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

Vascular targeted nanoparticles for imaging and treatment of brain tumors

Karnati Lakshmi Deepika
Gokarjau Rangaraju College of Pharmacy, India

The position of the pharmaceutical industry in the global market is not parallel as compared to other information and technology based industries. Among the Leading industries, the pharmaceutical industry far behind in the growth rate, innovative research, capital investment and government regulations are concern. Most of the countries are not focused on core research, they just depend on bulk production of the generic drugs. The pharmaceutical industries come at the 9th position while electronic & IT industry stands first in respect of growth rate. The new rule regarding the product patent had made a huge impact on growth of the pharmaceutical sector in developing country. Many of the small-scale pharmaceutical company in developing countries are either closed down or stopped their business activities in the last few years. It is due to un-favorable government policies, their inability to invest capital in research of new drugs which is essential to compete with large companies in the changing business environment. The world pharmaceuticals market is forecast to grow with 11% percent or more from until 2020 which can be increased if companies invest more in drug research sector as well promotion, shortens the period of clinical trials and specially the government has to focus more on growth of small scale sector in developing countries by liberalization of regulations and policies like exemptions in taxes and more research oriented funding to improve the future of the pharmaceutical sector globally.

karnati.deepika26@gmail.com

Good automated manufacturing practice (GAMP)

K.Vaishnavi and N.Vishal Gupta
JSS University, India

Good Automated Manufacturing Practice (GAMP) is a trademark of the International Society for Pharmaceutical Engineering (ISPE). The program suggests and specifies various procedures to be used in all aspects of pharmaceutical production to make sure the end product is of the best quality possible. The Good Automated Manufacturing Practice is Guide for Validation of Automated Systems in Pharmaceutical Manufacturing. It describes a set of principles and procedures that help to ensure that pharmaceutical products have the required quality. One of the core principles of GAMP is that quality cannot be tested into a batch of product but must be built into each stage of the manufacturing process. As a result, GAMP covers all aspects of production; from the raw materials, facility and equipment to the training and hygiene of staff. Standard operating procedures (SOPs) are essential for processes that can affect the quality of the finished product. The improved GAMP guide offers a more flexible risk based approach to compliant GxP systems based on scale able specifications and verification. The first draft was issued for comment in 1994 and since then three subsequent revisions have been published as the GAMP guide to computer and automated system validation. Each addition has built on previous version adding details of best practice as they evolve. GAMP provides a documented assurance that a system is appropriate for the intended use before it goes "live." Suppliers can use GAMP to test for avoidable defects in the supplied system to ensure quality product leaves the facility. GAMP Version 1.0 was published in 1995 with follow-on versions in 1996, 1998 and finally 2001 for GAMP Version 4, so called GAMP4. GAMP5 was launched on 28th February 2008. It is a major rewrite of GAMP4 with significant changes having primary goals like bringing procedures in line with the dynamic life science industry and reducing the cost of compliance. This is one of the best parts of the guide as it has an in-built risk assessment. GAMP5 covers all aspects of pharmaceutical production, including materials, production procedures, equipment and hygienic issues. GAMP 5 is "not a prescriptive method or standard, but rather provides pragmatic guidance, approaches and tools for the practitioners.

Biography

K. Vaishnavi is currently pursuing her 2nd year M. Pharmacy in Pharmaceutical Quality Assurance from JSS University, Mysore. She has done her graduation from Rajiv Gandhi University, Bangalore. She has attended 63rd IPC and presented a poster on "GMP- A comparison between regulated and rest of the world countries" and also attended an International conference on "Recent advances in pharmaceutical sciences" held by the Kathmandu University in Nepal and presented a poster on "Good Laboratory Practice".

kasireddy.vaishnavi6@gmail.com