Pharmaceut Reg Affairs 2012, 1:4
http://dx.doi.org/10.4172/2167-7689.S1.008

OMICS Group Conferences
Accelerating Scientific Discovery

2nd International Conference and Exhibition on
Pharmaceutical Regulatory Affairs

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

Good Automated Manufacturing Practice (GAMP)

K.Vaishnavi
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

Application of Nanoparticles in Biology and Medicine

Pavan Reddy
J.S.S University, S.S.Nagar, Mysore

Nano materials are at the leading edge of the rapidly developing field of nanotechnology. Their unique size-dependent properties make these materials superior and indispensable in many areas of human activity. This brief review tries to summarise the most recent developments in the field of applied nano materials, in particular their application in biology and medicine, and discusses their commercialisation prospects.

Biography

I Pavan Kumar Reddy studying 1st M.Pharmacy ,Industrial Pharmacy, J.S.S.CP, J.S.S University, S.S.Nagar, Mysore