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Abstract

The Role of Validations and Quality Management systems Related Regulatory observations in the Global Pharmaceutical sector

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Abstract:

It is very essential to reflect upon the fact that validation activities play a very important and critical role in the Pharmaceutical manufacturing sector. During the project execution the organization should pay a close attention for these activities. And there must be a Risk assessment and risk mitigation program. The Documentation of these activities must be Designed and executed properly. The review of the recent regulatory observations shows that there is a big gap in this regard which leads to the issue of the 483 observations.

Once again it is very interesting to reflect upon the fact that the number. In the GMP warning letters were increased In this presentation we are going to focus on the trends of the warning letters issued in 2018-19 and the trend of the 483 issued by the regulatory authorities.

It is very essential to reflect upon the fact that Documentation activities play a very important and play critical role in the Global Pharmaceutical manufacturing sector. Designee and execution of procedure is possible only thorough Good documentation Practice only During the Regulatory audits the presentation of Documentation roll is very critical and the organization should pay a close attention for these activities. And there must be a Risk assessment and risk mitigation program. The Documentation of these activities must be designed and executed properly.

Biography:

Dr. 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's in the respective field. His approach and ideologies to investigate the most consistent concepts of science have enabled him to initiate his career as a research scientist along with which he specialized in the field of technology transfer.

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 specialty 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 Director of training in the Department of Pharmacy, college of health science.

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