, guard them from breaking down and promoting regulated release. These nanocarriers can be made amenable to target particular tissues or cells, minimizing effects on healthy ones.

Controlled Drug Release Systems:

Definition:

Systems that provide controlled and sustained release of drugs over time, ensuring therapeutic concentrations are maintained.

Methods: Implantable devices, patches, and drug-eluting stents are examples of controlled-release systems. These technologies help maintain a constant drug concentration, reducing the need for frequent dosing and minimizing side effects.

Targeted Drug Delivery:

Definition:

Techniques that enable the specific delivery of drugs to the intended site in question, furthering efficacy and checking systemic exposure.

Methods: Ligand-based targeting, antibody–drug conjugates, and aptamer-functionalized nanoparticles allow for precise drug delivery to cells or tissues expressing specific receptors. This approach minimizes damage to healthy tissues.

3D Bioprinting for Drug Testing:

Definition: 3D bioprinting is utilized to create three-dimensional tissue models for drug testing, providing more physiologically relevant information.

Methods: Bioprinted tissues can mimic the microenvironment of target organs, allowing researchers to assess drug responses in a more accurate context before clinical trials. This optimization aids in predicting drug efficacy and potential side effects.

Intracellular Drug Delivery:

Definition:

Strategies to enhance the delivery of drugs into the interior of target cells, overcoming cellular barriers.

Methods: Cell-penetrating peptides, nanocarriers with endosomal escape capabilities, and viral vectors can facilitate the intracellular delivery of drugs. This is crucial for targeting diseases at the cellular and molecular levels.

Smart Drug Delivery Systems:

Definition:

Systems that respond to specific stimuli to release drugs at the right time and in the right location.

Methods: Responsive polymers, such as temperature-sensitive or pH-sensitive materials, can be used to design smart drug delivery systems. These systems release drugs in response to changes in physiological conditions, improving therapeutic outcomes.

Biosensors for Real-Time Monitoring:

Definition:

Biosensors are employed to monitor drug concentrations in real-time within the body, providing valuable data for treatment optimization.

Methods: Implantable biosensors and wearable devices can measure drug levels, allowing healthcare professionals to adjust dosages or treatment regimens based on individual patient responses.

Artificial Intelligence (AI) in Drug Delivery:

Definition:

AI algorithms are employed to analyze patient data and optimize drug delivery regimens.

Methods: Machine learning models can predict patient responses to medications, helping to tailor drug delivery strategies for individual patients. This personalized approach enhances therapeutic outcomes and minimizes adverse effects.

Magnetic Drug Targeting:

Definition:

Magnetic nanoparticles are used to deliver drugs to intended sites within the body under the influence of an external magnetic field.

Methods: Nanoparticles loaded with therapeutic agents are guided to target locations using external magnets, improving drug concentration at the desired site and reducing systemic exposure.

The optimization of drug delivery methods is an interdisciplinary endeavor that involves expertise in chemistry, materials science, biology, and engineering. Advances in these technologies not only improve treatment outcomes but also pave the way for personalized and patient-centric approaches to healthcare.

1.4 Conclusion

As we stand on the cusp of a new era in biosystems, biomedical, and drug delivery, the amalgamation of cutting-edge technologies is reshaping the landscape of healthcare. The characterization of biological systems at unprecedented scales, the restoration of genetic anomalies, and the optimization of drug delivery methods are converging to provide tailored and effective solutions for previously incurable diseases.

The optimization of drug delivery is a critical aspect of modern healthcare, aiming to enhance the effectiveness, safety, and precision of therapeutic interventions. This involves developing innovative strategies to deliver drugs to target sites within the body while minimizing side effects. Here are key aspects and methodologies related to the optimization of drug delivery:

This editorial celebrates the incredible strides made in these fields, acknowledging the collaborative efforts of researchers, clinicians, and technologists. The journey toward a future where personalized medicine is the norm is underway, and the novel technologies explored herein are the guiding lights leading us to that transformative.

Part I
Novel Technologies in Biosystems, Biomedical, and Drug Delivery: Characterization

Chapter 2
Characterization Tools for Current Drug Delivery Systems

Nitish Bhatia, Priya Malik, and Sunita Sampathi

Abstract The chapter "Characterization of Present Drug Delivery Systems" provides a comprehensive exploration of methodologies used to assess contemporary Drug delivery methods are critical in the ever-changing field of pharmaceutical research. medications for therapeutic benefits is known as "drug delivery", has been revolutionized by nanotechnology, enabling precise drug targeting and reduced adverse effects. Nanomedicine, with its microscopic applications, enhances stability, minimizes side effects, and optimizes efficacy through small size and expansive surface area. This chapter explores analytical approaches, experimental parameters, and key theories underpinning drug delivery system characterization. The chapter emphasizes the importance of characterizing these systems to study drug molecules and their carriers during formulation, storage, and in-vitro and in-vivo transport. Advanced characterization techniques and their underlying theories are outlined, providing insights into cutting-edge tools used to assess drug carriers, their interactions with therapeutic compounds, and their behaviour in biological environments. The text discusses methodologies for employing experimental parameters, preparing samples, and evaluating data. It highlights the significance of characterizing stability, release kinetics, and targeting precision, crucial factors in optimizing drug efficacy. The chapter offers valuable insights for researchers, scientists, and practitioners, enhancing their understanding of contemporary drug delivery systems. It addresses present difficulties and potential, contributing to the evolution of drug delivery science and technology. This comprehensive examination serves as a resource for those keen on advancing their knowledge in the field.

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S. Kulkarni et al. (eds.), *Biosystems, Biomedical & Drug Delivery Systems*,
https://doi.org/10.1007/978-981-97-2596-0_2

2.1 Introduction

Over the past decade, biosystems, biomedical advancements, and nano drug delivery systems have transcended mere conceptualization, evolving into tangible realities within the realm of science. Their progress has been steadfast in enhancing medication stability, bolstering bioavailability, and refining organ-targeting capabilities. Leveraging their size and remarkable adaptability, innovative drug delivery nanocarriers have emerged as versatile treatment conduits for a spectrum of conditions (Majumder et al. 2019). This shift towards the nanoscale has propelled these materials into a realm where heightened molecular reactivity, stemming from their amplified surface-to-volume ratio, unveils unique characteristics distinct from their bulk counterparts. Beyond their electrical, optical, and chemical properties, the mechanical aspects of nanomaterials exhibit notable variability.

The adoption of nano-based drug delivery brings forth manifold advantages, encompassing heightened stability, precise targeting, and the ability to accommodate both hydrophilic and hydrophobic therapeutic molecules. These systems find application through diverse administration routes such as topical, parenteral, nasal, and oral methods (Kolluru et al. 2021; Paiva-Santos et al. 2021; Reboredo et al. 2021; Tolentino et al. 2021; Vachhani and Kleinstreuer 2021; Yao et al. 2021). Crucially, the physiological behavior of biomaterials and nanomaterials hinges largely upon their physicochemical attributes encompassing size, shape, molecular weight, stability, solubility, purity, and surface traits. The quest for quality, biocompatibility, and safety, while steering the prudent evolution of nanomedicines, necessitates a meticulous characterization approach.

Understanding how these traits influence in vivo distribution and behavior stands as a pivotal concern. Hence, the quest for robust, reliable characterization techniques adaptable to this domain becomes imperative. Characterization methodologies pivot on a synergy between theoretical frameworks and empirical validation. This synergy fosters widespread recognition of models and facilitates practical applications. Consequently, Over the past few decades, a variety of characterization methods have been put forth and used to control and predict the behavior of nanocarriers in both vitro and in vivo circumstances.

A comprehensive exploration of various characterization methodologies employed in delivery systems can illuminate their strengths and limitations. Within this review, we've curated essential characterization techniques frequently deployed in the majority of nanocarrier drug delivery systems (DDSs). Furthermore, we delve into the constraints of these techniques and the hurdles entwined with regulations and scalability confronting the nanocarrier manufacturing industry.

2.2 Techniques Employed in Characterizing Drug Delivery Systems

A comprehensive understanding of nanoparticles' mechanical properties necessitates a deep dive into their physical characteristics. The pivotal parameters under scrutiny during nanoparticle characterization encompass size, size distribution, shape, aggregation degree, surface charge, and surface area.

Within this gamut of considerations, size emerges as a paramount influencer governing myriad facets of nanosystems. It dictates drug content uniformity, dissolution rates, active ingredient absorption, behavior in the bloodstream, traversal through physiological drug barriers, specific cellular or tissue localization, and capacity to evoke cellular responses. Additionally, early scrutiny of the crystal structure and chemical composition of nanoparticles serves as a crucial benchmark for quality and performance across various domains, notably in nanotechnology.

Numerous trending approaches exist for determining nanoparticle size, with method selection contingent upon specific application needs (Fig. 2.1). These techniques not only elucidate particle size but also shed light on associated factors such as shape and distribution breadth, typically represented by the Polydispersity Index (PDI) (Danaei et al. 2018a).

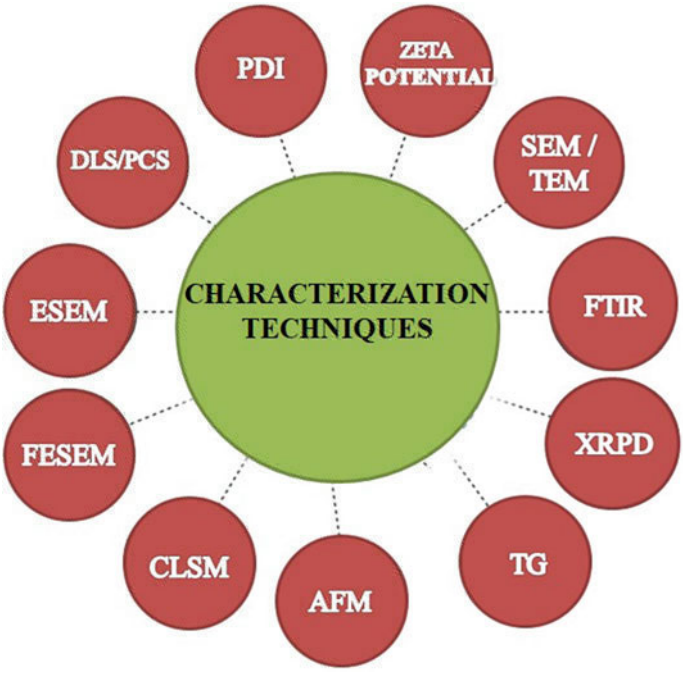

Fig. 2.1 Pictorial representation of various characterization techniques