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The role of "c" in cGMP

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C in cGMP denotes for current good manufacturing practices which signifies to follow current scenario in the manufacturing of pharmaceuticals. In fact, the 'prefix c' was introduced by WHO in 1992 to introduce the concept of 'Cross contamination and Sanitation' in manufacturing of Pharmaceutical industry which was not prevalent in earlier defined law/guide of FDA /EU.

The facility and instruments to be designed to fit for the intended use, the manufacturing process has to be developed and technology to be transferred to the commercial scale and need to be monitored frequently and ensure that the process is in a state of control. Quality has to be ensured for the developed manufacturing process at each and every step which has to be monitored frequently for the desired quality characteristics.

Quality Management System:

Quality management system (QMS) integrating GMP into ISO 9001: 2008 which comprises of elements through a quality manual comprises quality policy, company profile, process map, general requirements like documentation, control of documents, records, management responsibilities, quality objectives, responsibilities, authority and communication, management review, resource management, planning, design and development, purchasing process, control of production and service provision, product identification and traceability, customer property, preservation of product, control of monitoring, measuring instrument/ equipment, improvement, internal audits, control of non confirming product, corrective and preventive action (CAPA), training and statistical techniques, from a business perspective the potential benefits to all stake holders of an effective QMS may be grouped as customer focus, continuous improvement, regulatory compliance and inspection readiness, recognized best practice, reduced stress.

During the manufacturing/storage/handling of pharmaceutical products, one should ensure that there is no contamination or cross contamination through a standard sanitization and cleaning validation procedures. The products should be manufactured to avoid any planned deviations and if any unplanned deviations occur they should be thoroughly investigated for the root cause and appropriate CAPA should be prepared. Any quality failures and errors should be identified and investigated.

The manufacturing process and testing method should be developed and validated and ensure that the process and method meet the pre determined quality characteristics. Facilities, equipment and instruments should be designed and procured to meet intended purpose and need to ensure that qualification cycle is completed before releasing for the regular use.

The personnel proposed to be appointed need to qualify to fit the requirement, the personnel need to be trained/qualified for job specific and cGMP training and monitored routinely for the updates to be aware on current GMP/regulatory requirements.

Biography

Naveen Kumar Venkatesham has completed Master of 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. He has a rich experience of around 15 years in Quality and Regulatory, has supported and faced various US, Europe and Indian MNC customers 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.

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