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Modern quality systems & Risk management approaches

Naveen Kumar Venkatesham

Laurus Labs Private Limited, India

Abstract

The role of Quality Assurance describes a policy, philosophy and essential elements required and to ensure the implementation of Quality Management System (QMS) at different stages during the manufacturing and testing of Pharmaceuticals Products. In 1990 International Conference on Harmonization (ICH) has evolved for Registration of Pharmaceuticals for Human Use and is unique in bringing together the regulatory authorities and pharmaceutical Industries of Europe, US and Japan, In November 2000 ICH Q 7 "Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients", was released for the implementation, WHO cGMP of APIs and EU GMP Part-II "Basic Requirements for Active Substances used as Starting Materials" are also made in line with the ICHQ7 expect Quality Risk Management. The international law of major countries became a guidance to the manufacturing industry. 21 CFR Part 210 and 211 current good manufacturing practice in manufacturing, processing, packing, or holding of drugs; general and current good manufacturing practice for finished pharmaceuticals The requirements include Quality Management, personnel, Building and facilities, Process Equipment, Documents and Records, Material Management, Production and In Process Control, Packaging and identification labelling of APIs and Intermediates, . Storage and distribution, Laboratory Controls, Validation, Change Control, Rejection and Re-use of Materials, Complaints and Recalls, Contract Manufacturers (including laboratories) Risk based Quality Management is the current Mantra of the regulators. Risk is defined as the combination of the probability of occurrence of the harm and the severity of that harm, based on the nature of the risk it can be identified as low, medium and high for severity , wherever the risk is high that shall be considered putting actions to mitigate the risk. Quality control labs involve so many potential risks during the activities they perform right from the sampling of Raw Materials, Intermediates and finished products. Analysis by handling numerous instruments. Impurities in APIs (Drug Substances) are the potential risk if exceeds the required content whether in terms of chemical, residual solvent, degradation and Genotoxic impurities, excipients in Drug products, heavy metals, These should be appropriately classified, identified, set the limits and develop the analytical methods accordingly Stability of drug substance and drug products are tested to attain a re-test/expiry date and shelf life respectively, this enable to provide the duration that the product is stable if stored with respective packing and storage conditions

Biography

Naveen has completed his Masters in Science (M.Sc) in applied Analytical Chemistry from All Indian Institute of Chemist, Kolkata and Post Graduate Diploma in Chemical Analysis and Quality Management (PGDCAQM) from Hyderabad Central University, Hyderabad. Having a rich experience of around 15 years in Quality and Regulatory has supported and faced various US, Europe and Indian MNC Customer and regulatory audits. Prior to joining Laurus, he was associated with various MNC Companies like Strides Arcolab Limited, Mylan (Matrix) Laboratories Limited and Dr. Reddys Laboratories in Quality and Support to Regulatory Functions.