

8th International Conference and Exhibition on

Pharmaceutical Regulatory Affairs and IPR

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Pharma Audit, GMP, GCP & Quality Control

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Pharma regulatory affairs as well as importance of ISO 9001:2015, ISO 14001:2004, ISO 18001:2007 standards and related audits for quality pharma products

Regulatory affairs related legal acts are framed in various countries across the globe to manufacture and deliver quality products. They are Drugs and Cosmetics Act 1940 and amendments in India, United States of America Food and Administration Act, European Drugs Act and Australian Drugs Act. All address about Good Manufacturing Practices (GMP) and requirements to produce quality products. All they address about location and surrounding of the factory, building requirements for production under hygienic conditions, water supply for manufacture, disposal of waste, health, clothing and sanitary requirements for the staff, medical services, working benches for manufacture, requirements of facilities and equipment's for various dosage forms (solid, liquid and semisolids), requirements of manufacturing areas and basic hygienic conditions, labelling, packaging and storage etc. All countries follow ICH guidelines regarding quality, safety and efficacy issues for easy import and export of goods among the countries. All factories should follow ISO 9001:2018 standards related to understanding of the organization and the context, developing Quality Management System (QMS), establishing quality policy, developing competency, documentation information, operational planning and control, requirements of products and services, design and development of products and services, identification and traceability, performance evaluation, internal audit, management review, non-conformity and corrective actions and continual improvement. Getting ISO 9001:2015 certificate is an added value to pharma companies to ease import and export potential of quality products. Following ISO 14001:2004 standards in pharma companies indicate that the companies carry out the processes in such a way that lesser pollutants are produced (Environmental Management System). Following quality management system as ISO 18001:2007 (ISO Standards) indicate that occupational health and safety management systems are established in the company. Following GMP guidelines and the above standards assure both regulatory affairs as well as various standards regarding quality management system, environmental management system as well as occupational health and safety management system. All will be addressed.

Biography

Manavalan R has pursued his PhD from Birla Institute of Technology and Science (BITS Pilani) Rajasthan, India. He is working as Professor and Research Director at RVS College of Pharmaceutical Sciences, Sullur, Coimbatore, Tamil Nadu which is a premier pharmacy school caters PG and Doctoral programme in Pharmacy. He has published more than 150 research papers in reputed journals. He has produced 33 PhD's in Pharmacy.

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