

Drug approval in regulated and non-regulated markets

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This topic aims to explain and compare the different regulations and processes for approval of drugs in regulated and non regulated market. The pharmaceutical industry is one of the highly regulated industries, to protect the health and well being of the masses. The overall objective of a stringent drug approval system is to ensure that medicinal products of acceptable quality and efficacy are manufactured.

By law, all new drugs must first be shown to be safe and effective before they can be approved for marketing. A regulated market is the provision of services that is regulated by a government approved body. Drug approval standards in regulated countries are considered by many to be the most demanding in the world. Discovering a new drug, and shepherding it through various review process, can take many years. To a large degree, these costs are mostly associated with the clinical testing.

Coming to approval of drugs in typical non-regulated markets, they are becoming an important player in drug manufacture, in particular, the production of generics. Many of the generics produced are now found in all parts of the world.

In conclusion, this study deals with the comparison of drug approval requirements between various regulated and non-regulated markets that could result in a clear understanding of the market positions of different countries and most importantly revise regulations for a healthier tomorrow.

Biography

V. Sowmya is a student of JSS College of Pharmacy, JSS University, Mysore. She has completed her B.Pharm from JSS College of Pharmacy under RGUHS, Bangalore, India during 2007-2011. She is presently pursuing M.Pharm in Pharmaceutical Quality Assurance. Her areas of interest are Quality Management, Drug Regulatory Affairs, GMP Auditing.

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Nanostructured materials as drug-delivery systems

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The development of nanotechnology provides opportunities to characterize, manipulate and organize matter systematically at the nanometer scale. Biomaterials with nano-scale organizations have been used as controlled release reservoirs for delivery of drugs. Drug-delivery systems can be synthesized with controlled composition, shape, size and morphology. Their surface properties can be manipulated to increase solubility, immunocompatibility and cellular uptake. The limitations of current drug delivery systems include suboptimal bioavailability, limited effective targeting and potential cytotoxicity. Promising and versatile nano-scale drug-delivery systems include nanoparticles, nanocapsules, nanotubes, nanogels, dendrimers etc., They can be used to deliver both small-molecule drugs and various classes of biomacromolecules such as peptides, proteins, plasmid DNA and synthetic oligodeoxynucleotides. Nano-scale drug-delivery systems can be devised to tune release kinetics, to regulate biodistribution and to minimize toxic side effects, thereby enhancing the therapeutic index of a given drug. This presentation will give an overlook of different novel drug delivery systems, their current status (recent advances) and future prospects.

Keywords: Nanomaterials, biomaterials, drug delivery, nanoparticles, nanocapsules, nanotubes, nanogels, dendrimers.