Pharmaceut Reg Affairs 2012, 1:4
http://dx.doi.org/10.4172/2167-7689.S1.007

OMICS Group Conferences
Accelerating Scientific Discovery

2nd International Conference and Exhibition on
Pharmaceutical Regulatory Affairs

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

Comparitive study of generic drug registration process in EU, USA & China

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Generic drug approval is a very strenuous and complicated process in countries. It varies from country to country based on their regulations. Due to various regulations, the ICH came into picture introducing 'CTD' (common technical document) for countries which come under it. Common Technical Document provides a standardized structure for regulatory submissions that is acceptable in all ICH countries. Although the CTD makes multinational filings easier, there are significant differences in the dossier submission requirements in these countries in this study the countries which belong to ICH are US and Europe. This study deals with the differences in registration requirements for generics in European Union, United States and china Generic drugs in EU are approved under the Marketing Authorization Application and in US they are approved under the Abbreviated New Drug Application, whereas in china it is under the filing of provincial FDA. Bioavailability and Bioequivalence study data is critical in the generic drug approval process as clinical trials can be omitted. This study also deals with the few comparisons of generic drug registration requirements in these three countries. Understanding the differences in registration process will have a substantial impact on the success of its multicounty submissions strategy. Therefore, the appropriate submission strategy in advance could make a smooth review process without any significant delays or failures.

Biography

Gowtham Vajjhala has completed his B.Pharm in JSS College of pharmacy, Mysore and currently pursuing II M.Pharm – Pharmaceutical Quality Assurance in the same College (i.e.) JSS College of Pharmacy, Mysore, Karnataka. He has given many seminars and poster presentations in National and International level Symposiums.

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A review of regulatory requisites for registration process of medical devices in the regulated countries United States, Europe and Canada

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The term medical devices cover a vast range of equipment, from simple tongue depressors to haemodialysis machines. Like medicines and other health technologies, they are essential for patient care. In the light of escalating use of medical devices, stringent regulatory standards are required to ensure that the devices are safe, well studied and have least adverse reactions. Recently introduced guidelines and the amendment in the law will provide adequate guidance for both the manufacturers and competent authorities to manage cases efficiently and appropriately. A defective device may result in inaccurate patient results leading to misdiagnosis, delays in treatment, adverse events, injuries, or even death. Therefore, a thorough review of the medical device prior to being released for use by the public and effective monitoring of the medical device once placed on the market is crucial. This paper presents the regulatory requirements for medical devices in United States, European Union and Canada and also compares the regulatory requirements for the registration of the medical devices for the three countries.

Biography

G.V.S.S.N Jyothi pursuing M.Pharmacy (2nd year) with specialization in Regulatory Affairs at JSS College of Pharmacy, JSS University, Mysore. She completed B.Pharmacy in RBVRR College of Pharmacy, Hyderabad. She has published two articles titled "Non-Communicable Diseases-An Eye Opener" in FIP journal and Orphan Drug Act: History, Perspective and Challenges for Future" and prsented two posters at national level conferences.

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