POLICY ON QUALITY RISK ASSESSMENT

INTRODUCTION:

This document provides a policy for quality risk management which defines the principles and stages of quality risk management that can enable more effective and consistent risk-based decisions.

SCOPE:

This policy applies to different aspects of pharmaceutical quality throughout the life cycle of drug substance and drug products. Applicable to product, processes and services.

POLICY DETAILS:

Principles of Quality Risk Management:

Two primary principles of quality risk management are:

• The evaluation of the risk to quality shall be based on scientific knowledge and ultimately link to the protection of the patient; and

• The level of effort, formality and documentation of the quality risk management process shall be commensurate with the level of risk.

RESPONSIBILITIES:

- Responsibilities of Quality risk management activities should be usually, but not always, undertaken by interdisciplinary teams. Team shall include experts from the appropriate areas (e.g., quality unit, business development, engineering, regulatory affairs, production operations, sales and marketing, legal, statistics and clinical) in addition to individuals who are knowledgeable about the quality risk management process.
- Responsibility for coordinating quality risk management across various functions and departments of their organization shall be defined.
- It shall be assured that a quality risk management process is defined, deployed and reviewed and that adequate resources are available.
- Quality risk management shall be a systematic process designed to co-ordinate facilitate and improve science-based decision making with respect to risk.
- Methodology for quality risk management shall be as defined in ICH Q9 “Quality Risk Management”.
- There shall be written procedures to provide guidance on the principles and some of the tools of quality risk management that shall enable effective and consistent risk-based decisions.
- FMEA or FMECA or HACCP or any other tool shall be deployed for risk assessment.

Quality Risk Management shall be performed in 4 stages:

- Risk Assessment (Risk Identification and initiating a quality risk management process)
- Risk Control (Risk reduction and acceptance)
- Risk communication
- Risk Review

Risk Assessment (Risk Identification and initiating a quality risk management process): All the steps involved in a process / product / service which is subject to risk assessment shall undergo a risk identification.
The identified risk shall be assessed for acceptability.

Risk Control: A quantitative assessment of identified hazards or risks shall be made for the risk estimation. Risk reduction plan shall be clearly defined for mitigation or avoidance of quality risk when it exceeds a specified (acceptable) level. Where risks cannot be reduced, operational controls shall be in place and routinely monitored.
Risk acceptance shall be signed off before initiation of the activity.

Risk Communication: The result of the quality risk management process shall be documented and appropriately communicated to applicable stakeholders through Risk Communication.

Risk Review: Risk assessment document shall be reviewed periodically and/or whenever a major change is made in the system.

AMENDMENT AND WAIVER:
The company reserves the right to amend, alter and/or terminate this policy at any time.

DEFINITION:
QUALITY RISK MANAGEMENT:
A systematic process for the assessment, control, communication and review of risks to the quality of the drug (medicinal) product across the product lifecycle.

RISK:
The combination of the probability of occurrence of harm and the severity of that harm.

SEVERITY:
A measure of the possible consequences of a hazard and other stakeholders.

RISK IDENTIFICATION:
The systematic use of information to identify potential sources of harm (hazards) referring to the risk question or problem description.

RISK ASSESSMENT:
A systematic process of organizing information to support a risk decision to be made within a risk management process. It consists of the identification of hazards and the analysis and evaluation of risks associated with exposure to those hazards.

RISK COMMUNICATION:
The sharing of information about risk and risk management between the decision maker

RISK CONTROL:
Actions implementing risk management decisions.

RISK ACCEPTANCE:
The decision to accept risk.

RISK REVIEW:
Review or monitoring of output/results of the risk management process considering (if appropriate) new knowledge and experience about the risk.

ABBREVIATIONS:

FMEA	:	Failure Mode and Effects Analysis
FMECA	:	Failure mode, effects and criticality analysis
HACCP	:	Hazard analysis & critical control points
ICH	:	The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use
TRS	:	Technical Report Series
WHO	:	World Health Organization

REFERENCE:
ICH Q9 Quality Risk Management
WHO guidelines on Quality Risk Management TRS 981, Annex 2.