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Quality risk management system

In the pharmaceutical industry every product and every process is associated with risks. To maintain product quality throughout the product life cycle, too much time and resources are allocated. Risk is described in recent guidance as a combination of the probability of occurrence of harm and the severity of that harm. The Quality Risk Management (QRM) approach initiated by regulatory agencies with recognized management tools along with support of statistical tools in combination allows for a risk-based approach to quality management, thus ensuring that resources are deployed in a timely and expeditious manner to areas that need those most. QRM improves risk awareness and accelerates detection of potential issues by analyzing and comparing existing data from a quality perspective to manage product quality, manufacturing processes, validation and compliance within a risk based Quality Management System. In addition, QRM improves decision making if a quality problem arises. It should include systemic processes designated to co-ordinate, facilitate and improve science-based decision-making with respect to risk. Quality Risk Management can be applied not only in the manufacturing environment, but also in connection with pharmaceutical development and preparation of the quality part of marketing authorization dossiers. The guideline applies also to the regulatory authorities in the fields of pharmaceutical assessment of the quality part of the marketing authorization dossier, GMP inspections and the handling of suspected quality defects. ICH Q9 - Quality Risk Management provides an excellent high-level framework for the use of risk management in pharmaceutical product development and manufacturing quality decision making applications. It is a landmark document in acknowledging risk management as a standard and acceptable quality system practice to facilitate good decision-making wit h regard to risk identification, resource prioritization, and risk mitigation / elimination, as appropriate.

Biography

Rashid Mahmood has 13 years diversified experience of Quality Control, Quality Assurance, Registration Affairs, NDA, ANDA, BLA, GMP Requirements, Drugs Laws, Statistical Methodology, Method Validation, Process & Cleaning Validation, Equipment Validation, etc. Currently, he is working as a Senior Executive Manager Quality Assurance & Quality Management Representative for Surge Labs. (Manufacturer of Microencapsulated APIs, Liquid & Dry Powder Parenterals) which is the best export oriented company in Pakistan and we are the only manufacturer of microencapsulated APIs in Pakistan using European Technology and has taken over lot of Business of Ranbaxy & Ind. Swift India worldwide. We are participating as an exhibitor in all the CPhIs taking place worldwide round the year. Stancos Private Limited (Cosmetic Plant), it is the only Cosmetic plant in Pakistan which is ISO 22716:2007 GMP & ISO 9001:2008 QMS Certified by BVC and we are also exporting our cosmetic products to European countries. We are the contract manufacturer of L'OREAL Products and Sanofi famous brand (Selsun Blue Shampoo) in Pakistan.

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