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Pharma industry and regulatory compliance:Vision for success, case studies

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Pharma industry is heavily regulated all over the world, rightly so since it deals with human lives. Need for strict regulation was realized and implemented over the world after havoc created by Thalidomide. Over a period of three decade industry has seen phenomenon change in acceptance standards of international regulatory agencies over the world. Setting up of standards for organization and preparing organization for international regulatory compliance is a big task for pharma industry who would like to be a global player in manufacturing and supply chain management of drugs and pharmaceuticals. Top management commitment is a must for excellence in quality system. Support for creating hardware is not enough, where human being plays a major role. Regulatory compliant facility must be supported by a quality system which has to be made as a culture, a way of working. Dual standards; one for the country and another for regulated market does not work. Acceptance level and ensuring adherence to controls is a task to be complied with by every individual. This presentation will cover importance of continuous training, development and monitoring at a regular interval and updating of systems. Scientific investigation of every observation in a situation and that by international regulatory agency will be presented as case studies: Non-compliance to environmental controls in a recently completed maintenance of parenteral manufacturing facility; Compliance to validation requirements in changeover to high speed operation insisted by a regulatory agency; Abnormal odour experienced in a bulk pack of anti-TB drug product supplied to international regulating agency; Role of package design and environmental control for antibiotic suspension investigation to solution; Recreating market complaint referred by importing regulatory agency; and Issue of not meeting the requirement of weight of content of capsule referred by a QP of a regulated market, etc.

Biography

P G Shrotriya has worked for over four decades in every facet of Pharma industry in India and overseas and was responsible for achieving international quality compliance and approvals for number of organizations. He has worked for number of WHO standards for drugs and pharmaceuticals. He was the Chairman for Parenteral Preparation in Indian Pharmacopoeia, Government of India and delivered several lectures at national and international levels. He is working with academic institutes and training students and professionals from industry and regulatory agencies for international regulatory compliance.

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