

POLICY ON MANAGEMENT CONTROLS

INTRODUCTION:

This document provides policy for establishing management controls.

SCOPE:

This policy is applicable to all and its associates sites.

POLICY DETAILS:

- ✧ Management shall ensure that an effective quality system is in place to achieve quality objectives.
- ✧ Management shall participate in design, implementation, monitoring and maintenance of effective quality system.shall drive its quality through a defined 'Quality Policy'.
- ✧ Quality manual shall be established to contain the description of pharmaceutical quality system.
- ✧ Quality manual shall be approved by Corporate Quality Assurance and the frequency of its review shall be defined.
- ✧ Senior management shall ensure the quality objectives as defined in quality manual needed to implement the quality policy are defined and communicated.
- ✧ Management shall provide the required resources, knowledge and training to achieve the quality objective.
- ✧ KPI's shall be defined in quality metrics which shall measure the performance of unit/function. These should be documented in form of score cards.
- ✧ Quality metrics shall be used as tool to keep the management informed on the sites performance and the requirement on improvement.
- ✧ Management review shall be conducted at various levels within, shall be chaired by Senior Management and shall facilitate continuous improvement.
- ✧ Escalation mechanism shall be in place to raise quality issues to the appropriate levels of management.
- ✧ There shall be a procedure for 'Rapid Alert Notification' to the management, which shall be raised to communicate/report emergencies associated with quality of products.
- ✧ Senior Management of Quality shall review the organizations 'Quality Management System' at planned intervals, to ensure its continuing suitability, adequacy, effectiveness and encourage on continuous improvements.

AMENDMENT AND WAIVER:

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

DEFINITION:

Senior Management: Persons who direct and control a company or site at the highest levels with the authority and responsibility to mobilise resources within the company or site.

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ABBREVIATIONS:

KPI : Key performance indicator

REFERENCES:

ICH Q 10 : International conference on harmonisation, pharmaceutical quality system.