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DIAZ ROBERSON

Biopharmaceuticals CRC Press
WINNER OF THE PULITZER PRIZE • Winner of The New York Public Library’s Helen Bernstein Book Award • “A new classic of science reporting.”—The New York Times The riveting true story of a small town ravaged by industrial pollution, Toms River melds hard-hitting investigative reporting, a fascinating scientific detective story, and an unforgettable cast of characters into a sweeping narrative in the tradition of A Civil Action, The Emperor of All Maladies, and The Immortal Life of Henrietta Lacks. One of New Jersey’s seemingly innumerable quiet seaside towns, Toms River became the unlikely setting for a decades-long drama that culminated in 2001 with one of the largest legal settlements in the annals of toxic dumping. A town that would rather have been known for its Little League World Series champions ended up making history for an entirely different reason: a notorious cluster of childhood cancers scientifically linked to local air and water pollution. For years, large chemical companies had been using Toms River as their private dumping ground, burying tens of thousands of leaky drums in open pits and discharging billions of gallons of acid-laced wastewater into the town’s namesake river. In an astonishing feat of investigative reporting, prize-winning journalist Dan Fagin recounts the sixty-year saga of rampant pollution and inadequate oversight that made Toms River a cautionary example for fast-growing industrial towns from South Jersey to South China. He tells the stories of the pioneering scientists and physicians who first identified pollutants as a cause of cancer, and brings to life the everyday heroes in Toms River who struggled for justice: a young boy whose cherubic smile belied the fast-growing tumors that had decimated his body from birth; a nurse who fought to bring the alarming incidence of childhood cancers to the attention of authorities who didn’t want to listen; and a mother whose love for her stricken child transformed her into a tenacious advocate for change. A gripping human drama rooted in a centuries-old scientific quest, Toms River is a tale of dumpers at midnight and deceptions in broad daylight, of corporate avarice and government neglect, and of a few brave individuals who refused to keep silent until the truth was exposed. NAMED ONE OF THE BEST BOOKS OF THE YEAR BY NPR AND KIRKUS REVIEWS “A thrilling journey full of twists and turns, Toms River is essential reading for our times. Dan Fagin handles topics of great complexity with the dexterity of a scholar, the honesty of a journalist, and the dramatic skill of a novelist.”—Siddhartha Mukherjee, M.D., author of the Pulitzer Prize–winning The Emperor of All Maladies “A complex tale of powerful industry, local politics, water rights, epidemiology, public health and cancer in a gripping, page-turning environmental thriller.”—NPR “Unstoppable reading.”—The Philadelphia Inquirer “Meticulously researched and compellingly recounted . . . It’s every bit as important—and as well-written—as A Civil Action and The Immortal Life of Henrietta Lacks.”—The Star-Ledger “Fascinating . . . a gripping environmental thriller.”—Kirkus Reviews (starred review) “An honest, thoroughly researched, intelligently written book.”—Slate “[A] hard-hitting account . . . a triumph.”—Nature “Absorbing and thoughtful.”—USA Today
Biosimilars U of Nebraska Press
This volume provides a comprehensive review of China's healthcare system and policy reforms in the context of the global economy. Following a value-chain framework, the 16 chapters cover the payers, the providers, and the producers (manufacturers) in China's system. It also provides a detailed analysis of the historical development of China's healthcare system, the current state of its broad reforms, and the uneasy balance between China's market-driven approach and governmental regulation. Most importantly, it devotes considerable attention to the major problems confronting China, including chronic illness, public health, and long-term care and economic security for the elderly. Burns and Liu have assembled the latest research from leading health economists and political scientists, as well as senior public health officials and corporate executives, making this book an essential read for industry professionals, policymakers, researchers, and students studying comparative health systems across the world.
Understanding Patents, FDA and Pharmaceutical Life-Cycle Management (Sixth Edition) Academic Press
BiosimilarsRegulatory, Clinical, and Biopharmaceutical DevelopmentSpringer
Transforming Proteins and Genes into Drugs CRC Press
Unable to kill, a young Cheyenne is scorned by his tribe when he chooses to become a horse catcher rather than a warrior.
Contemporary Issues in Pharmaceutical Patent Law Academic Press
Patent Law: Cases, Problems, and Materials is a free casebook, co-authored by Professor Jonathan S. Masur (University of Chicago Law School) and Professor Lisa Larrimore Ouellette (Stanford Law School). The casebook is made available under a Creative Commons Attribution-NonCommercial-NoDerivatives 4.0 International License. A digital version of the casebook can be downloaded free online at patentcasebook.org, and a printed copy can be purchased on Amazon at cost.
Approved Prescription Drug Products BrownWalker Press
Accompanied by supplements.
FDA Orange Book 36th Edition (2016) U of Nebraska Press
FDA Orange Book 36th Edition - 2016 (Approved Drug Products With Therapeutic Equivalence Evaluations)
Vademecum International John Wiley & Sons
Based on the lives of John J. Cozad and Robert Henri.
Approved Drug Products with Therapeutic Equivalence Evaluations - FDA Orange Book 36th Edition (2016) Jones & Bartlett Learning
Biopharmaceuticals: Challenges and Opportunities This book highlights how the traditional microbial process technology has been upgraded for the production of biologic drugs how manufacturing processes have evolved to meet the global market demand with quality products under the guidelines of internally recognized regulatory bodies. It also carries information on how, armed with a deeper understanding of life-threatening diseases, biopharmaceutical companies and the life sciences industry have developed formal and informal partnerships with researchers in institutes, universities, and other R&D organizations to fulfil timely, quality production with perfect safety and security. One of the most interesting aspects of this book is the conceptual development of personalized medicine (or precision medicine) to provide the right treatment to the right patient, at the right dose at an earlier stage of development, for genetic diseases. Besides this, it also highlights the most challenging aspects of modern biopharmaceutical science, focusing on the hot topics such as design and development of biologic drugs; the use of diversified groups of host cells belonging to animals, plants, microbes, insects, and mammals; stem cell therapy and gene therapy; supply chain management of biopharmaceuticals; and the future scope of biopharmaceutical industry development. This book is the latest resource for a wide circle of scientists, students, and researchers involved in understanding and implementing the knowledge of biopharmaceuticals to develop life-saving biologic drugs and to bring awareness to the development of personalized treatment that can potentially offer patients a faster diagnosis, fewer side effects, and better outcomes. Features: Explains how the traditional cell culture methodology has been changed to a fully continuous or partially continuous process Explains how to design and fabricate living organs of body by 3D bioprinting technology Focuses on how a biopharmaceutical company deals with various problems of regulatory bodies and develops innovative biologic drugs Narrates in detail the updated information on stem cell therapy and gene therapy Explains the development strategies and clinical significance of biosimilars and biobetters Highlights the supply chain management of biopharmaceuticals
Physicians' Desk Reference Kluwer Law International B.V.
A young Sioux warrior earns the right to be called historian for his tribe after numerous adventures and trials which test his ability to tell the story of his people with truth and courage.
PDR. SEEd
Biotechnology and Biopharmaceuticals: Transforming Proteins and Genes into Drugs, Second Edition addresses the pivotal issues relating to translational science, including preclinical and clinical drug development, regulatory science, pharmaco-economics and cost-effectiveness considerations. The new edition also provides an update on new proteins and genetic medicines, the translational and integrated sciences that continue to fuel the innovations in medicine, as well as the new areas of therapeutic development including cancer vaccines, stem cell therapeutics, and cell-based therapies.
Competition Law of the European Union Taylor & Francis
History of Modern Clinical Toxicology describes the extraordinary advances in the practice of clinical toxicology within the past 70 years and brings together stories of the people – the champions of clinical toxicology - who contributed to these advances, discovered new therapies and antidotes, and made change happen. This book lays out the poison control system they built and the fascinating story of how they created a new and evolving medical specialty. With the participation of renowned international experts as authors, the book showcases the development of poison control centers around the world and the growth of the professional societies that represent and support them today. This book also tells the stories of the modern-day toxic disasters and recent toxic exposures that gained worldwide attention and notoriety. It outlines the public health responses to such calamities which have led to improvements in our understanding of the science and changes in public health policies and regulations to forestall future such events. Finally, the book covers key policies and agencies affecting poison control centers, addresses the challenges facing clinical toxicologists of today, and predicts advances and future innovations in the field. History of Modern Clinical Toxicology is a unique resource that provides the historical and international perspective that will help students, practitioners, scientists, and health policy makers put current issues and methods in perspective. It will help them understand how infrastructure and processes in clinical toxicology have evolved and why poison control systems are configured as they are. Offers descriptions of the key regulatory advances affecting clinical toxicology Provides synopses of modern-day poisoning disasters Outlines the development of modern antidotes and future directions in clinical toxicology Describes the origins and development of the U.S. poison control system Includes the origins and features of professional clinical toxicology societies from around the world Includes descriptions of the history of clinical toxicology and poison control in more than 35 countries
Spearheads of Empire Springer
An evocative fictional portrait of the impact of the Depression on the Great Plains captures working-class people of the period as they struggle to overcome the hardships, challenges, and pain of everyday life in the face of poverty, political and economic upheaval, and corruption. Reprint.
Substitution – Immunomodulation – Monoclonal Immunotherapy Pharmaceutical Press
This collection reflects on contemporary and contentious issues in international rulemaking in regards to pharmaceutical patent law. With chapters from both well-established and rising scholars, the collection contributes to the understanding of the regulatory framework governing pharmaceutical patents as an integrated discipline through the assessment of relevant laws, trends and policy options. Focusing on patent law and related pharmaceutical regulations, the collection addresses the pressing issues governments face in an attempt to resolve policy dilemmas involving competing interests, needs and objectives. The common theme running throughout the collection is the need for policy and law makers to think and act in a systemic manner and to be more reflective and responsive in finding new solutions within and outside the patent system to the long-standing problems as well as emerging challenges
Son of the Gamblin' Man Edward Elgar Publishing
"The Sioux Indians came into my life before I had any preconceived notions about them," writes Mari Sandoz about the visitors to her family homestead in the Sandhills of Nebraska when she was a child. These Were the Sioux, written in her last decade, takes the reader far inside a world of rituals surrounding puberty, courtship, and marriage, as well as the hunt and the battle.
Handbook of Drug Administration via Enteral Feeding Tubes, 3rd edition Elsevier Health Sciences
Intellectual property (IP) is a key component of the life sciences, one of the most dynamic and innovative fields of technology today. At the same time, the relationship between IP and the life sciences raises new public policy dilemmas. The Research Handbook on Intellectual Property and the Life Sciences comprises contributions by leading experts from academia and industry to provide in-depth analyses of key topics including pharmaceuticals, diagnostics and genes, plant innovations, stem cells, the role of competition law and access to medicines. The Research Handbook focuses on the relationship between IP and the life sciences in Europe and the United States, complemented by country-specific case studies on Australia, Brazil, China, India, Japan, Kenya, South Africa and Thailand to provide a truly international perspective.
Pharmacy Practice and the Law Rowman & Littlefield
Only those who are sure of their origin can know their destination. True to this principle, Anna Bálint for the first time presents the history of Clariant, the globally operating chemical company which was formed by a merger of Sandoz and Hoechst. Eyewitness accounts complete the portrait and give an informative as well as entertaining insight into the demanding

task of successfully melding two distinct corporate cultures into a single strong and innovative enterprise.

Pharmaceutical Market Access in Developed Markets U of Nebraska Press

This practical manual, written by well-known experts, reviews current indications for the use of IgG concentrates and some other modern immunomodulators and provides fundamental information on present-day immunomodulation in patients (and mice). The book opens by tracing the transition from IgG substitution to IgG immunomodulation and providing expert updates on immunomodulatory indications in autoimmune and inflammatory disorders, including hematologic, neurologic, dermatologic, and other diseases. Basic aspects of IgG concentrates, including methods of production, safety, currently available products, and mechanisms of action, are then discussed. An entire chapter is devoted to the different aspects of immunomodulatory IgG treatment in the bleeding disorder immune thrombocytopenia (ITP). Finally, the transition from polyclonal to monoclonal antibody (mAb) treatment is addressed in detail, covering mAb development, methods, mechanisms of action, adverse effects, and more. Particular attention is paid to the example of anti-CD20 (B-cell) antibody.

Old Jules Cambridge University Press

When a biological drug patent expires, alternative biosimilar products are developed. The development of biosimilar products is complicated and involves numerous considerations and steps. The assessment of biosimilarity and interchangeability is also complicated and difficult. Biosimilar Drug Product Development presents current issues for the development of biosimilars and gives detailed reviews of its various stages and contributing factors as well as relevant regulatory pathways and pre- and post-approval issues.

Biosimilar Drug Product Development Logos Press

Written by leading experts in the field and designed for dermatologists and residents, this book includes evidence-based medicine that underscores the clinical data, as well as practical tips on how to use both biologic and systemic agents in the field of dermatology. In the past decade, there have been several groundbreaking advances in medical dermatology. Novel biologic and systemic agents have been developed to treat inflammatory disorders, including psoriasis and atopic dermatitis, as well as skin malignancies such as melanoma. Biologic and Systemic Agents in Dermatology encompasses these developments by describing the mechanism of action of these various agents and the clinical efficacy and safety to treating these respective disorders. The utilization of biologic and systemic agents in other dermatologic conditions, pharmacoeconomics, pharmacovigilance, and clinical trials outcomes are discussed as well as topics including tumor necrosis, conventional systemic agents for psoriatic disease, and oral agents for atopic dermatitis.