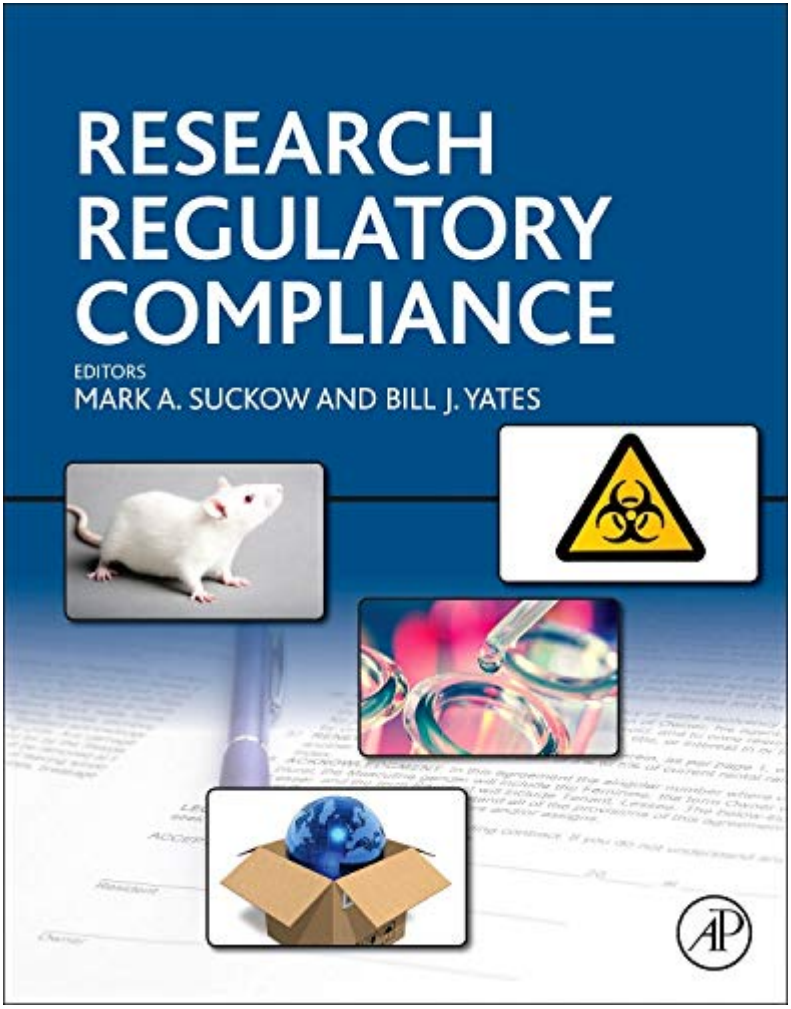

[Books] Research Regulatory Compliance

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Research Regulatory Compliance-Mark A. Suckow 2015-06-14 Research Regulatory Compliance offers the latest information on regulations and compliance in the laboratory. With the increasing complexity of regulations and need for institutional infrastructure to deal with compliance of animal use issues, as well as a requirement surrounding human subjects, this publication provides reputable guidance and information.

The book is extremely helpful as a resource for researchers, administrators, and technicians in the laboratory, and is also a great asset for faculty or new researchers coming in to the laboratory environment. It will help prepare users for the deluge of regulatory and compliance issues they will face while conducting their scientific programs. The book is edited and authored by known leaders in the field of compliance and regulations, and contains extensive research on the topics. It represents the new standard

for information in every laboratory. Provides a “one-stop" , go-to resource for the many regulatory and compliance issues that affect laboratory study and research models Extremely helpful as a resource for researchers, administrators, and technicians in the laboratory, and also a great asset for faculty or new researchers coming in to the laboratory environment Focuses on United States regulations, covering both animal models and human subjects Written and edited by known leaders in the field of regulatory compliance who bring many years of collective experience to the book

Clinical Trials and Human Research-Fay A. Rozovsky, JD, MPH 2003-06-10 This easy-to-read reference book provides a practical approach for dealing with the legal and regulatory compliance issues involved in human research. Covering a broad range of topics, such as consent, confidentiality, subject recruitment and selection, the role of the investigator and Institutional Review Board, it offers timely and useful strategies for achieving regulatory compliance while reducing liability. In addition, insurance, quality management, accreditation, and risk management are topics examined in the book. The practical insights found in this volume are not found in other books on the subject. Clinical Trials and Human Research is a practical tool to help anyone involved in clinical research.

Management of Animal Care and Use Programs in Research, Education, and Testing-Robert H. Weichbrod 2017-09-07 AAP Prose Award Finalist 2018/19 Management of Animal Care and Use Programs in Research, Education, and Testing, Second Edition is the extensively expanded revision of the popular Management of Laboratory Animal Care and Use Programs book published earlier this century. Following in the footsteps of the first edition, this revision serves as a first line management resource, providing for strong advocacy for advancing

quality animal welfare and science worldwide, and continues as a valuable seminal reference for those engaged in all types of programs involving animal care and use. The new edition has more than doubled the number of chapters in the original volume to present a more comprehensive overview of the current breadth and depth of the field with applicability to an international audience. Readers are provided with the latest information and resource and reference material from authors who are noted experts in their field. The book: - Emphasizes the importance of developing a collaborative culture of care within an animal care and use program and provides information about how behavioral management through animal training can play an integral role in a veterinary health program - Provides a new section on Environment and Housing, containing chapters that focus on management considerations of housing and enrichment delineated by species - Expands coverage of regulatory oversight and compliance, assessment, and assurance issues and processes, including a greater discussion of globalization and harmonizing cultural and regulatory issues - Includes more in-depth treatment throughout the book of critical topics in program management, physical plant, animal health, and husbandry. Biomedical research using animals requires administrators and managers who are knowledgeable and highly skilled. They must adapt to the complexity of rapidly-changing technologies, balance research goals with a thorough understanding of regulatory requirements and guidelines, and know how to work with a multi-generational, multi-cultural workforce. This book is the ideal resource for these professionals. It also serves as an indispensable resource text for certification exams and credentialing boards for a multitude of professional societies Co-publishers on the second edition are: ACLAM (American College of Laboratory Animal Medicine); ECLAM (European College of Laboratory Animal Medicine);

IACLAM (International Colleges of Laboratory Animal Medicine); JCLAM (Japanese College of Laboratory Animal Medicine); KCLAM (Korean College of Laboratory Animal Medicine); CALAS (Canadian Association of Laboratory Animal Medicine); LAMA (Laboratory Animal Management Association); and IAT (Institute of Animal Technology).

Research Ethics and Integrity for Social Scientists-Mark Israel 2014-10-20 Ethics and integrity in research are increasingly important for social scientists around the world. We are tackling more complex problems in the face of expanding and not always sympathetic regulation. This book surveys the recent developments and debates around researching ethically and with integrity and complying with ethical requirements. The new edition pushes beyond the work of the first edition through updated and extended coverage of issues relating to international, indigenous, interdisciplinary and internet research. Through case studies and examples drawn from all continents and from across the social science disciplines, the book: demonstrates the practical value of thinking seriously and systematically about ethical conduct in social science research identifies how and why current regulatory regimes have emerged reveals those practices that have contributed to the adversarial relationships between researchers and regulators encourages all parties to develop shared solutions to ethical and regulatory problems.

Ethical Conduct of Clinical Research Involving Children-Institute of Medicine 2004-07-09 In recent decades, advances in biomedical research have helped save or lengthen the lives of children around the world. With improved therapies, child and adolescent mortality rates have decreased significantly in the last half century.

Despite these advances, pediatricians and others argue that children have not shared equally with adults in biomedical advances. Even though we want children to benefit from the dramatic and accelerating rate of progress in medical care that has been fueled by scientific research, we do not want to place children at risk of being harmed by participating in clinical studies. Ethical Conduct of Clinical Research Involving Children considers the necessities and challenges of this type of research and reviews the ethical and legal standards for conducting it. It also considers problems with the interpretation and application of these standards and conduct, concluding that while children should not be excluded from potentially beneficial clinical studies, some research that is ethically permissible for adults is not acceptable for children, who usually do not have the legal capacity or maturity to make informed decisions about research participation. The book looks at the need for appropriate pediatric expertise at all stages of the design, review, and conduct of a research project to effectively implement policies to protect children. It argues persuasively that a robust system for protecting human research participants in general is a necessary foundation for protecting child research participants in particular.

Research Ethics for Social Scientists-Mark Israel 2006-06-29 Ethics is becoming an increasingly prominent issue for all researchers across the western world. This comprehensive and accessible guide introduces students to the field and encourages knowledge of research ethics in practice. Research Ethics for Social Scientists sets out to do four things: The first is to demonstrate the practical value of thinking seriously and systematically about what constitutes ethical conduct in social science research. Second, the text identifies how and why current regulatory regimes have emerged. Third, it seeks to reveal those practices that have contributed to the adversarial relationships

between researchers and regulators. Finally, the book hopes to encourage both parties to develop shared solutions to ethical and regulatory problems.

Ethical and Regulatory Aspects of Clinical Research-Ezekiel J. Emanuel 2003 Professionals in need of such training and bioethicists will be interested.

Preparing for Future Products of Biotechnology-National Academies of Sciences, Engineering, and Medicine 2017-07-28 Between 1973 and 2016, the ways to manipulate DNA to endow new characteristics in an organism (that is, biotechnology) have advanced, enabling the development of products that were not previously possible. What will the likely future products of biotechnology be over the next 5â€"10 years? What scientific capabilities, tools, and/or expertise may be needed by the regulatory agencies to ensure they make efficient and sound evaluations of the likely future products of biotechnology? Preparing for Future Products of Biotechnology analyzes the future landscape of biotechnology products and seeks to inform forthcoming policy making. This report identifies potential new risks and frameworks for risk assessment and areas in which the risks or lack of risks relating to the products of biotechnology are well understood.

Clinical Research Law and Compliance Handbook-John E. Steiner 2006 Written in clear, practical language, this title will help you navigate the clinical research maze as it addresses critically important legal, operational, ethical and business issues associated with clinical research trials.

Assuring Data Quality and Validity in Clinical Trials for Regulatory Decision Making-Institute of Medicine 1999-07-27 In an effort to increase knowledge and understanding of the process of assuring data quality and

validity in clinical trials, the IOM hosted a workshop to open a dialogue on the process to identify and discuss issues of mutual concern among industry, regulators, payers, and consumers. The presenters and panelists together developed strategies that could be used to address the issues that were identified. This IOM report of the workshop summarizes the present status and highlights possible strategies for making improvements to the education of interested and affected parties as well as facilitating future planning.

Registries for Evaluating Patient Outcomes-Agency for Healthcare Research and Quality/AHRQ 2014-04-01 This User's Guide is intended to support the design, implementation, analysis, interpretation, and quality evaluation of registries created to increase understanding of patient outcomes. For the purposes of this guide, a patient registry is an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes. A registry database is a file (or files) derived from the registry. Although registries can serve many purposes, this guide focuses on registries created for one or more of the following purposes: to describe the natural history of disease, to determine clinical effectiveness or cost-effectiveness of health care products and services, to measure or monitor safety and harm, and/or to measure quality of care. Registries are classified according to how their populations are defined. For example, product registries include patients who have been exposed to biopharmaceutical products or medical devices. Health services registries consist of patients who have had a common procedure, clinical encounter, or hospitalization. Disease or condition registries are defined by patients having the same diagnosis, such as cystic fibrosis or heart failure.

The User's Guide was created by researchers affiliated with AHRQ's Effective Health Care Program, particularly those who participated in AHRQ's DEcIDE (Developing Evidence to Inform Decisions About Effectiveness) program. Chapters were subject to multiple internal and external independent reviews.

Contextualizing Compliance in the Public Sector-Saba Siddiki 2018-07-06 Studying compliance to uncover whether compliance is occurring, and what motivates it, is central to the broader study of governance. Contextualizing Compliance in the Public Sector: Individual Motivations, Social Processes and Institutional Design develops an interdisciplinary approach for answering a classic and essential question in any rule-governed context: What factors influence the decision of an individual or organization to comply (or not) with governing rules? Analyzing compliance from an interdisciplinary and multi-level perspective, this book examines the question of what motivates compliance in the context of salient policy issues, such as energy policy, water governance, police profiling, and drug policy, among others. The book brings together an interdisciplinary group of experts who explore the psychological, social, and institutional factors that shape compliance with formal rules embodied in laws and regulations and/or informal rules embodied in social norms. In doing so, they offer a platform for assessing individual compliance, compliance by or in the context of groups, and compliance on a systemic or societal level. Contextualizing Compliance in the Public Sector: Individual Motivations, Social Processes and Institutional Designis an excellent resource for researchers and scholars of public administration and public policy conducting research on compliance, rules, behavior, and policy outcomes.

Enterprise, Business-Process and Information

Systems Modeling-Terry Halpin 2009-04-30 This book contains the proceedings of two long-standing workshops: The 10th International Workshop on Business Process Modeling, Development and Support, BPMDS 2009, and the 14th International Conference on Exploring Modeling Methods for Systems Analysis and Design, EMMSAD 2009, held in connection with CAiSE 2009 in Amsterdam, The Netherlands, in June 2009. The 17 papers accepted for BPMDS 2009 were carefully reviewed and selected from 32 submissions. The topics addressed by the BPMDS workshop are business and goal-related drivers; model-driven process change; technological drivers and IT services; technological drivers and process mining; and compliance and awareness. Following an extensive review process, 16 papers out of 36 submissions were accepted for EMMSAD 2009. These papers cover the following topics: use of ontologies; UML and MDA; ORM and rule-oriented modeling; goal-oriented modeling; alignment and understandability; enterprise modeling; and patterns and anti-patterns in enterprise modeling.

Use of Laboratory Animals in Biomedical and Behavioral Research-National Research Council 1988-02-01 Scientific experiments using animals have contributed significantly to the improvement of human health. Animal experiments were crucial to the conquest of polio, for example, and they will undoubtedly be one of the keystones in AIDS research. However, some persons believe that the cost to the animals is often high. Authored by a committee of experts from various fields, this book discusses the benefits that have resulted from animal research, the scope of animal research today, the concerns of advocates of animal welfare, and the prospects for finding alternatives to animal use. The authors conclude with specific recommendations for more consistent government action.

Implementing a Comprehensive Research Compliance Program-Aurali Dade 2015-07-01 The senior research compliance administrator has emerged as a critically important position as universities and other research organizations face an increasingly intricate regulatory environment. These administrators are tasked with a special challenge: ensuring that their institutions conduct safe, ethical, and compliant research while also helping researchers understand and meet compliance requirements and achieve their research goals. These competing responsibilities can make the role of the research administrator complex; however, those who serve in this role may find that they have limited preparation for the challenges and little or no formal education in the field. Thus, the goal of this handbook is to provide practical guidance to research administrators who are responsible for a wide variety of compliance programs. Previous volumes on these topics have focused primarily on educating research faculty, staff, and students. An assumption in many of these handbooks is that all additional questions related to research ethics and regulations should be directed to the senior research administrator; yet, the books have limited guidance intended for the senior research administrators themselves. This handbook is designed, therefore, to serve as a detailed program implementation manual for these administrators, who are expected to be conversant on a broad range of complex ethical and regulatory topics and to provide guidance to those conducting research, as well as upper administration and others interested in safe, ethical, and compliant research.

The Changing Face of Compliance-Sharon Ward 2016-04-01 In the current business climate the impact of the volume and nature of regulatory change and the regulatory risk arising from this is a significant business risk for regulated firms and regulators alike. As a

consequence, management of this risk is increasingly high on the board agenda of regulated firms, with those business functions whose activities support this, such as Compliance, facing increasing levels of challenge in their efforts to be effective. The Changing Face of Compliance addresses core aspects of this challenge, considering the relationship between regulation and compliance and key influences on both, offering insight into the effectiveness of current approaches and addressing practical compliance challenges. Sharon Ward explains how the role of Compliance might be strengthened and those who work within it further enabled to support the current focus on improving standards in business, offering recommendations for enhancing this role. The text includes a mix of hands-on advice, examples and research based on the experiences of practitioners, educators and regulators drawn from across a wide range of jurisdictions and sectors. This is a thoughtful and timely book, whether you are concerned about the growing and changing implications of regulatory risk; the benefit of leveraging additional value from your Compliance function or your own Compliance role; or ways of transforming and sustaining the function to ensure its continued relevance to the business.

Optimizing the Nation's Investment in Academic Research-National Academies of Sciences, Engineering, and Medicine 2016-07-29 Research universities are critical contributors to our national research enterprise. They are the principal source of a world-class labor force and fundamental discoveries that enhance our lives and the lives of others around the world. These institutions help to create an educated citizenry capable of making informed and crucial choices as participants in a democratic society. However many are concerned that the unintended cumulative effect of federal regulations undercuts the productivity of

the research enterprise and diminishes the return on the federal investment in research. Optimizing the Nation's Investment in Academic Research reviews the regulatory framework as it currently exists, considers specific regulations that have placed undue and often unanticipated burdens on the research enterprise, and reassesses the process by which these regulations are created, reviewed, and retired. This review is critical to strengthen the partnership between the federal government and research institutions, to maximize the creation of new knowledge and products, to provide for the effective training and education of the next generation of scholars and workers, and to optimize the return on the federal investment in research for the benefit of the American people.

The Regulatory Craft- Malcolm K. Sparrow 2011-01-01 The Regulatory Craft tackles one of the most pressing public policy issues of our time—the reform of regulatory and enforcement practice. Malcolm K. Sparrow shows how the vogue prescriptions for reform (centered on concepts of customer service and process improvement) fail to take account of the distinctive character of regulatory responsibilities—which involve the delivery of obligations rather than just services.In order to construct more balanced prescriptions for reform, Sparrow invites us to reconsider the central purpose of social regulation—the abatement or control of risks to society. He recounts the experiences of pioneering agencies that have confronted the risk-control challenge directly, developing operational capacities for specifying risk-concentrations, problem areas, or patterns of noncompliance, and then designing interventions tailored to each problem. At the heart of a new regulatory craftsmanship, according to Sparrow, lies the central notion, "pick important problems and fix them." This beguilingly simple idea turns out to present enormously complex implementation

challenges and carries with it profound consequences for the way regulators organize their work, manage their discretion, and report their performance. Although the book is primarily aimed at regulatory and law-enforcement practitioners, it will also be invaluable for legislators, overseers, and others who care about the nature and quality of regulatory practice, and who want to know what kind of performance to demand from regulators and how it might be delivered. It stresses the enormous benefit to society that might accrue from development of the risk-control art as a core professional skill for regulators.

Disrupting Finance-Theo Lynn 2018-01-01 This open access Pivot demonstrates how a variety of technologies act as innovation catalysts within the banking and financial services sector. Traditional banks and financial services are under increasing competition from global IT companies such as Google, Apple, Amazon and PayPal whilst facing pressure from investors to reduce costs, increase agility and improve customer retention. Technologies such as blockchain, cloud computing, mobile technologies, big data analytics and social media therefore have perhaps more potential in this industry and area of business than any other. This book defines a fintech ecosystem for the 21st century, providing a state-of-the art review of current literature, suggesting avenues for new research and offering perspectives from business, technology and industry.

Impact of Regulatory Compliance Costs on Small Airports- 2013 "TRB's Airport Cooperative Research Program (ACRP) Report 90: Impact of Regulatory Compliance Costs on Small Airports explores the cumulative costs of complying with regulatory and other federal requirements at small hub and non-hub airports."--Publisher's description.

Clinical Research

Compliance Manual-Brent 2007 For anyone receiving or applying for clinical research funding, Clinical Research Compliance Manual: An Administrative Guide covers today's most crucial topics, including: Human subject protections Institutional Review Board regulations and requirements Conflicts of interest Scientific misconduct Reimbursement issues And much more! Clinical Research Compliance Manual helps you establish best practices and carry out all administrative tasks in a compliant manner while keeping you completely up-to-date on the most recent developments: Covers the major clinical research issues - with chapters written by experts in the field Provides legal explanations of the major regulatory issues in an easy-to-understand format Includes summaries of federal regulatory agencies, analysis of major cases, flow-charts, checklists, and footnotes to in compliance program development, auditing and monitoring Clinical Research Compliance Manual has been updated to include: A new chapter on "Protecting Research Materials, Research Results, and Inventions: A University's Perspective" A new section on "Recent Proposed Changes to the Common Rule" Updated discussion of federal-wide assurance (FWA) OHRP's revision of its FAQs to be consistent with its Final Guidance on Engagement of Institutions in Human Subject Research Recent OHRP guidance on when institutions are not engaged in human subject research And much more!

Regulating Human Research-Sarah Babb 2020 This book traces the historic transformation of institutional review boards (IRBs) from academic committees to compliance bureaucracies. Sarah Babb opens the black box of contemporary IRB decision-making, which is increasingly outsourced to specialized private firms.

Opportunities for Organ Donor Intervention Research-National Academies of Sciences, Engineering, and Medicine

2018-01-21 The organ donation and transplantation system strives to honor the gift of donated organs by fully using those organs to save and improve the quality of the lives of their recipients. However, there are not enough donated organs to meet the demand and some donated organs may not be recovered, some recovered organs may not be transplanted, and some transplanted organs may not function adequately. Organ donor intervention research can test and assess interventions (e.g., medications, devices, and donor management protocols) to maintain or improve organ quality prior to, during, and following transplantation. The intervention is administered either while the organ is still in the deceased donor or after it is recovered from the donor but before it is transplanted into a recipient. Organ donor intervention research presents new challenges to the organ donation and transplantation community because of ethical questions about who should be considered a human subject in a research study, whose permission and oversight are needed, and how to ensure that such research does not threaten the equitable distribution of a scarce and valuable resource. Opportunities for Organ Donor Intervention Research focuses on the ethical, legal, regulatory, policy, and organizational issues relevant to the conduct of research in the United States involving deceased organ donors. This report provides recommendations for how to conduct organ donor intervention research in a manner that maintains high ethical standards, that ensures dignity and respect for deceased organ donors and their families, that provides transparency and information for transplant candidates who might receive a research organ, and that supports and sustains the public's trust in the process of organ donation and transplantation.

Financial Regulation and Compliance-H. David Kotz 2015-07-06 Devise an organized, proactive approach to financialcompliance

Financial Regulation and Compliance provides detailed,step-by-step guidance for the compliance professional seeking tomanage overlapping and new regulatory responsibilities. Written byDavid Kotz, former Inspector General of the SEC with additionalguidance provided by leading experts, this book is a one-stopresource for navigating the numerous regulations that have beenenacted in response to the financial crisis. You'll learn how bestto defend your organization from SEC, CFTC, FINRA, and NFAEnforcement actions, how to prepare for SEC, FINRA, and NFAregulatory examinations, how to manage the increasing volume ofwhistleblower complaints, how to efficiently and effectivelyinvestigate these complaints, and more. Detailed discussion of theregulatory process explains how aggressive you should be inconfronting federal agencies and self-regulatory organizations anddescribes how commenting on issues that affect your business areacan be productive or not. The companion website includes a glossaryof terms, regulations and government guidance, relevant case law,research databases, and FAQs about various topics, giving you acomplete solution for keeping abreast of evolving complianceissues. These days, compliance professionals are faced with a myriad ofoften overlapping regulatory challenges. Increased aggressivenesson the part of regulators has led to increased demand on financialfirms, but this book provides clear insight into navigating thechanges and building a more robust compliance function. Strengthen internal compliance and governance programs Manage whistleblower programs and conduct effectiveinvestigations Understand how to minimize exposure and liability fromEnforcement actions Learn how to prepare for the different types of regulatoryexaminations Minimize exposure from FCPA violations Understand the pros and cons of commenting on regulations The volume and pace of regulatory change

is causing new anddiverse pressures on compliance professionals. Navigate the choppywaters successfully with the insider guidance in FinancialRegulation and Compliance.

International Animal Research Regulations-National Research Council 2012-06-26 Animals are widely used in neuroscience research to explore biological mechanisms of nervous system function, to identify the genetic basis of disease states, and to provide models of human disorders and diseases for the development of new treatments. To ensure the humane care and use of animals, numerous laws, policies, and regulations are in place governing the use of animals in research, and certain animal regulations have implications specific to neuroscience research. To consider animal research regulations from a global perspective, the IOM Forum on Neuroscience and Nervous System Disorders, in collaboration with the National Research Council and the Institute for Laboratory Animal Research, held a workshop in Buckinghamshire, UK, July 26-27, 2011. The workshop brought together neuroscientists, legal scholars, administrators, and other key stakeholders to discuss current and emerging trends in animal regulations as they apply to the neurosciences. This document summarizes the workshop.

Laboratory Auditing for Quality and Regulatory Compliance-Donald C Singer 2019-08-30 Identifying current tools, techniques, and approaches for the evaluation of laboratory operations, this reference reviews the latest regulatory standards and auditing practices to test laboratory safety, quality, and performance.

Regulatory Theory-Peter Drahos 2017-02-23 This volume introduces readers to regulatory theory. Aimed at practitioners, postgraduate students and those interested in regulation as a cross-cutting theme in the social

sciences, Regulatory Theory includes chapters on the social-psychological foundations of regulation as well as theories of regulation such as responsive regulation, smart regulation and nodal governance. It explores the key themes of compliance, legal pluralism, meta-regulation, the rule of law, risk, accountability, globalisation and regulatory capitalism. The environment, crime, health, human rights, investment, migration and tax are among the fields of regulation considered in this ground-breaking book. Each chapter introduces the reader to key concepts and ideas and contains suggestions for further reading. The contributors, who either are or have been connected to the Regulatory Institutions Network (RegNet) at The Australian National University, include John Braithwaite, Valerie Braithwaite, Peter Grabosky, Neil Gunningham, Fiona Haines, Terry Halliday, David Levi-Faur, Christine Parker, Colin Scott and Clifford Shearing.

Microbiological Sensors for the Drinking Water Industry-Tapio Katko 2019-02-15 The book addresses the interdisciplinary area of water quality monitoring and binds together interests and competences within sensing technology, system behaviour, business needs, legislation, education, data handling, and artificial response algorithms.

Interagency Coordination in Drug Research and Regulation-United States. Congress. Senate. Committee on Government Operations 1963

Responsible Research with Biological Select Agents and Toxins-National Research Council 2010-02-12 The effort to understand and combat infectious diseases has, during the centuries, produced many key advances in science and medicine--including the development of vaccines, drugs, and other treatments. A subset of this research is conducted with agents that, like anthrax, not

only pose a severe threat to the health of humans, plants, and animals but can also be used for ill-intended purposes. Such agents have been listed by the government as biological select agents and toxins. The 2001 anthrax letter attacks prompted the creation of new regulations aimed at increasing security for research with dangerous pathogens. The outcome of the anthrax letter investigation has raised concern about whether these measures are adequate. Responsible Research with Biological Select Agents and Toxins evaluates both the physical security of select agent laboratories and personnel reliability measures designed to ensure the trustworthiness of those with access to biological select agents and toxins. The book offers a set of guiding principles and recommended changes to minimize security risk and facilitate the productivity of research. The book recommends fostering a culture of trust and responsibility in the laboratory, engaging the community in oversight of the Select Agent Program, and enhancing the operation of the Select Agent Program.

Enhancing Global Competitiveness Through Sustainable Environmental Stewardship-Subhash C. Jain 2011-01-01 It is apparent that environmental issues affect the livelihoods and well being of individuals, communities and businesses the world over. In that vein, this book examines the impact that climate change and other environmental factors have on business. The effect of climate change, while a significant factor, will influence business slowly, but inexorably. Executives should manage environmental risk at three levels: regulatory compliance, potential liability from industrial accidents, and pollutant release mitigation.Companies that are proactive in mitigating their exposure to climate-change risks will not only generate new profitable opportunities, but also gain competitive advantage over their rivals in a carbon-constrained future. Enhancing Global Competitiveness through

Sustainable Environmental Stewardship provides frameworks for identifying how climate change might affect a business, and suggests strategy guidelines to manage the risks and seek opportunities.This seminal collection of research will be of particular interest to students and scholars of sustainability studies, business and management, and business professionals concerned with the role they will play in the changing and challenging times that lie ahead for business growth and environmental consciousness.

Impact of Regulatory Compliance Costs on Small Airports- 2013 "TRB's Airport Cooperative Research Program (ACRP) Report 90: Impact of Regulatory Compliance Costs on Small Airports explores the cumulative costs of complying with regulatory and other federal requirements at small hub and non-hub airports."--Publisher's description.

The IACUC Handbook, Third Edition-Jerald Silverman 2014-05-20 Ever since its establishment by USDA regulation in the mid-1980s, the Institutional Animal Care and Use Committee (IACUC) has evolved as the premier instrument of animal welfare oversight within research institutions in the United States. As biomedical research continuously grows, the role and impact of the IACUC has increased in scope and complexity. The IACUC Handbook has become "the Bible" for individuals when the time comes for them to serve on their institution’s IACUC. It provides a foundation for understanding and implementing the many and varied responsibilities of this committee. This Third Edition comprehensively addresses the significant changes in the pertinent regulatory environment and interpretation of applicable federal laws, regulations, and policies. It provides multiple references and commentary on the new edition of the Guide for the Care and Use of Laboratory Animals, the new AVMA Guidelines for the

Euthanasia of Animals: 2013 Edition, and the Office of Laboratory Animal Welfare's Frequently Asked Questions. The Third Edition also features an updated survey of IACUC practices from institutions around the United States, offering wisdom gained from their experience. In addition, it includes a chapter that provides an international perspective on how animal welfare reviews can function in other countries.

The Regulatory Environment for Science-1986

Prudent Practices in the Laboratory-National Research Council 1995-09-16 This volume updates and combines two National Academy Press bestsellers--Prudent Practices for Handling Hazardous Chemicals in Laboratories and Prudent Practices for Disposal of Chemicals from Laboratories--which have served for more than a decade as leading sources of chemical safety guidelines for the laboratory. Developed by experts from academia and industry, with specialties in such areas as chemical sciences, pollution prevention, and laboratory safety, Prudent Practices for Safety in Laboratories provides step-by-step planning procedures for handling, storage, and disposal of chemicals. The volume explores the current culture of laboratory safety and provides an updated guide to federal regulations. Organized around a recommended workflow protocol for experiments, the book offers prudent practices designed to promote safety and it includes practical information on assessing hazards, managing chemicals, disposing of wastes, and more. Prudent Practices for Safety in Laboratories is essential reading for people working with laboratory chemicals: research chemists, technicians, safety officers, chemistry educators, and students.

The Regulatory environment for science.-

The Regulatory Compliance Almanac-Les Schnoll 2008

FDA Regulatory Affairs-David Mantus 2014-02-28 FDA Regulatory Affairs is a roadmap to prescription drug, biologics, and medical device development in the United States. Written in plain English, the concise and jargon-free text demystifies the inner workings of the US Food and Drug Administration (FDA) and facilitates an understanding of how the agency operates with respect to compliance and product approval, including clinical trial exemptions, fast track status, advisory committee procedures, and more. The Third Edition of this highly successful publication: Examines the harmonization of the US Federal Food, Drug, and Cosmetic Act with international regulations on human drug, biologics and device development, research, manufacturing, and marketing Includes contributions from experts at organizations such as the FDA, National Institutes of Health (NIH), and PAREXEL Focuses on the new drug application (NDA) process, cGMPs, GCPs, quality system compliance, and corresponding documentation requirements Provides updates to the FDA Safety and Innovation Act (FDASIA), incorporating pediatric guidelines and follow-on biologics regulations from the 2012 Prescription Drug User Fee Act (PDUFA) V Explains current FDA inspection processes, enforcement options, and how to handle FDA meetings and required submissions Co-edited by an industry leader (Mantus) and a respected academic (Pisano), FDA Regulatory Affairs, Third Edition delivers a compilation of the selected US laws and regulations as well as a straightforward commentary on the FDA product approval process that's broadly useful to both business and academia.

Preserving Public Trust-Institute of Medicine 2001-07-02 Amid increasing concern for patient safety and the shutdown of prominent research operations, the need

to improve protections for individuals who volunteer to participate in research has become critical. Preserving Public Trust: Accreditation and Human Research Participant Protection Programs considers the possible impact of creating an accreditation system to raise the performance of local protection mechanisms. In the United States, the system for human research participant protections has centered on the Institutional Review Board (IRB); however, this report envisions a broader system with multiple functional elements. In this context, two draft sets of accreditation standards are reviewed (authored by Public Responsibility in Medicine & Research and the National Committee for Quality Assurance) for their specific content in core areas, as well as their objectivity and validity as measurement tools. The recommendations in the report support the concept of accreditation as a quality improvement strategy, suggesting that the model should be initially pursued through pilot testing of the proposed accreditation programs.

Sharing Clinical Trial Data- Institute of Medicine 2015-04-20 Data sharing can accelerate new discoveries by avoiding duplicative trials, stimulating new ideas for research, and enabling the maximal scientific knowledge and benefits to be gained from the efforts of clinical trial participants and investigators. At the same time, sharing clinical trial data presents risks, burdens, and challenges. These include the need to protect the privacy and honor the consent of clinical trial participants; safeguard the legitimate economic interests of sponsors; and guard against invalid secondary analyses, which could undermine trust in clinical trials or otherwise harm public health. Sharing Clinical Trial Data presents activities and strategies for the responsible sharing of clinical trial data. With the goal of increasing scientific knowledge to lead to better therapies for patients, this book identifies guiding principles and makes recommendations to maximize

the benefits and minimize risks. This report offers guidance on the types of clinical trial data available at different points in the process, the points in the process at which each type of data should be shared, methods for sharing data, what groups should have access to data, and future knowledge and infrastructure needs. Responsible sharing of clinical trial data will allow other investigators to replicate published findings and carry out additional analyses, strengthen the evidence base for regulatory and clinical decisions, and increase the scientific knowledge gained from investments by the funders of clinical trials. The recommendations of Sharing Clinical Trial Data will be useful both now and well into the future as improved sharing of data leads to a stronger evidence base for treatment. This book will be of interest to stakeholders across the spectrum of research--from funders, to researchers, to journals, to physicians, and ultimately, to patients.