J Develop Drugs 2016, 5:3(Suppl)
http://dx.doi.org/10.4172/2329-6631.C1.018

Regulatory compliance: Strategic operational tool to move up the value chain

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Enforcement agencies regulate almost every aspect of the pharmaceutical business. Global Pharmaceutical Industry is experiencing regulatory scrutiny across the globe and across the spectrum of the industry, throughout the 'Product Life Cycle' from Clinical Research-Manufacturing-Marketing and Post-Marketing. It has resulted in the companies being questioned about their regulatory compliance systems & practices, penalized and in extreme cases barred from marketing the drugs in the developed countries, affecting the industry's ability to deliver values to its stakeholders. Global Pharmaceutical Market is projected to reach over ≥ US$ 1.3 Trillion by 2018 out of which ≈ US$ 824 Billion Markets (Europe, Japan and N. America) necessitates regulatory compliance of highest standards, including anti-counterfeiting measures. Even the standards of regulatory compliances in the ROW are becoming harmonized with these referred countries. Considering the business value of good compliance, greater importance needs to be placed on building excellent compliance structures and programs. Regulatory Compliance, therefore, is the key to commercial success, which is related to the confidence of healthcare professionals, the consumer and other stakeholders in the company and its products. It can minimize the risks associated with imbalances in the compliance mechanism and improve the topline as well as the bottom line. Past studies have shown that the total compliance related costs (direct and indirect) for internal quality systems and external regulations for a typical medium to large dosage form manufacturing facility may be is as high as 20-25% of the total site operating budget (exclusive of raw material costs) and in today's increasing .regulatory environment, it may be expected to be still higher, 30-35%R3, as the amount of regulation on the pharmaceutical industry increased by 40% since 2000. Best-in-class companies that have systematically reduced their compliance risk have noticed that, surprisingly, as the level of compliance improved, the cost of compliance actually decreased, by 40-50%. In this presentation, commercial benefits of regulatory compliances to move up the value chain and the risks of imbalances in the compliance mechanism will be discussed, with case studies.

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Obtaining regulatory approvals for pharmaceuticl products in MENA region

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Obtaining Regulatory approvals for pharmaceutical products in MENA region is an essential requirement to market and sell pharmaceutical products in the fast growing market of the Middle East and North Africa region. My presentation will address the Regulatory Climate in MENA region, Regulations, Regulatory Pathways, Basic Registration Requirements, overview of Registration Files details, a brief comparison between the MENA requirements and the USFDA requirements to obtain regulatory approval to market pharmaceutical products.

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