Soumah A. Qutob, J Develop Drugs 2013, 2:4
http://dx.doi.org/10.4172/2329-6631.S1.004

OMICS Group Conferences
Accelerating Scientific Discovery

2nd International Summit on
GMP, GCP & Quality Control
November 12-14, 2013 DoubleTree by Hilton Hotel Chicago-North Shore, IL, USA

Quality requirements for pharmaceutical product

Soumah A. Qutob
Gulf Pharmaceutical Industries, UAE

The quality assurance of pharmaceutical products is a wide-ranging concept covering all matters that individually or collectively influence the quality of a product. It is the totality of the arrangements made to ensure that pharmaceutical products are of the quality required for their intended use.

Considerable developments in GMP have taken place in the intervening years and it has come to be realized that only controlling the quality of final products is no longer appropriate, since sampling test have statistically inherent limitation assuring the quality of pharmaceutical products and since the test items do not necessary cover all of the possible quality defects.

This presentation "Quality requirements of Pharmaceutical product" have two parts, of which part one outlines "the general concepts of cGMP" as well as the principal components or subsystems of GMP. These include hygiene, validation, self-inspection, personnel, premises, equipment, materials and documentation.

Part two outlines "the basic concepts of Bioavailability and Bioequivalence" for generic formulation. These include Bio study protocol design, study execution and results evaluation.

The focus points are regulatory requirements and quality assurance of the products to achieve the efficacy and desired safety. The approach is patient centric in each stage of production and patient safety is prime concern.

Most importantly, emerging market is place where a lot of pharmaceutical business's attraction besides a lot of changes is required in healthcare system which is extremely important for the region with special reference of all stake holders, pharmaceutical industries, healthcare & regulatory bodies and social sectors.

The cGMP regulations and other quality management systems differ fairly in organization and in certain constituent elements; however, they are very similar and share underlying principles. For example, the cGMP regulations stress quality control. More recently developed are the quality systems stress quality management, quality assurance, and the use of risk management tools in addition to quality control. The QS working group decided that it would be very useful to examine exactly how the cGMP regulations and the elements of a modern, comprehensive quality system fit together in today's manufacturing world.

Conclusion: Quality system is more comprehensive and applies throughout the different stages of product life cycle.

Biography

Soumah A. Qutob has professional experience stretched over twenty years in the field of Regulatory Affairs, Quality Assurance, inspection and administration, pharmaceuticals regulatory compliance requirements and regulations Nationally and Internationally, professional trained and certified for regulatory inspection with special reference of compliance with cGMPs, certified and recognized consultant with numerous official regulatory agencies and with several pharmaceutical manufacturers (WHO inspector) Certified pharmacist in Jordan. Sound understanding of International Regulatory Compliance (European, FDA, WHO) practical experience in managing inspection activities, reporting on compliance, investigating technical complaints, follow up on inspection compliance status both with the pharmaceutical industries and with the governmental agencies. Good interpersonal skills, excellent communication skills with sensitivity for confidential information and socio-cultural issues, strong planning skills with proven competence in establishing new processes for faster market access, Expertise in developing and implementing regulatory compliance strategies. Fluent in English (oral and written communication) and Arabic.

soumah.qutob@julphar.net