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VIII. PURPOSE

Establish a risk-based instruction to evaluate and investigate major, moderate and minor incidents including deviations, out of specifications, non-conformances, etc. according to the Quality System Regulations and the ISO standards.

Moreover, it provides the requirements to assign responsibilities for identification, containment, damage control, correction, documentation, and disposition of any incident to prevent its future occurrences.

Finally, this procedure is intended to provide and describe the steps for the initiation and handling of the investigation process, the criteria and requirements to determine the effectiveness of the implemented actions and the QA approval requirements for the closure.

IX. SCOPE

This procedure applies to any incident observed, that may affect adversely the people, premises, processes, products and procedures (or paperwork).

It includes the communication of the corrective and preventive action activities to the responsible people. In addition, to provide relevant information for management review of reportable and recurrent incidents.

VI. REFERENCES AND RELATED DOCUMENTS

Reference Description
The Guidance for Industry Quality Systems Approach to Pharmaceutical CGMP Regulations
PART 820 -- Quality System Regulation. Subpart J--Corrective and Preventive Action, Sec. 820.100 Corrective and Preventive Action.
FDA Corrective and Preventive Actions (CAPA) https://www.fda.gov/medical-devices/postmarket-requirements-devices/quality-system-qs-regulationmedical-device-good-manufacturing-practices https://www.fda.gov/files/drugs/published/Overview-of-Quality-System-Regulation.pdf

VII. DEFINITIONS

Term Name	Terms Description'
ALARP	As Low As Reasonably Practical- Term used to classify a risk condition that is moderate or medium.
CAPA Project–	Investigation where an actual or potentials risk to Health, Regulatory Compliance or Business is identified.
CAPA Review Board - CRB	It is the multidisciplinary team (including QA department) responsible to evaluate and approve major and serious deviations.
Containment Actions	Actions taken to segregate and control suspect product until product is dispositioned. Containment may include product holds, supplier containment, line shutdowns, quarantines, etc.
Correction Action	Action taken to rectify a detected non-conformance, as repair, rework or adjustment. It is more related to the disposition and more immediate remediation of an existing non-conformance.
Corrective Actions	Action taken to eliminate the causes of an existing non-conformance, defect, or other undesirable situation to prevent recurrence. It is more related to the elimination of its causes.
Corrective and Preventive Action (CAPA)	It is the investigation requested by the QSR quality system regulations to collects, analyzes, identifies and investigates product and quality non conformances, and take appropriate and effective corrective and preventive action to prevent their recurrence.
Deviation	A deviation is a departure from the expected results, promoting a non-conforming material or processes, or where there have been unusual or unexplained events which have the potential to impact on product quality, system integrity or personal safety. It is an event that is against a written instruction or specification, like: standard operating procedures, protocols, manufacturing instructions, company polices, test method, etc. Exist two types of deviations: Planned and Unplanned.
Incident	Event that is against the GMP Good Manufacturing Practices or can affect the people, premises, processes,

Term Name	Terms Description'
	products and procedures (or paperwork)
Incident Owner	The person responsible to make and lead the investigation, implement the actions and completes all requirements/steps according to the action plan.
Incident Project Team Leader	The person responsible to coordinate, facilitate, supervise and review the implementation, it documentation, conclusions and closing the investigation while ensuring that all requirements are fulfilled completely.
Initial Corrective Action –	Those actions that impact the root cause immediately, but are not sustainable over the long-term.
Major or Critical Deviation	Deviation from Company Standards, and/or current regulatory expectations that provide immediate and significant risk to product quality, patient safety or data integrity, or a combination /repetition of major deficiencies that indicate a critical failure of systems
Moderate or Serious Deviation	Deviation from Company Standards and/or current regulatory expectations that provide a potentially significant risk to product quality, patient safety or data integrity, or could potentially result in significant observations from a regulatory agency, or a combination /repetition of “other” deficiencies that indicate a failure of system(s).
Minor or Standard Deviation	Observations of a less serious or isolated nature that are not deemed Critical or Major, but require correction, or suggestions given on how to improve systems or procedures that may be compliant, but would benefit from improvement (e.g. incorrect data entry).
Non-Conformance (NC)	An event that deviates from an expected result, written procedure, established process, approved instruction or specification.
Nonconformance Report (NCR):	A document used to capture information in response to a nonconformance event.
Non-Conformity	It is an observation that is contrary to a standard or requirement. Non-fulfillment of a requirement related to an intended or specified use. The acronym used in this procedure is NC.

Term Name	Terms Description'
Permanent Corrective Action	Actions that permanently remove the root cause of the problem or address the root cause for escape.
Planned Deviation	A deviation or change to test methods, laboratory or manufacturing procedures that has been planned and approved as part of temporary change.
Preventive Action	Action taken to eliminate the cause of a potential non-conformity, defect, or other undesirable situation in order to prevent occurrence.
Priority Level –	It establishes level action a high, medium or low.
Root Cause Level I	The cause that directly leads to a problem or cause a problem to occur.
Root Cause Level II	A cause that do not directly create the problem; but may trigger it, by means of the cause-and-effect relationship that ultimately leads to the creation of the problem, usually related to systemic (also known as cause for escape). Also, known as an indirect cause.
Verification of Effectiveness	It is the final check in the problem-solving process. After the solution has been implemented, this verification must take place to ensure and confirm that the root cause level I or level II has been addressed and the problem eliminated.
Unplanned Deviation	A deviation or change to test methods, laboratory or manufacturing procedures that was unplanned and was the result of an incident or error.

VIII. INVESTIGATION RESPONSIBILITIES

Investigation Initiator	**Responsibilities**
CAPA Specialist or RA/QA Management	Recognizes adverse situation, notifies and request the investigation number.
	Initiates investigation documenting the Investigation Request when an incident is observed.
	Identify the investigation owner or the personnel responsible to manage the documentation and action plan.
	Shall be independent of the issues and activities being addressed in the CAPA's. Shall have the authority to reject any actions and escalate those to management which are not compliant to the requirements in this procedure. Shall be knowledgeable of : a. Effective risk assessment, b. Problem solving activities, c. Proper documentation. Should review CAPA's for completeness, consistency and accuracy.
	Should be able to provide assistance, coaching and mentoring for other persons who are involved in CAPA activities.
	Should review CAPA records for consistent and proper documentation.
	Shall has the authority to cancel a record that had been saved/opened in the system and/or reopen a closed record.
Investigation Owner	**Responsibilities**
CAPA Owner or Project Team Leader(s)	Assumes responsibility for timely completion of the investigation.
	Assign additional task owners as necessary.
	Give follow up to corrective actions and ensure the compliance with expected completion dates.
	Provide status updates
	Identifies root cause.
	Submit corrective action list for approval before execution of items.
	Shall have the authority and responsibility for leading the activities

	of the CAPA Project Plan.
	Shall ensure that all requirements of documentation, actions regarding the CAPA Project are completed, due dates are met and drives the CAPA project to completion.
	Shall be knowledgeable of: a. Project Management; (Team Leader) b. Effective risk assessment; c. Problem solving activities; d. Proper documentation; e Products, processes or systems, which need to be improved.
	Submit investigation report for approval.
Management	Responsibilities
QA Management Representative or CAPA Review Board (CRB)	Decide about if an investigation project needs to be opened, according to the risk results.
	The person responsible to assign the investigation number and has the control of the investigation log and registration process.
	For opened investigation projects, assigning a priority for CAPA projects. Assigning the CAPA Project Team Leader; Ensuring the required resources. Monitor and Review active CAPA projects. Monitor and control the efficiency and effectiveness of the CAPA system itself. For any other issues which are escalated. Document and maintain records of attendance and meeting minutes (actions items, owner, due dates, etc.) which will be reviewed at the next CRB meeting.
	Makes final review, disposition and approval of the investigation.
	Review investigation for compliance and accuracy.
	Trending of investigations
	Review the investigation report and request changes to owner if necessary.
	Verify and confirm the effectiveness of the actions to solve and prevent the occurrence of the situation in the future. Approve investigation conclusions.
	Document and approves closure of the investigation.

IX.WORK FLOW DIAGRAM