Pharmaceut Reg Affairs 2012, 1:4
http://dx.doi.org/10.4172/2167-7689.S1.008

OMICS Group Conferences
Accelerating Scientific Discovery

2nd International Conference and Exhibition on
Pharmaceutical Regulatory Affairs

November 23-24, 2012 Hyderabad International Convention Centre, India

Developing regulatory environment in South Asia and challenges for regulatory affairs professionals

Nadeem H. Alamgir
Drugs Regulatory Agency, Pakistan

South Asia, is the southern region of the Asian continent, which comprises the sub-Himalayan countries including Bangladesh, Bhutan, India, Maldives, Nepal, Pakistan, and Sri Lanka. It is home to well over one fifth of the world's population, thus is the most densely populated geographical region in the world. This Region includes the countries that were part of the former British Empire including India, Pakistan, and Bangladesh at the core, but also including Sri Lanka, Burma. The Drug Regulations developed by the British during their rule in this region are still the bases of Drug Regulation in these countries. The common issues are a colonial mindset of bureaucracy, lack of resources for capacity building of regulatory authorities/MOH. But the prevailing law gives immense powers to the bureaucrats in these authorities. With new emerging regulations for Pharmaceutical, Medical Devices and Biological Drugs in the developed world, a need for having the same set of regulations is felt by the regulators as well. But the resource constraints and lack of training in emerging of relevant regulations is either nonexistent or painstakingly slow and the authorities are trying to manage in unique ways. Thus becoming a challenge for Regulatory Affairs Professionals as the authorities are coming up with novel ideas nonexistent elsewhere.. To tap the immense potential of this huge market the issues in regulation of the drugs shall be addressed for the benefit of all.

Biography

Nadeem Alamgir started his carrier as a Sales Representative in MSD in 1985. He grew over the years in sales in different Pharmaceutical firms and then switched to Regulatory Affairs. While working as regulatory affairs professional he worked with the Government of Pakistan for Pharmaceutical Sector Reforms and amendment of The Drugs Act 1976 of Pakistan, formulation of regulations for Biological Drugs and Medical Devices Regulation. He was instrumental for membership of Pakistan Asian Harmonization Working Party (AHWP) and was able to motivate the authorities to create a separate Medical Device and Biological Drugs department in Drugs Regulatory Agency of Pakistan. He is also the Non Regulatory Primary Member of (AHWP) Asian Harmonization Working Party.

nadeemalamgir@yahoo.com

Medical representatives with gifts: To whom to give and why

Naseem Akhtar Qureshi and Abdullah Al-Bedah
Ministry of Health, Saudi Arabia

Medical representatives offer gifts to health providers and managers with their hidden agenda and this behavior could have diverse implications. This presentation aims to address regulatory measures against gifts-derived behaviors both of healthcare providers and pharmaceutical representatives. Using keywords, many rounds of computer searches of PubMed, MEDLINE, Google Scholar and Quertile were made to retrieve relevant peer-reviewed papers published in literature over the past 10 years. Regulatory measures against gift-related behaviors are in place in most of high-income-countries and are followed strictly and USA-FDA is reported to lead the world. The landscape in Eastern world is not at par and needs collective efforts to address this important issue by pharmaceutical giants in collaboration with health authorities. Regulatory checks need to be in sight for controlling the gift-derived behaviors of all stakeholders across the world.

Biography

Naseem Akhtar Qureshi has completed his PhD at the age of 48 years from Erasmus University, Rotterdam, The Netherlands and pre-doctoral studies from King George's Medical College (now King George Medical University), Lucknow. He is the director of Research and Studies Division of General Directorate of Research and Studies, Ministry of Health (MOH) Riyadh Saudi Arabia. MOH is the largest healthcare service organization in Saudi Arabia. He has published more than 120 papers in reputed journals and serving as an editorial board member of 5 repute journals.

drnaseem.qureshi@gmail.com