

POLICY ON ESCALATION OF CRITICAL NON-CONFORMANCES

INTRODUCTION:

This document provides a policy for escalation of critical non-conformances to the Senior Quality Management Team.

SCOPE:

Applicable to all manufacturing sites for critical non-conformances observed during product manufacturing; testing and post marketing surveillance.

POLICY DETAILS:

- 1.1 A notification in the form of daily dashboard comprising of critical non-conformances/incidents occurred across all manufacturing sites shall be shared with Senior Quality Management team by respective site QA head. This team comprises of President - Global Quality and direct reports - L1 group (Level 1).
- 1.2 The critical non-conformance includes but is not limited to critical complaints logged, update of critical complaints logged in the last 48 hours, overdue critical complaints, new OOS logged, number of confirmed OOS, critical deviations, stability OOS's for commercial product, critical observation during regulatory inspections, safety incidents, etc. Additionally, any other non-conformance which has direct impact on patient health and safety.
- 1.3 The data shall be obtained from internal systems not limited to automated systems, including LIMS, SAP, TrackWise, etc. (as applicable).
- 1.4 The initial notification shall be sent to senior quality management by respective site QA head within 1 working day of identification of critical non-conformance, as per rapid alert notification process.
- 1.5 For any clarification or more information on any non-conformance, the responsible unit team shall be contacted.
- 1.6 The Senior Quality Management team shall review the notification and discuss the further action plans with respective site quality and operation heads.
- 1.7 Follow-up notification shall be sent based on further action/ resolution made as per 'rapid alert notification' process.

AMENDMENT AND WAIVER:

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

DEFINITION: Not Applicable

ABBREVIATIONS:

LIMS: Laboratory Information Management system

OOS: Out of Specification

SAP: Systems, Applications & Products in Data Processing system

USA: United States of America

REFERENCES:

SOP: Rapid alert notification