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Quality risk management system

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Abstract

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 with regard to risk identification, resource prioritization, and risk mitigation / elimination, as appropriate. Quality risk management is a systematic process for the assessment, control, communication and review of risks to the quality of the product. It can be applied both proactively and retrospectively.

The quality risk management system should ensure that:

- The evaluation of the risk to quality is based on scientific knowledge, experience with the process and ultimately links to the protection of the patient.

- The level of effort, formality and documentation

Biography

Rashid Mahmood has 10 years diversified work endurance of Laboratory Management, Quality Assurance, Registration Affairs, GMP Requirements, Drugs Laws, Statistical Methodology, Method Validation, Process & Cleaning Validation, Certificate Courses on cGMP, cGLP, Process Validation, ISO/IEC 17025:2005, 14001:2004, OHSAS 18001:2007, and 9001:2008 with strong scientific, analytical, statistical, planning, managerial and training skills. Currently he is working as a Quality Manager for Surge Labs.(Pharmaceutical Plant) which is the best export oriented company in Pakistan.