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Regulatory requirements for compilation of dossier and registration of aNDA for parenterals in USA

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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.N.S. Krishna Chaitanya has completed his Bachelors in Pharmacy from JSS College of Pharmacy, Mysore. After that entered in to Sales and Marketing and was Associated with Wockhardt Health care for four months and then to Abbott Health Care in critical cardiac division as Territory Business Manager for Eight Months and Joined in Masters in Pharmacy In JSS College of Pharmacy, Mysore in Regulatory affairs group. He has attended many conferences, Presented Posters and published few Review articles in Journals.

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New drug development and approval process in US and EU

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Drug development is defined as the process of bringing new drug to the market once a lead compound has been identified through the process of drug discovery, it includes many stages such as drug discovery, preclinical research, clinical research and include the step of obtaining regulatory approval to market the drug. It takes about 15years and an average of $800million to $1.2billion to develop a drug. Drug development is a progressive elaboration firstly one should Explore whether there is a medical need for a drug, Discover the right molecule and Develop the molecule. In the process of drug development Regulatory Authorities (RA) play a very important role. Certain regulations are laid down by regulatory agencies as finally the drug or the product is used by human beings. The process by which regulatory authorities approve new drugs is different. The drug approval process for US and EU are quite different and discussed in this article. USFDA& EMA are RAs of US and EU. The submissions to both RA are different, for instance IND is submitted to USFDA and an CTA is applied to EMA to initiate the clinical trials and to market the drug one should submit NDA to USFDA and an MAA to EMA ,but in EU we can opt for different procedures they are Centralized, Decentralized, Mutual recognition Procedure& National procedures . Inspite of many differences in the approval processes the all approve drugs based on the benefit risk ratio and well being of the human beings.

Biography

Ms. Harsha Pulipati and Mr. Sunny Kumar Mamidala has completed B.pharmacy and presently pursuing their M.S. in Drug Development and Regulatory Affairs and M.S in Pharmaceutical Analysis from JNT University Hyderabad. They have presented papers at few national level pharma symposiums and has a good academic record.

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