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The challenges in documentation and data in the global pharmaceutical sector & their impact in regulatory management

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It is very interesting to reflect up on the fact that the recent regulatory observations reveal that most of the observations were deficient of understanding and implementing of the correct documentation and quality and authenticated data collection reporting system. In every sector documentation is playing a very critical role. The criticality lies in designing, adopting, training, executing and making the people to realise their accountability and finally monitoring the effectiveness of the document. The documents are the excellent tools to control the procedures which ultimately lead to control over the quality. The consistent process control leads to the consistence in the quality of product and this is possible only through good documentation practice. Documentation play the critical role for maintaining the sustain growth in global regulatory market the Prompt, transparent and detailed technical documentation only the ultimate tool even to handle the regulatory audits. Health care industries play very critical role in the people's progress, happiness and the growth of every nation. Global regulatory requirements are changing spontaneously to strengthen the security and safety of the patients and the Small and Medium Business Units (SMBU) across the globe are continuously under pressure to execute and achieve the global regulatory requirement. The gaps between SMBU and the regulatory expectations are communication, understanding and proper execution of global regulatory agencies expectations. The quality assurance, Compliance and regulatory professionals must lead the situation in confidential manner to support the SMBU"s Growth and to sustain the global pharmaceutical business competition. In this presentation we discuss how to initiate the practice of good documentation practices. In this regard the quality of the data is also play a very critical role how we can maintain authentic, genuine and quality of data and traceability of data these are the critical things which play very important role during the handling regulatory matters.

Biography

Sudhakar Sagaram pursued his PhD in the concentration of Organic Chemistry from Gujarat University, India. He is a reputed official with extensive knowledge in Pharmaceutics and also known for scientific publishing in the respective field. It was his contemplating thought process that channeled his innovative ideas towards the integration of improved quality management systems with regulatory compliances in polymer and Pharmaceutical sectors. His area of expertise also includes certifications from the International register of certified auditors (ISRA) and International Organization for Standardization (ISO). As a credible individual, Dr. Sagaram has functioned the role of a lead auditor for a range of large-scale pharmaceutical sectors in the speciality of Quality Management Systems (QMS) of which, Orchid Chemicals and Pharmaceuticals, Hospira Healthcare, and Pfizer limited. can be referred to few of his associations, at which he contributed his skills and made sure of their accountability. As of now, he is working the position of Associated professor in the Department of Pharmacy, College of Health Science, Wollega University, Ethiopia.

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