A new edition of one of Zola's lesser-known novels from the Rougon-Macquart Cycle Finding the young Angélique on their doorstep one Christmas Eve, the pious Hubert couple decide to bring her up as their own. As the girl grows up in the vicinity of the town's towering cathedral and learns her parents' trade of embroidery, she becomes increasingly fascinated by the lives of the saints, a passion fueled by her reading of the Golden Legend and other mystical Christian writings. One day love, in the shape of Félicien Hautecoeur, enters the dream world she has constructed around herself, bringing about upheaval and distress. Although it provides a detailed portrait of provincial 19th-century life and it adheres to a naturalist approach, The Dream eschews many of the characteristics of Zola's other novels of the Rougon-Macquart cycle—such as a pronounced polemical agenda or a gritty subject matter—offering instead a timeless, lyrical tale of love and innocence.
Chapter 1: Introduction

Chapter 2: Integumentary System

Chapter 3: Mammary Gland

Chapter 4: Haemopoietic and Lymphatic Systems

Chapter 5: Musculoskeletal System

Chapter 6: Respiratory Tract

Chapter 7: Cardiovascular System

Chapter 8: Gastrointestinal tract

Chapter 9: Liver and Pancreas

Chapter 10: Urinary System

Chapter 11: Male Genital Tract

Chapter 12: Female Genital Tract

Chapter 13: Endocrine System

Chapter 14: Nervous System and Special Sense Organs

Subject index

Nonclinical Development of Novel Biologics, Biosimilars, Vaccines and Specialty Biologics

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 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 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.

OECD Guidelines for Testing of Chemicals

This atlas contains more than 700 illustrations that the authors have collected over the years as well as references and information pertaining to recently developed drug classes, including biologics. It is a useful bench reference for practicing pathologists and may also be used as a reference text by other experts from related fields. The atlas is organised into different chapters based on systemic pathology. Each chapter has illustrations with legends, and the atlas includes some rare examples of unique lesions found during toxicity studies over many years.

Background Lesions in Laboratory Animals E-Book

Guidelines for reproductive toxicity risk assessment

This practical guide presents a road map for safety assessment as an integral part of the development of new drugs and therapeutics. Helps readers solve scientific, technical, and regulatory issues in preclinical safety assessment and early clinical drug development Explains scientific and philosophical bases for evaluation of specific concerns – including local tissue tolerance, target organ toxicity and carcinogenicity, developmental toxicity, immunogenicity, and immunotoxicity Covers the development of new small and large molecules, generics, 505(b)(2) route NDAs, and biosimilars Revises material to reflect new drug
Standards for Ocular Toxicology and Inflammation

There has been a growing interest in toxicologic pathology, especially as related to its impact on the safety assessment of pharmaceuticals and chemicals, and in drug development. Thus, there is a growing need for an Illustrated Dictionary of Toxicology Pathology and Safety Science (IDTP) that this dictionary aims to fill.

The language of toxicologic pathology may be less familiar to a broad range of safety scientists, especially those involved in the safety evaluation of pharmaceuticals and chemicals. The IDTP format provides the brevity and clarity that the user is not likely to receive in a textbook, even if adequately indexed.

With the inclusion of descriptions for terms used in toxicology, drug metabolism/pharmacokinetics, and regulatory science, the scope of the IDTP is considerably broadened and decidedly unique in its appeal to all safety scientists. With over 800 photos and illustrations to provide visual context, an important aim of the IDTP is to present pathological changes as reference examples for terminology, nomenclature, and term descriptions for the entry level as well as seasoned toxicologic pathologist. It will also aid students and non-pathology specialists such as study directors, senior toxicology report reviewers, scientific management of contract research organizations, regulatory agencies, and drug development companies to better understand the biological significance of tissue changes. The IDTP provides a single reference volume for these users to further their understanding and appreciation of biologically significant pathology findings. The IDTP consists of four major areas: 1. A-Z Dictionary of Pathology encompassing all organ systems, together with relevant non-pathology terms supported by references in "For Further Reading" sections. 2. Appendix 1: An Overviews of Drug Development, Nonclinical Safety & Toxicologic Pathology, and Important/Special Topics. 3. Appendix 2: Diagnostic Criteria of Proliferative Lesions in Rodents (Rat and Mouse) and Selected Non-Rodent Laboratory Species containing illustrations with detailed references and links to source material. 4) Appendix 3: Mini-Atlas of Organ System Anatomy and Histology to help re-acquaint the non-pathologist safety scientist with many normal anatomical structures. The editors and contributing scientists (board-certified veterinary pathologists, board-certified toxicologists, allied health safety scientists, health regulatory representatives) have experience from bench-level pathology and toxicology to managing global preclinical safety units in leading pharmaceutical companies. They have considerable experience mentoring pharmaceutical industry project team members, interacting with industry clinicians and representatives of decision-making bodies within the industry, as well as with global health authorities, such as the FDA and EMA. These activities convinced them of the necessity for and usefulness of the IDTP. As experts in their field, they have undertaken the hard work of writing and compiling the information, making the IDTP an exceptional, go-to reference. *Illustrations Editor: Gregory Argentieri

Biomarkers can be defined as indicators of any biologic state, and they are central to the future of medicine. As the cost of developing drugs has risen in recent years, reducing the number of new drugs approved for use, biomarker development may be a way to cut costs, enhance safety, and provide a more focused and rational pathway to drug development. On October 24, 2008, the IOM's Forum on Drug Discovery, Development, and Translation held "Assessing and Accelerating Development of Biomarkers for Drug Safety," a one-day workshop, summarized in this volume, on the value of biomarkers in helping to determine drug safety during development.

The Nonhuman Primate in Nonclinical Drug Development and Safety Assessment

Wildlife Toxicity Assessments for Chemicals of Military Concern is a compendium of chemical-specific toxicity information with discussions on the rationale and...
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 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 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.
In the years since the third edition of this indispensable reference was published, a great deal has been learned about the nutritional requirements of common laboratory species: rat, mouse, guinea pig, hamster, gerbil, and vole. The Fourth Revised Edition presents the current expert understanding of the lipid, carbohydrate, protein, mineral, vitamin, and other nutritional needs of these animals. The extensive use of tables provides easy access to a wealth of comprehensive data and resource information. The volume also provides an expanded background discussion of general dietary considerations. In addition to a more user-friendly organization, new features in this edition include: A significantly expanded section on dietary requirements for rats, reporting substantial new findings. A new section on nutrients that are not required but that may produce beneficial results. New information on growth and reproductive performance among the most commonly used strains of rats and mice and on several hamster species. An expanded discussion of diet formulation and preparation—including sample diets of both purified and natural ingredients. New information on mineral deficiency and toxicity, including warning signs. This authoritative resource will be important to researchers, laboratory technicians, and manufacturers of laboratory animal feed.
Infant Formula

Infant formulas are unique because they are the only source of nutrition for many infants during the first 4 to 6 months of life. They are critical to infant health since they must safely support growth and development during a period when the consequences of inadequate nutrition are most severe. Existing guidelines and regulations for evaluating the safety of conventional food ingredients (e.g., vitamins and minerals) added to infant formulas have worked well in the past; however, they are not sufficient to address the diversity of potential new ingredients proposed by manufacturers to develop formulas that mimic the perceived and potential benefits of human milk. This book, prepared at the request of the Food and Drug Administration (FDA) and Health Canada, addresses the regulatory and research issues that are critical in assessing the safety of the addition of new ingredients to infants.

Drug Safety Evaluation: Methods and Protocols

Nutrient Requirements of Laboratory Animals, non-clinical drug safety evaluation, the assessment of the safety profile of therapeutic agents through the conduct of laboratory studies in in vitro systems and in animals, is an essential step in the progress of new pharmaceuticals heading toward the ultimate goal of clinical trials and, eventually, approval. In Drug Safety Evaluation: Methods and Protocols, expert researchers detail a compendium of analytical technologies with a focus on clarity and applicability in real-life laboratory practice. These meticulous contributions feature key topics such as acute to chronic general toxicity studies, histopathology studies, reproductive toxicity studies, genotoxicity studies, safety pharmacology studies, investigative toxicity studies, and safety biomarker studies. As a volume in the highly successful Methods in Molecular Biology series, chapters include brief introductions to their respective subjects, lists of the necessary materials, step-by-step, readily reproducible protocols, and tips on troubleshooting and avoiding known pitfalls. Comprehensive and authoritative, Drug Safety Evaluation: Methods and Protocols serves as an ideal guide to this field, helpful to pharmaceutical scientists, toxicologists, biochemists, and molecular biologists as well as scientists from all other disciplines who wish to translate these thorough methods into their own work.
Background Lesions in Laboratory Animals will be an invaluable aid to pathologists needing to recognize background and incidental lesions while examining slides taken from laboratory animals in acute and chronic toxicity studies, or while examining exotic species in a diagnostic laboratory. It gives clear descriptions and illustrations of the majority of background lesions likely to be encountered. Many of the lesions covered are unusual and can be mistaken for treatment-related findings in preclinical toxicity studies. The Atlas has been prepared with contributions from experienced toxicological pathologists who are specialists in each of the laboratory animal species covered and who have published extensively in these areas. Over 600 high-definition, top-quality color photographs of background lesions found in rats, mice, dogs, minipigs, non-human primates, hamsters, guinea pigs and rabbits, a separate chapter on lesions in the reproductive systems of all laboratory animals written by Dr. Dianne Creasy, a world expert on testicular lesions in laboratory animals, a chapter on common artifacts that may be observed in histological glass slides, extensive references to each lesion described, aging lesions encountered in all laboratory animal species, particularly in rats and mice which are used for carcinogenicity studies.

Guide for the Care and Use of Laboratory Animals

On behalf of the editorial board and the organizing committee of the 4th congress of the International Society of Ocular Toxicology (ISOT), held in Annecy-Neyrier-du-Lac, France, October 9-13, 1994, we are pleased to present to the ocular toxicology community this indexed volume of our congress proceedings. The 4th congress was designed primarily to facilitate and update the knowledge in ocular electrophysiology and ocular pharmacokinetics, in both the clinical and preclinical aspects. The outcome of this 4th congress, established in this volume, is a useful contribution to the methodology in both fields and will hopefully assist in the evaluation and interpretation of ocular findings recorded in animal studies on drugs and other chemicals, in order to protect human health. Undoubtedly, work on the mechanisms of ocular toxicology in the process of pharmaceutical development must continue and these proceedings, embodying the presented papers, will add to the data base. The editors, the congress organizing committee and the members of the International Society of Ocular Toxicology thank the speakers who gave their time, knowledge, and expertise to assist us in this project. The following manuscripts contain the main substance of each of the platform presentations and, in some cases, much more. Moreover, our thanks go to all the participants coming from a range of backgrounds—regulatory, academic and industrial—for their attention and excellent contributions during the discussion.

Atlas of Experimental Toxicological Pathology

Histopathological assessment of tissue sections is an important component of many preclinical studies which are conducted to support the safety and clinical development of novel therapeutic agents for use in the treatment of human diseases. The drug discovery process, aided by modern biotechnology, is now capable of generating highly potent, pharmacologically active agents which can give rise to quite unusual constellations of tissue pathology. The complexity and the number of histopathological findings in individual studies indicate the need for lucidity in descriptions and conclusions. In the light of these and other difficulties, this text is aimed towards bringing together into one volume a description of histopathological changes which relate to toxicity testing of therapeutic agents in the usual test species: rat, mouse, dog and non-human primate. This book is an excellent starting point for the analysis of drug-induced findings in toxicity studies.

Toxicologic Pathology

Toxicity testing in laboratory animals provides much of the information used by the Environmental Protection Agency (EPA) to assess the hazards and risks associated with exposure to environmental agents that might harm public health or the environment. The data are used to establish maximum acceptable concentrations of environmental agents in drinking water, set permissible limits of exposure of workers, define labeling requirements, establish tolerances for pesticides, and regulate the use of industries to prevent the adverse health effects from the release of toxic substances. The results from the studies constitute important information which is presented in the Toxicologic Pathology journal. The journal is an excellent starting point for the analysis of drug-induced findings in toxicity studies.
pesticides residues on food, and set other kinds of limits on the basis of risk assessment. Because the number of regulations that require toxicity testing is growing, EPA called for a comprehensive review of established and emerging toxicity-testing methods and strategies. This interim report reviews current toxicity-testing methods and strategies and near-term improvements in toxicity-testing approaches proposed by EPA and others. It identifies several recurring themes and questions in the various reports reviewed. The final report will present a long-range vision and strategic plan to advance the practices of toxicity testing and human health assessment of environmental contaminants.

Pharmaceutical Medicine

This book is a comprehensive guide to radiopharmaceutical chemistry. The stunning clinical successes of nuclear imaging and targeted radiotherapy have resulted in rapid growth in the field of radiopharmaceutical chemistry, an essential component of nuclear medicine and radiology. However, at this point, interest in the field outpaces the academic and educational infrastructure needed to train radiopharmaceutical chemists. For example, the vast majority of texts that address radiopharmaceutical chemistry do so only peripherally, focusing instead on nuclear chemistry (i.e. nuclear reactions in reactors), heavy element radiochemistry (i.e. the decomposition of radioactive waste), or solely on the clinical applications of radiopharmaceuticals (e.g. the use of PET tracers in oncology). This text fills that gap by focusing on the chemistry of radiopharmaceuticals, with key coverage of how that knowledge translates to the development of diagnostic and therapeutic radiopharmaceuticals for the clinic. The text is divided into three overarching sections: First Principles, Radiochemistry, and Special Topics. The first is a general overview covering fundamental and broad issues like "The Production of Radionuclides" and "Basics of Radiochemistry". The second section is the main focus of the book. In this section, each chapter's author will delve much deeper into the subject matter, covering both well established and state-of-the-art techniques in radiopharmaceutical chemistry. This section will be divided according to radionuclide and will include chapters on radiolabeling methods using all of the common nuclides employed in radiopharmaceuticals, including four chapters on the ubiquitously used fluorine-18 and a "Best of the Rest" chapter to cover emerging radionuclides. Finally, the third section of the book is dedicated to special topics with important information for radiochemists, including "Bioconjugation Methods," "Click Chemistry in Radiochemistry", and "Radiochemical Instrumentation." This is an ideal educational guide for nuclear medicine physicians, radiologists, and radiopharmaceutical chemists, as well as residents and trainees in all of these areas.

Pharmaceutical Toxicology

A Comprehensive Guide to Toxicology in Nonclinical Drug Development, Second Edition, is a valuable reference designed to provide a complete understanding of all aspects of nonclinical toxicology in the development of 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 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 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.
solvents and intermediates), and other chemicals are the cornerstone of human safety evaluations in the development, use, and/or regulation of these agents. Those who perform the pathological evaluations from these studies need standard diagnostic criteria and pathology terminology. Pathology of the Fischer Rat is a comprehensive pathology reference text on the Fischer 344 rat, the strain widely used for safety evaluations and almost exclusively by the National Toxicology Program. Every chapter follows the same format of introduction; embryology; normal anatomy, histology, and physiology; and congenital, degenerative, inflammatory and vascular, hyperplastic and neoplastic, miscellaneous, and toxicological lesions. The spectrum of spontaneous and treatment-related, neoplastic and nonneoplastic lesions found in each tissue is described and photographed. The text is useful not only to pathologists but also to investigators from a variety of disciplines who use the rat as an animal model. It will also prove valuable to toxicologists, biologists, and other scientists engaged in regulatory toxicology who must make the transition from pathology results to promulgation of meaningful regulations.

Histopathology of Preclinical Toxicity Studies

A respected resource for decades, the Guide for the Care and Use of Laboratory Animals has been updated by a committee of experts, taking into consideration input from the scientific and laboratory animal communities and the public at large. The Guide incorporates new scientific information on common laboratory animals, including aquatic species, and includes extensive references. It is organized around major components of animal use: Key concepts of animal care and use. The Guide sets the framework for the humane care and use of laboratory animals. Animal care and use program. The Guide discusses the concept of a broad Program of Animal Care and Use, including roles and responsibilities of the Institutional Official, Attending Veterinarian and the Institutional Animal Care and Use Committee. Animal environment, husbandry, and management. A chapter on this topic is now divided into sections on terrestrial and aquatic animals and provides recommendations for housing and environment, husbandry, behavioral and population management, and more. Veterinary care. The Guide discusses veterinary care and the responsibilities of the Attending Veterinarian. It includes recommendations on animal procurement and transportation, preventive medicine (including animal biosecurity), and clinical care and management. The Guide addresses distress and pain recognition and relief, and issues surrounding euthanasia. Physical plant. The Guide identifies design issues, providing construction guidelines for functional areas; considerations such as drainage, vibration and noise control, and environmental monitoring; and specialized facilities for animal housing and research needs. The Guide for the Care and Use of Laboratory Animals provides a framework for the judgments required in the management of animal facilities. This updated and expanded resource of proven value will be important to scientists and researchers, veterinarians, animal care personnel, facilities managers, institutional administrators, policy makers involved in research issues, and animal welfare advocates.

Toxicokinetics

The inaugural volume in the Current Topics in Nonclinical Drug Development Series explores the critical issues and current topics in nonclinical drug development. This first volume covers individual topics and strategies in drug development from compound characterization to drug registration. Written by a variety of experts in the field, recent and rapid advances in technologies and associated changes in regulatory guidance are discussed. Additional features include: Deals with day-to-day issues in study design, evaluation of findings, and presentation of data. Explains new approaches in the development of medical devices. Includes dedicated chapters on the use of bioinformatics in drug development. Addresses strategies for photosafety testing of drugs. Current Topics in Nonclinical Drug Development, Volume I will aid toxicologists, toxicologic pathologists, consultants, regulators, Study Directors, and nonclinical scientists dealing with day-to-day issues in study design, evaluation of findings, and presentation of data. In addition, the book will be a valuable reference for academicians and graduate students pursuing research related to nonclinical drug development.
The major organs of the body are targets for chemically-induced effects in animals and humans. This book reviews the mechanisms of these toxic effects and the structure/functional changes which occur in the target organ tissues as a result.

Pathology for Toxicologists

Non-pathologists, such as toxicologists and study personnel, can find it difficult to understand the data they receive from pathologists. Toxicological pathologists write long, detailed and highly technical reports. Study personnel are under daily pressure to decide whether lesions described in pathology reports are treatment-related and thus important to the pharmaceutical company or whether the lesions are background changes and thus of little significance. Written by experienced toxicological pathologists, Pathology for Toxicologists: Principles and Practices of Laboratory Animal Pathology for Study Personnel serves to bridge the gap in the understanding of pathology data, enabling non-pathologists to more easily comprehend pathology reports, better integrate pathology data into final study reports and ask pathologists relevant questions about the test compound. This succinct, fully referenced, full colour book is suitable for toxicologists at all stages of their training or career who want to know more about the pathology encountered in laboratory animals used in safety studies. Key features include important chapters on spontaneous and target organ lesions in rats, mice, non-human primates, mini pigs, rabbits and beagle dogs as well as information on general pathology, macroscopic target organ lesions, ancillary pathology techniques, haematology, biochemistry and adversity. Pathology for Toxicologists: Principles and Practices of Laboratory Animal Pathology for Study Personnel includes:

- Colour diagrams explaining how lesions are caused by either external compounds or spontaneously
- The anatomic variations and background lesions of laboratory animals
- Advice on sampling tissues, necropsy, ancillary pathology techniques and recording data
- A chapter on the haematology and biochemistry of laboratory animals
- Full colour photographs of common macroscopic lesions encountered in laboratory animals
- A comprehensive glossary

Accelerating the Development of Biomarkers for Drug Safety

Our aim in producing a colour atlas of toxicological guidelines itemize the investigations to be carried out pathology was to present a catalogue of histopathological lesions which we had encountered over the years in clinical observations and behaviour; food intake and body various laboratory animal species exposed to a vast range of pharmaceuticals, agrochemicals and industrial toxicology; ECG and ophthalmology. At the end of a study, examinations of the way to share our experiences with others, it quickly became clear to us that for the atlas to be meaningful the associated text must be comprehensive and contain ample literature references. The atlas is intended for both the trainee and the experienced toxicological pathologist working with laboratory animals in the pharmaceutical, agrochemical or Toxicity studies are commonly carried out in rats, chemical environment.

Histopathology of Preclinical Toxicity Studies

Pluripotent stem cells have the potential to revolutionize treatment options for a range of diseases and conditions. This book presents recent advances in our understanding of the biological mechanisms of stem cell self-renewal, reprogramming and regeneration. Also covered are novel methodological advances in the field of stem cell research.