Editorial

Regulatory Stratagem in Health Care Environment - Need for Success

Pharmaceutical innovation is always a complex creative process that encompasses the application of regulatory knowledge, creativity for inventing developing and bringing new drugs for betterment of life of patients. Successful pharmaceutical is a journey which involves both time and cost to bring a new drug from the “scientific idea” through clinical trial regulatory approval and delivery to the patient. Now regulatory bodies are becoming very stringent, so undoubtedly proper regulatory strategy is very much essential to make drug finally available to society. This special issue will provide an opportunity to enrich knowledge, latest development in the area of drug discovery, development and most importantly its regulatory requirements.

I am extremely delighted to invite you to walk through to special issue of Applied Clinical Research, Clinical Trials and Regulatory Affairs (ACCTRA) on the theme of Regulatory Stratagem in Health Care Environment - Need for Success.

Parveen Kumar et al., “Pharma Emerging Market’s Scanning by Look and Feel of its Opportunities and Challenges” discuss how the emerging market’s Pharma environment can be dealt for profitability, regulatory filing, handling deficiency, managing post approval changes, IPR issues, phase lag, rudimentary health care system. In Malika Arora and Ashish Baldi, “Comparative Account of Quality Management and Regulatory Aspects of Products with Health Claims: Existing Approaches and Future Challenges for Probiotics and Herbal Products, an attempt has been made to discusses various factors associated with safety concern of all the health care products and also it highlights various concerns associated with effective monitoring of it also the safety of traditional medicines including herbal products and live microorganisms i.e. probiotics, nutraceuticals in comparison to widely accepted pharmaceuticals. Dimple Chaudhary et al., “Drug and Cosmetic Amendment Bill in India: A Promising Hope for Healthy Medical Device Regulatory Environment, manifests the impact of draft medical device policy on India is medical devices market. By going through it, we will get to know what policy is and how these initiatives will separate regulation of drugs, cosmetics. It promises to improve efficiently and appropriately so called unorganized medicinal devices regulatory environment in India.

Shivaji Rai et al., “Regulations of Cosmetics Across the Globe” throws light on comparative regulatory framework for cosmetic products in Canada, United States, European Union and India with respect to applicable acts, regulations, ingredients, heavy metals, labeling, notification procedures, good manufacturing practices and cosmetic standards. Swagat Tripathy et al., “Product Life Cycle Management for Pharmaceutical Innovation” emphasizes the scope of various PLM strategies for innovators in four different countries namely, USA, EU, Canada and India. It will act as a roadmap for the innovators to sublime competency for their survival of innovation. Prerna Kaushik et al., Anti-Monopoly and Competition Laws - Impact on the Indian Pharmaceutical Industry” confers the purpose of competition laws for grappling with the monopolies and restrictive trade practices with a particular focus on pharmaceuticals. Also it emphasizes what new competition law is and also discusses prohibition of anti-competitive treaties, prevention of misuse of dominance and combinations which prove detrimental to the competition in the market. Ajmer Grewal et al., “Regulatory Overview of Biosimilars: Current Scenario and Future Opportunities” not only briefs basic facts about the biosimilars but also discusses the regulatory aspects of the biosimilars. The recent developments in the area of biosimilars along with future opportunities and challenges in the field of manufacturing and marketing are also explored. Malika Arora and Ashish Baldi “Good Manufacturing Practice Regulations for Probiotic Based Pharmaceuticals: Current Scenario and Suggestive Recommendations” describes the current regulatory aspects in regard to GMP of the probiotic based drug products and discusses various concerns and recommends suggestive consolidations to be followed for the manufacturing of the probiotic products.

I want to express my sincere appreciation and thank to one and all, who generously contributed, patiently waited for the peer-review, and revised the manuscripts for this special issue to uphold the high quality of this journal. Spell bound to acknowledge sincerest thanks to the editorial board and Ms, Tabinda Rao’s constructive and timely reviews and all the support to shape this special issue I hope that all of you will enjoy this special issue.

Dr. Harish Dureja
Guest Editor
Associate Professor in Pharmaceutics
Department of Pharmaceutical Sciences, M. D. University, Rohtak, INDIA-124 001
Member Secretary- Institutional Human Ethical Committee, M. D. University, Rohtak
E-mail: harishdureja@gmail.com