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The legacy of male bias within pharmaceutical research, regulation, and commercialisation needs to be rectified, argue Sundari Ravindran and colleagues Women have been excluded from pharmaceutical research for many reasons.<sup>1</sup> The thalidomide tragedy of the 1960s prompted a protectionary ban on pregnant women and women of child-bearing age from participating in clinical trials.

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Pharmaceutical regulations, or medicines regulations, have been defined as the combination of legal, administrative, and technical measures that governments take to ensure the safety, efficacy, and quality of medicines, as well as the relevance and accuracy of product information [12,13] [12] [13]. The term "regulation" includes a variety of texts (e.g. guidelines, recommendations, procedures, policies, etc.) that have different legal bases and authority.

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Spain: Pharmaceutical Advertising Laws and Regulations 2020. ICLG - Pharmaceutical Advertising Laws and Regulations - Spain covers common issues in pharmaceutical advertising laws and regulations – including advertisements to healthcare professionals, gifts and financial incentives, hospitality and related payments, and transparency and disclosure – in 24 jurisdictions.

With more than 250 cases patient-profile case studies and more 2,000 questions with answers and explanations, this book presents the challenges of real-life situations that pharmacists must address on the exams and in their practices. This book thoroughly prepares newly-graduated pharmacists for the NAPLEX and the MPJE (federal drug law exam).

As one of the most massive and successful business sectors, the pharmaceutical industry is a potent force for good in the community, yet its behaviour is frequently questioned: could it serve society at large better than it has done in the recent past? Its own internal ethics, both in business and science, may need a careful reappraisal, as may the extent to which the law - administrative, civil and criminal - succeeds in guiding (and where necessary constraining) it. The rules of behavior that may be considered to apply to today's pharmaceutical industry have emerged over a very long period and the process goes on. Even the immensely detailed standards for quality, safety and efficacy laid down in drug law and regulation during the second half of the twentieth century have their limitations as tools for ensuring that the public interest is well served. In particular, national and regional regulatory agencies are heavily dependent on industrial data for their decision-making, their standards and competence vary, and even the existing network of agencies does not cover the entire world. What is more there are many areas of law and regulation affecting the industry, concerning for example the pricing of medicines, the conduct of clinical studies, the health protection of workers and concern for the environment. In some fields it is indeed hardly possible to maintain standards through regulation. Professor N.M. Graham Dukes, a physician and lawyer with long term experience in industrial research management, academic study and international drug policy, provides here a powerfully documented analysis into the way this industry thinks, acts, and is viewed, and examines the current trends pointing to change. \*Provides a balanced picture of the current role of the pharmaceutical industry in society \*Includes indices of conventions, laws, and regulations; as well as judicial and disciplinary cases \*This is the only book addressing the legal implications of big pharma activities and ethical standards

The fifth edition of Pharmacy Law and Practice provides a straightforward and useable guide for students, practitioners, academics and others interested in pharmacy law and practice in the United Kingdom. This multi-dimensional book includes discussions of socio-political influences on legal developments to provide greater insight to the reader. It clearly sets out the background to regulatory issues together with

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simple and practical statements of what a pharmacist has to do to obey the law. As in previous editions, this book discusses topics thematically rather than by statute. It is a unique and reader-friendly guide that boils down the complex or difficult language of the law, describes the reasons behind it, and illustrates the application to pharmacy practice. Thoroughly updated to reflect regulatory and legal developments in areas including employment law, online transactions and internet pharmacies, non-medical prescribing and more Takes an intuitive, problem-solving approach and discusses topics thematically rather than by statute to show how all of the larger pieces fit together The electronic version of this book contains valuable links to provide readers with the most current information in a rapidly changing subject area

The field of contract research and manufacturing broadly encompasses those services in the pharmaceutical and biotechnology sectors that require extensive research and development and large-scale manufacturing facilities. The field has great potential for growth in the Indian outsourcing industry, which is world-renowned for its provision of cheap and highly-skilled services. Contract research and manufacturing services (CRAMS) in India provides a detailed account of the current scenario in India and the advantages that the Indian outsourcing industry can offer in the field of CRAMS. Following an overview of the services and their emergence in India, chapters in the book begin by discussing the legal and regulatory scenario and major concerns and issues. In the latter part of the book, topics covered include service agreements, dispute resolution and contract negotiations, followed by a discussion of the outlook for CRAMS in India and some concluding remarks. Several appendices are included, offering a list of major players in the field and various forms for use in licence applications. Simple and accessible presentation using tables, charts and diagrams Practical tips from leading practitioners Inclusion of relevant case laws and other legal considerations

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.

Pharmaceutical Medicine and Translational Clinical Research covers clinical testing of medicines and the translation of pharmaceutical drug research into new medicines, also focusing on the need to understand the safety profile of medicine and the benefit-risk balance. Pharmacoeconomics and the social impact of healthcare on patients and public health are also featured. It is written in a clear and straightforward manner to enable rapid review and assimilation of complex information and contains reader-friendly features. As a greater understanding of these aspects is critical for students in the areas of pharmaceutical medicine, clinical research, pharmacology and pharmacy, as well as professionals working in the pharmaceutical industry, this book is an ideal resource. Includes detailed coverage of current trends and key topics in pharmaceutical medicine, including biosimilars, biobetters, super generics, and Provides a comprehensive look at current and important aspects of the science and regulation of drug and biologics discovery

This is an inclusive reference exploring the scientific basis and practice of drug therapy. The key concept is to look at the balance between the benefits and risks of drugs but in this context also the social impact which drugs have in modern societies is highlighted. Taking an evidence-based approach to the problem, the practice of clinical pharmacology and pharmacotherapy in the developing as well as the developed world is examined. For this purpose the book \* Covers general clinical pharmacology, pharmacology of various drug groups and the treatments specific to various diseases \* Gives guidance on how doctors should act so that drugs can be used effectively and safely \* Encourages the rational use of drugs in society This book brings together a large amount of excellent content that will be invaluable for anyone working within, or associated with, the field of clinical pharmacology and pharmacotherapy - undergraduates, postgraduates, regulatory authorities and the pharmaceutical industry.

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