QUALITY RISK MANAGEMENT SYSTEM

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ABSTRACT

In the pharmaceutical industry every product and every process 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 statistic al 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 them 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 quality risk management 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.



Recent Publications:

1. ICH Harmonized Tripartite Guideline. ICH Q9: Quality Risk Management.
2. Raschiatore, M. (2013): Pharmaceutical Product Manufacturing. In: Mollah, A.H. et al. (eds.): Risk Management Applications in Pharmaceutical and Biopharmaceutical Manufacturing. New Jersey: John Wiley & Sons Inc.
3. Lotlikar, M.V. (2013): Quality Risk Management (QRM): A Review. In: Journal of Drug Delivery & Therapeutics, Vol. 3, No. 2, pp. 149-154.
4. Hopkin, P. (2012): Fundamentals of Risk Management, 2nd edition. Great Britain, USA: Kogan Page Limited.
5. Purdy, G. (2010): ISO 31000:2009 – Setting a New Standard for Risk Management. In: Risk Analysis, Vol. 30, No. 6, pp. 881-886.



Biography

Rashid Mahmood has Master Degree in Analytical Chemistry and MS in Total Quality Management. He has 13 years of experience of Pharmaceutical Quality Operations and has attended many international conferences as a keynote speaker. He has presented various talks in USA & China on Cleaning Validation, cGMP Guidelines and Quality Risk Management.

Currently he is working as a Senior Executive Manager Quality Operations for Surge Lab.(Manufacturer of Microencapsulated APIs, Liquid & Dry Powder Parentrals) which is the best export oriented company in Pakistan.