



AULA VIRTUAL de RADIOFARMACIA

Plataforma Virtual de Formación Continuada en Radiofarmacia

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Recomendamos la lectura de este libro de reciente publicación

“Regulatory Requirements for Drug Development and Clinical Research” to be released

“Regulatory Requirements for Drug Development and Clinical Research”, a multi-author book, edited by Dr Nilima Kshirsagar, Tejashree Kulkarni, Dr Anish Desai and Dr Jatin Shah will be released tomorrow.

The book is relevant as drug development and clinical research has grown exponentially in past 5 years. Many new regulations and rules have been framed to ensure that besides being scientifically right, it is ethical and benefit patients.

This book will be released by Dr David Lehmann, USA and chaired by Dr Robin Ferner (UK) on August 27, 2011 at the 5th International Conference on “Clinical Pharmacology – Discovery, Development and beyond” organized by the South Asian Chapter of American College of Clinical Pharmacology and department of clinical pharmacology, Seth GSMC and KEM Hospital, Mumbai in collaboration with National Institute for Research in Reproductive Health, ICMR, Mumbai, advanced centre for treatment, research and education in cancer, Navi Mumbai and Maharashtra University of Health Sciences, Nashik, India.

The book is divided into three sections. The first section deals with basic regulations for drug development, section two focuses on Investigational New Drug (IND) Application and various phases of clinical trials and the third section highlights regulations on specialized areas of development and commercialization.

This book is a distillate of knowledge of expert academicians, researchers and industry experts with unique perspective and experience in Clinical research. It contains chapters on regulatory framework and guidelines for ethics, animal house, toxicological studies, Investigational New Drug (IND) Application, various phases of clinical trials, phase IV, epidemiological and observational studies, Pharmacovigilance, dos and don'ts for an IND application, regulations for development and marketing of vaccines, biologicals, cosmetics, devices, traditional medicines, imports of narcotics, radiopharmaceuticals, clinical trials with pregnant and lactating women.

Each chapter provides background information on the topics. Important issues and points are discussed, Indian regulations are elaborated upon with outline of International Regulation. Wherever possible interesting cases that illustrate regulations have been included. Regulatory approvals required, authority providing it and time required is given in a tabular form for quick reference. Some key messages and points to remember are provided in boxes.

This first comprehensive multi-author book will be useful for students, scholars, teachers, researchers and industry engaged in drug development, translational and clinical research.



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