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technology. This new patent brings ...

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New Patent for Know Labs Marks Latest Step
Toward Commercial Launch of Bio-RFID™ Non-
Invasive Medical Diagnostic Technology
But the field is relatively new, and
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Antisense & RNAi Therapeutics Market to Touch
Valuation of US\$ 1.90 Bn by 2028

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skills through virtual/real-world clinical
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A Comprehensive Guide to Toxicology in
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is a valuable reference designed to provide a
complete understanding of all aspects of
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small molecules and biologics. This updated
edition has been reorganized and expanded to
include important topics such as stem cells
in nonclinical toxicology, inhalation and

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dermal toxicology, pitfalls in drug development, biomarkers in toxicology, and more. Thoroughly updated to reflect the latest scientific advances and with increased coverage of international regulatory guidelines, this second edition is an essential and practical resource for all toxicologists involved in nonclinical testing in industry, academic, and regulatory settings. Provides unique content that is not always covered together in one comprehensive resource, including chapters on stem cells, abuse liability, biomarkers, inhalation toxicology, biostatistics, and more Updated

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with the latest international guidelines for nonclinical toxicology in both small and large molecules Incorporates practical examples in order to illustrate day-to-day activities and the expectations associated with working in nonclinical toxicology

This open access book, published under a CC BY 4.0 license in the Pubmed indexed book series Handbook of Experimental Pharmacology, provides up-to-date information on best practice to improve experimental design and quality of research in non-clinical pharmacology and biomedicine.

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A single-source reference with a broad and holistic overview of nonclinical studies, this book offers critical training material and describes regulations of nonclinical testing through guidelines, models, case studies, practical examples, and worldwide perspectives. The book: Provides a complete overview of nonclinical study organization, conduct, and reporting and describes the roles and responsibilities of a Study Director to manage an effective study Covers regulatory and scientific concepts, including international testing and Good Laboratory

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Practice (GLP), compliance with guidelines,
and animal models Features a concluding
chapter that compiles case studies / lessons
learned from those that have served as a
Study Director for many years Addresses the
entire spectrum of nonclinical testing,
making it applicable to those in the
government, laboratories and those actively
involved in in all sectors of industry

Bringing a new drug to market is a costly
time-consuming process. Increased regional
and international regulation over the last
twenty years, while necessary, has only

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served to amplify these costs. In response to this escalation, developmental strategies have shifted towards a more global approach. In order to create the most cost-effective and safe processes, it is critical for those bringing drugs to market to understand both the globally accepted regulations and the local variations. Nonclinical Safety Assessment: A Guide to International Pharmaceutical Regulations provides a practical description of nonclinical drug development regulations and requirements in the major market regions. It includes: ICH – the International Conference on Harmonisation

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of Technical Requirements for Registration of
Pharmaceuticals for Human Use National
regulations, including US FDA, Canada,
Mercosur and Brazil, South Africa, China,
Japan, India and Australia Repeated dose
toxicity studies Carcinogenicity;
Genotoxicity; Developmental and reproductive
toxicology; Immunotoxicology Biotechnology-
derived pharmaceuticals Vaccine development
Phototoxicity and photocarcinogenicity
Degradants, impurities, excipients and
metabolites Primarily intended for those
professionals actively involved in the
nonclinical and clinical development of a

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pharmaceutical product, including toxicologists, pharmacologists, clinicians and project managers, this book provides a roadmap for successful new drug approval and marketing.

Intravenous infusion is a necessary mode of delivery for many pharmaceuticals currently on the market or undergoing clinical trials. The technique of prolonged intravenous delivery in conscious, free-moving animal models has broadened the opportunity to study and evaluate the safety and efficacy of these therapeutic products. For the first time, the

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collective sciences involved in the understanding of this mode of drug delivery are brought together in one publication. *Non-Clinical Vascular Infusion Technology, Volume I: The Science* covers the scientific principles behind the delivery systems, from both physical and physiological standpoints. The book addresses body fluid dynamics, describes the scientific processes necessary to understand the various aspects of the physico-chemical issues relating to vascular infusion delivery, and discusses vascular infusion dynamics. It also considers all the essential elements of the preparation of a

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formulation intended for vascular delivery as well as assessment of compatibility of the formulation with the dosing apparatus. This volume, along with Volume II: The Techniques, provides a foundation of knowledge on infusion technology and its importance for safe clinical use of substances via this route of delivery. Features Identifies and shares best practices for non-clinical vascular infusion Presents modern practices and procedures in line with up-to-date equipment development Offers recommendations for in-life assessments in order to monitor the success or problems with the vascular

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introduction delivery Makes comparisons with
human data in many areas

A Comprehensive Guide to Toxicology in Preclinical Drug Development is a resource for toxicologists in industry and regulatory settings, as well as directors working in contract resource organizations, who need a thorough understanding of the drug development process. Incorporating real-life case studies and examples, the book is a practical guide that outlines day-to-day activities and experiences in preclinical toxicology. This multi-contributed reference

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Introductions To Philosophy provides a detailed picture of the complex and highly interrelated activities of preclinical toxicology in both small molecules and biologics. The book discusses discovery toxicology and the international guidelines for safety evaluation, and presents traditional and nontraditional toxicology models. Chapters cover development of vaccines, oncology drugs, botanic drugs, monoclonal antibodies, and more, as well as study development and personnel, the role of imaging in preclinical evaluation, and supporting materials for IND applications. By incorporating the latest research in this

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area and featuring practical scenarios, this reference is a complete and actionable guide to all aspects of preclinical drug testing. Chapters written by world-renowned contributors who are experts in their fields Includes the latest research in preclinical drug testing and international guidelines Covers preclinical toxicology in small molecules and biologics in one single source

The breadth of the pharmaceutical medicine can be daunting, but this book is designed to navigate a path through the speciality. Providing a broad overview of all topics

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relevant to the discipline of pharmaceutical medicine, it gives you the facts fast, in a user-friendly format, without having to dive through page upon page of dense text. With 136 chapters spread across 8 sections, the text offers a thorough grounding in issues ranging from medicines regulation to clinical trial design and data management. This makes it a useful revision aid for exams as well as giving you a taster of areas of pharmaceutical medicine adjacent to your current role. For healthcare professionals already working in the field, this book offers a guiding hand in difficult situations

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as well as supplying rapid access to the latest recommendations and guidelines. Written by authors with experience in the industry and drug regulation, this comprehensive and authoritative guide provides a shoulder to lean on throughout your pharmaceutical career.

The Nonhuman Primate in Drug Development and Safety Assessment is a valuable reference dedicated to compiling the latest research on nonhuman primate models in nonclinical safety assessment, regulatory toxicity testing and translational science. By covering important

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topics such as study planning and conduct, inter-species genetic drift, pathophysiology, animal welfare legislation, safety assessment of biologics and small molecules, immunotoxicology and much more, this book provides scientific and technical insights to help you safely and successfully use nonhuman primates in pharmaceutical toxicity testing. A comprehensive yet practical guide, this book is intended for new researchers or practicing toxicologists, toxicologic pathologists and pharmaceutical scientists working with nonhuman primates, as well as graduate students preparing for careers in

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this area. Covers important topics such as species selection, study design, experimental methodologies, animal welfare and the 3Rs (Replace, Refine and Reduce), social housing, regulatory guidelines, comparative physiology, reproductive biology, genetic polymorphisms and more Includes practical examples on techniques and methods to guide your daily practice Offers a companion website with high-quality color illustrations, reference values for safety assessment and additional practical information such as study design considerations, techniques and procedures and

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Nonclinical Development of Novel Biologics, Biosimilars, Vaccines and Specialty Biologics is a complete reference devoted to the nonclinical safety assessment of novel biopharmaceuticals, biosimilars, vaccines, cell and gene therapies and blood products. This book compares and contrasts these types of biologics with one another and with small molecule drugs, while incorporating the most current and essential international regulatory documents. Each section discusses a different type of biologic, as well as

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early characterization strategies, principles of study design, preclinical pharmacokinetics and pharmacodynamics and preclinical assays. An edited book that is authored by leading experts in the field, this comprehensive reference provides critical insights to all researchers involved in early through late stage biologics. Provides in-depth coverage of the process of nonclinical safety assessment and comprehensive reviews of each type of biopharmaceutical Contains the most pertinent international regulatory guidance documents for nonclinical evaluation Covers early de-risking strategies and designs of

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safety assessment programs for novel biopharmaceuticals and vaccines, as well as follow-on biologics or "biosimilars" A multi-authored book with chapters written by qualified experts in their respective fields

The premise of Quality by Design (QbD) is that the quality of the pharmaceutical product should be based upon a thorough understanding of both the product and the manufacturing process. This state-of-the-art book provides a single source of information on emerging statistical approaches to QbD and risk-based pharmaceutical development. A

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comprehensive resource, it combines in-depth explanations of advanced statistical methods with real-life case studies that illustrate practical applications of these methods in QbD implementation.

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