INTRODUCTION

Pharmaceutical Industry being an important industry which is directly related to the health of people in society hence risks associated with the Pharmaceutical Industry are need to be evaluated. Every pharmaceutical product and every process has an associated risk. As per ICH Q9, Risk is defined as Combination of the probability of occurrence of harm and the severity of that harm. The word “risk” is widely used in general and technical applications with different meanings. Every product and every process has an associated risk.

Every enterprise should have a methodology for identifying and evaluating the risks it faces and it should have a process for generating intervention plans to reduce the risks to an acceptable level. This process is generally referred to as a Risk Management Plan.

The risk management is applied to different aspects of the pharmaceutical Industry. These aspects includes development, manufacturing, distribution, inspection, preparation of the quality part of the marketing authorization dossiers & handling of suspected quality defects throughout the lifecycle of the drug substance, drug product, biological, biotechnological products, raw materials, solvents, excipients, packing & labelling materials. Quality Risk Management must therefore provide an effective mechanism for identifying the risk and determining the potential harm that risk may cause to the various stakeholders such as users, (final dosage manufacturers) medical practitioners, regulators and above all, the patient.

The Quality Risk Management system should ensure that the evaluation of the risk to Quality is based on scientific knowledge, experience with the process. The level of effort, formality and documentation of the quality risk management process should be commensurate with the level of risk.
The risk to its Quality is just one component of the overall Risk. The Quality of the product should be maintained throughout the life cycle of the product.

Risk management is the process that helps to identify problems, analyze them and then to create an action plan to avoid or manage these problems. Risk characterization is used as a part of the basis for risk management decisions on appropriate measures to handle the risk. Total quality Management is defined as an integrated organizational effort designed to improve quality at every level. Total quality Management is also defined as quest of excellence, fitness for use, value for money, customer satisfaction etc. The International Organization for Standards (ISO) defines Total quality Management as “Total quality Management is a management approach for an organization, centred on quality, based on participation of all its members of the organization and to society.

Quality Risk Management is a systemic process for the assessment, control, communication & review of Risk to the Quality of the medicinal product.

G.- Claycamp, FDA, June 2006
The risk management program consists of four major components: risk assessment, risk control, risk review, and risk communication. All four components are essential. Team selection and method selection are also plays a vital role in the risk management process.  

To make risk-based decisions, a systematic approach is essential. The ICH Q9 guideline, Quality Risk Management, provides a structure to initiate and follow a risk management process. The following methods widely used in the industry for risk management.

- Basic risk management facilitation methods (flowcharts, check sheets, etc.)
- Failure Mode Effects Analysis (FMEA)
- Failure Mode, Effects, and Criticality Analysis (FMECA)
- Fault Tree Analysis (FTA)
- Hazard Analysis and Critical Control Points (HACCP)
- Hazard Operability Analysis (HAZOP)
- Preliminary Hazard Analysis (PHA)
- Risk ranking and filtering
- Supporting statistical tools

In most countries compliance with good manufacturing practices, drug regulatory activities and inspections together provide good assurance that risks are largely controlled. However, in countries where control is less effective, patients may be put at risk through the production of drugs of inadequate quality. The assessment of individual risks related to specific products and starting materials and the recognition of hazards at specific stages of production or distribution should permit regulatory authorities to improve control of medicines by increasing the effectiveness of their activities within the limits of the available resources.

The use of a risk-based approach provides a consistent method for decision making which was easily associated with resource allocation and ensuring patient safety.
Ultimately, applying risk management to pharmaceutical industry should reduce the number of threats or minimize their impact through the consistent use of the tools/methods and periodic review. The output of the risk management supports to the organization to meets the defined goals.