XX

Handling of Incidents

Standard Operating Procedure

Description	Prepared By	Reviewed By	Approved By
Department	Quality Assurance	Quality Assurance	Quality Assurance
Sign			
Date			

Standard Operating Procedure: Handling of Incidents

Overview

Purpose

This document describes the procedure for handling of incidents, from incident identification, notification, impact assessments, investigation, corrective action and preventive action (CAPA), documentation, review, approvals, closure to trending.

Applicability

This Standard Operating Procedure (SOP) is applicable to all units of XX's located in India.

Out of scope

This SOP is not applicable for handling of the following:

- Out of Specification
- Out of Trends
- Complaints
- Product recalls
- Documentation errors that can be corrected as per the defined procedure
- Any other Quality Management System aspect having defined procedure.

References

This SOP references the following documents:

Document No. (Current Version)	Title
GQA008	Quality Management Review
GQA033	Investigation Methodologies
GQA010	Quality Defect Notification

Flowchart

Refer Annexure GQA032/A01 for Flow Chart on Handling of Incidents.

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Overview, Continued

Annexures This document contains the following annexures:

Annexure no.	Details/Title	Format No. (Current Version)
GQA032/A01	Process Flow Chart – Handling of Incidents	NA
GQA032/A02	Examples of Incidents	NA
GQA032/A03	Incident Report	GQA032/F01
GQA032/A04	Initial Impact Assessment Report	GQA032/F02
GQA032/A05	Investigation report	GQA032/F03
GQA032/A06	Incident investigation extension request and status report	GQA032/F04
GQA032/A07	Incident Log	GQA032/F05

Contents

Section A: The Overall Flow

Overview

Introduction

This section of the document discusses the

- personnel involved during incident management and their responsibilities
- four categories of incidents, and
- overview of how an incident is managed.

Contents

The topics discussed in this section are listed below:

Roles and Responsibilities

Responsibilities

The table below lists the responsibilities of the personnel or department involved during the handling of incidents:

Role	Responsibility
All employees involved in cGMP activities	Report any incident upon identification, in a timely manner, to the Head of the Department (HOD) or designee.
• Business Unit (BU) Quality Head, or • Designee	Review and approve the investigation reports of category 3.
Central Investigation Team (CIT)	Support the site investigation team by involving Subject Matter Experts (SME) to identify the root cause and determine the CAPA.
• Cluster Quality Head, or • Designee	Approve the investigation report as per the applicable category of the incident.
• HOD, or • Designee of Concerned departments	Ensure adherence to all relevant requirements, from incident reporting to CAPA effectiveness check, as mentioned in this SOP.
Incident originator (Initiator)	• Log the incident through SAP, along with the supporting documents. • Notify HOD and Plant QA.
• Plant QA Head, or • Designee	• Confirm incident categorization and review. • Approve the initial impact assessment and necessity for an investigation. • Approve investigations according to the incident category, extension requests, product disposition and closure of the incidents. • Verify the effectiveness of CAPA.
Site Investigation Team (SIT)	• Investigate to identify the root cause and determine the CAPA. • Prepare the investigation report in a timely manner.

Categories of Incidents

Incident categories

The table below lists the incident categories:

If an incident…	And…	Then categorize it as…
does not impact the product quality, safety and efficacy	does not require an investigation	**1A.**
	requires an investigation	**1B.**
impact the • product quality, safety or efficacy • a critical process parameter, or • an equipment or instrument critical for a process or control	not likely the patients	**2.**
	impact to the patients is highly probable, and includes a life threatening situation	**3.**

Note: *Refer to Annexure GQA032/A02 for examples of incidents under each category.*

Handling of Incidents: The Flow

The flow The following activities occur when handling incidents:

Stage	Who	Does What
1	Originator	Identify an incident.
2	Originator	• Log the incident with supporting documents through SAP. • Categorize the incident. • Report the incident to HOD or Designee. • Notify the Plant QA.
3	Originator	• Assess the initial impact. • Prepare an Initial Impact Assessment (IIA) Report. • Send the report to HOD for review.
4	HOD, or Designee	Reviews the IIA Report.
5	Plant QA Head, or Designee	• Confirm the incident categorization. • Approve the initial impact assessment report. • Review the incident and assign an action plan.
6	Plant Quality Head Cluster Quality Head BU Quality Head	Process as follows: **When handling incidents of category...** / **Then follow directions given at...** 1A – Handling Category 1A Incidents. 1B – Handling Category 1B Incidents. 2 – Handling Category 2 Incidents.

***Note**: Refer Annexure GQA032/A01 for Flow Chart on Handling of Incidents.*

Section B: Identifying and Logging the Incident and Assigning an Action Plan

Overview

Introduction

This section explains how to

- identify and log an incident
- assess and report the initial impact, and
- review and assign an action plan.

Contents

The table below lists the topics discussed in this section:

Identifying and Logging an Incident

Timeline

Handle within 24 hours of its identification.

Approval

PQA Head or Designee.

Document Required

The table below provides the document required while identifying and logging an incident:

Document	Generated Through SAP	Prescribed Format in Annexure	Uploaded To SAP
Incident report	Yes	GQA032/A03 in case of manual reporting	NA

Identifying the incident

Do as follows when an incident occurs or you become aware of one:

Step	Action
1	Inform your HOD of the incident within the first 24 hours.
2	Do as follows: **If you...** / **Then ...** do have access to the documents → • take immediate action to correct it, and • inform your HOD again. do not have access to the documents → notify it to the higher level of supervision documentation and further action.

Note: *Refer Annexure GQA032/A01 for an overview of incident handling.*

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Identifying and Logging an Incident, Continued

Information to log

Log the following information for every incident:

- The incident's relation to equipment, material, process/product etc.
- Time and place of occurrence.
- The extent of the incident (i.e., identification of all potentially impacted lot/batch numbers, equipment or utilities).
- Any immediate correction done.
- Justification to continue manufacturing (including any interim controls as applicable).
- Interim controls made: with clear scope and timeline for use.

Note: *Refer annexure GQA032/A03 for the format of incident report.*

Logging all incidents

Log all incidents, with the corrective/immediate action preformed, within the first 24 hours:

Step	Action
1	• Categorize the incident based on the impact. Refer to Categories of Incidents. • Seek inputs from Quality Assurance for categorization of the incident, if required.
2	Record the actual, complete and accurate information of the incident (available at the time of logging) along with its category.

Assessing, Reporting and Approving the Initial Impact

Timeline

Handle within 3 calendar days from the date of logging of the incident.

Approval

PQA Head or Designee.

Document required

The table below provides the document required while assessing and reporting the incident and approving the initial impact:

Document	Generated Through SAP	Prescribed Format in Annexure	Uploaded To SAP
Initial impact assessment report	NA	GQA032/A04	Yes

Contents of the IIA Report

Include the following in the IIA Report:

- Details of applicable information as mentioned in Information to log.
- Impact of the incident on other areas/systems/other sites.
- Product distribution in the field.
- Possible and/or probable causes for the identified incident.
- Recurrence of the incident based on historical data for at least last 12 months.
- Requirement for communication to internal and/or external stake holders (which may include communication to a site or customer i.e., API Customer, Drug Product Customer, as per a Quality agreement, if applicable).
- Summary of the investigation, action taken and other relevant information for the recurring incidents.
- Impact on other batches, processes, procedures, other sites, products already in the market, regulatory filings, vendor qualification etc.
- Verification of the containment action.
- Verification and justification for the categorization as described at Incident categories.

Note: *Refer annexure GQA032/A04 for the format of the IIA Report.*

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Assessing, Reporting and Approving the Initial Impact, Continued

Assessing the initial impact

The following activities occur when assessing the initial impact of an incident:

Stage	Who	Does What
1	Originator	• Conduct an initial impact assessment. • Prepare an Initial Impact Assessment (IIA) Report within three (3) calendar days. • Send it to HOD for review and approval.
2	Concerned Department QA	• Review the initial impact assessment. • Approve it.
3	HOD Designee	• Review the IIA Report. • Forward it to the Plant QA.

Note: *For incidents that require submission of filed alert report/notification to the regulatory agencies, use SOP GQA010.*

Approving the IIA Report

As a member of QA, do the following when approving an IIA Report:

Step	Action
1	Verify the following: • category of the incident • authenticity and accuracy of the information, and • supporting data.
2	Is the category appropriate? • If yes, go to Step 3. • If no, – assign an appropriate category, and – return to Step 1.
3	Approve the report.

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Assessing, Reporting and Approving the Initial Impact, Continued

Reviewing and assigning

Do the following when reviewing the incident and assigning an action plan for it:

Step	Action
1	• Review the incident. • Determine the investigation requirements based on the recommended category. • Assign the tasks.
2	Evaluate the following requirements based on the initial impact assessment, historical check and incident category: • **Field Alert Report** (applies to US registered drug product only) or QP (Qualified person)/equivalent regulatory notification • **Medical Assessment** considering the impact of the incident on the distributed product
3	Escalate the requirement to BU Quality head and Global Quality head for taking appropriate decision and an action plan.

Section C: Handling the Different Categories

Overview

Introduction

This section explains how to handle each of the four categories of incidents.

Contents

The table below lists the topics discussed in this section:

Handling Category 1A Incidents

Timeline: Correction and closure of the incident

Handle within 10 calendar days from the date of logging of incident.

Approval

The approvals required for handling the category 1A incidents are listed below:

Process/Activity	Approved By
Correcting the incident	PQA Head or Designee
Closing the incident	PQA Head or Designee
Cancelling a record	PQA Head or Designee

Documents required

The category 1A incidents require the following document:

Document	Generated Through SAP	Prescribed Format in Annexure	Uploaded To SAP
• CAPA • Effectiveness check plan	Yes	NA	NA
Incident Log	Yes	GQA032/A07	NA

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Handling Category 1A Incidents, Continued

Correcting and closing the incident

The following activities occur when handling the category 1A incidents:

Stage	Who	Does What
1	• Concerned Department • Plant QA	Correct the incident.
2	Originator	Submit documents (upload in SAP) for the incident as an objective evidence for the completion of correction.
3	Plant QA or Designee	• Close the Incident. • Check the CAPA implementation and its effectiveness.

Handling Category 1B Incidents

Timeline

The table below lists the timeline for each process or activity while handling the category 1B incidents:

Process/Activity	Handle Within
Approving the investigation report	15 calendar days from the date of logging of incident.
Requesting an extension	On or prior to the due date of the closure date of incident..
Submitting the Status report	Every 15 days until the extended due date

Approval

The approvals required for handling the category 1B incidents are listed below:

Process/Activity	Approved By
Submitting the Investigation Report	PQA Head or Designee
Correcting the incident	PQA Head or Designee
• First request for an extension • First status report	PQA Head or Designee
• Second request for an extension • Second status report	Cluster Quality Head or Designee
Cancelling a record	PQA Head or Designee
Closing the incident	PQA Head or Designee

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Handling Category 1B Incidents, Continued

Documents required

The category 1B incidents require the following documents:

Document	Generated Through SAP	Prescribed Format in Annexure	Uploaded To SAP
Investigation report	NA	GQA032/A05	Yes
• CAPA • Effectiveness check plan	Yes	NA	NA
• Incident investigation extension request • Status Report	NA	GQA032/A06	Yes
Incident Log	Yes	GQA032/A07	NA
Supporting documents	NA	NA	Yes
Addendum ***Note:*** *Applicable only in case of availability of additional information after closure of incident.*	NA	NA	Yes

Investigating and correcting the incident

The following activities occur when correcting the category 1B incidents:

Stage	Who	Does What
1	• Concerned Department • Plant QA	Correct the incident.
2	Originator	Submit documents (upload in SAP) for the incident as an objective evidence for the completion of correction.
3	Plant QA or Designee	• Approve the investigation report and CAPA. • Close the Incident. • Check the CAPA implementation and its effectiveness.

Handling Category 2 Incidents

Timeline

The table below lists the timeline for handling each process/activity while handling a category 2 incident:

Process/Activity	Handle Within
Approving the investigation report	40 calendar days from the date of logging of incident.
Requesting an extension	On or prior to the due date of the closure date of incident.
Submitting the status report	Every 30 days until the extended due date.
Closure of the incident	40 calendar days from the date of logging the incident.

Approval

The approvals required while handling the category 2 incidents are listed below:

Process/Activity	Approved By
Submitting the investigation report	Cluster Quality Head or Designee
• First request for an extension • First status report	PQA Head or Designee
• Second request for an extension • Second status report	Cluster Quality Head or Designee
Correcting the incident	PQA Head or Designee
Closing the incident	PQA Head or Designee
Cancelling a record	Cluster Quality Head or Designee

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Handling Category 2 Incidents, Continued

Documents required

The category 2 incidents require the following documents:

Document	Generated Through SAP	Prescribed Format in Annexure	Uploaded To SAP
Investigation report	NA	GQA032/A05	Yes
• CAPA • Effectiveness check plan	Yes	NA	NA
• Incident investigation extension request • Status Report	NA	GQA032/A06	Yes
Incident Log	Yes	GQA032/A07	NA
Supporting documents	NA	NA	Yes
Addendum ***Note:*** *Applicable only in case of availability of additional information after closure of incident.*	NA	NA	Yes

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Handling Category 2 Incidents, Continued

Investigating and correcting the incident

The following activities occur while handling the category 2 incidents:

Stage	Who	Does What
1	SIT	Investigate the incident.
2	SIT	Identify the root cause. Is the root cause identified? • If yes, go to Stage 4. • If no, involve the CIT.
3	• SIT • CIT	Conduct further investigation.
4	SIT	• Prepare the investigation report. • Send it to Cluster Quality Head for approval.
5	Cluster Quality Head	Approve the investigation report.
6	Cluster/Plant QA Head	• Require any product disposal? If yes, dispose the product as described at Disposing the Product and Closing the Incident. • Assign the CAPA task.
7	Plant QA Head or Designee	• Close the incident. • Check for CAPA implementation and effectiveness.

Handling Category 3 Incidents

Timeline

Handle each process/activity during a category 3 incident within the timelines mentioned in the table below:

Process/Activity	Handle Within
Approving the investigation report	40 calendar days from the date of logging of incident.
Requesting an extension	On or prior to the due date of the closure date of incident.
Submitting the status report	Every 30 days until the extended due date.
Closing the incident	40 calendar days from the date of logging of incident.

Approval

The table below lists the approval matrix of various activities associated with a category 3 incident:

Process/Activity	Approved By
Correcting the incident	PQA Head or Designee
Investigation Report	BU Quality Head or Designee
Closing the incident	PQA Head or Designee
• First request for an extension • First status report	Cluster Quality Head or Designee
• Second request for an extension • Second status report	BU Quality Head or Designee
Cancelling a record	BU Quality Head or Designee

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Handling Category 3 Incidents, Continued

Documents required

The category 3 incidents require the documents listed below:

Document	Generated Through SAP	Prescribed Format in Annexure	Uploaded To SAP
Investigation report	NA	GQA032/A05	Yes
• CAPA • Effectiveness check plan	Yes	NA	NA
• Incident investigation extension request • Status Report	NA	GQA032/A06	Yes
Incident Log	Yes	GQA032/A07	NA
Supporting documents	NA	NA	Yes
Addendum ***Note:*** *Applicable only in case of availability of additional information after closure of incident.*	NA	NA	Yes

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Handling Category 3 Incidents, Continued

Investigating and correcting the incident

The following activities occur when correcting the Category 3 incidents:

Stage	Who	Does What
1	SIT	Investigate the incident.
2	CIT	• Review the incident. • Conduct further investigation.
3	SIT	• Prepare the investigation report. • Send it to the CU Quality Head.
4	BU Quality Head	Approve the investigation report.
5	Cluster/Plant QA Head	• Require any product disposal? If yes, dispose the product as described at Disposing the Product and Closing the Incident. • Assign the CAPA task.
6	Plant QA Head or Designee	• Close the incident. • Check for CAPA implementation and effectiveness.

Section D: Guidelines for the Main Activities

Overview

Introduction

This section describes the following:

- how to
  - investigate an incident
  - report the incident
  - dispose and close an incident, and
  - implement CAPA and check its effectiveness, and
- what to do when incidents require an IT intervention.

Contents

The table below lists the topics discussed in this section:

Investigating the Incident

Investigation methodology

Refer SOP GQA033 for methodology for conducting the investigation.

Modifying the incident's category

Modify the incident's category during the investigation based on the

- progress of the investigation, and
- availability of more information about the incident.

Under such circumstances, the timeline for completing the investigation will be as per the timeline of the re-assigned category, from the date of logging of the incident.

Additional investigation time

Make an extension request, on or before the closure date, for an additional time required, if any, for completing the investigation.

Extension Report

Use annexure GQA032/A06 preparing the extension report. Send it the QA for approval.

Number and duration of extensions

Use the table below for the extension allowed for different categories of incidents:

Category	Maximum number of extensions allowed	Preferred duration for each extension*
1B	2	15
2 and 3	2	30

Note: *Justify, appropriately, any extension beyond the specified duration.*

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Investigating the Incident, Continued

Details of an extension request

An extension request has the following details:

- Progress to date and any actions taken
- Justification/rationale for the extension
- Justification on continuation of the manufacturing (including any interim controls as applicable)
- Risk to the product/process due to extension
- Other relevant issues affecting investigations

Reporting the Incident

Contents of the investigation report

The investigation report contains the following in clear, succinct, logical terms and using the good documentation practices:

- Requirement of the report
- Conclusion of the investigation (including supporting data and trends)
- Root cause analysis (RCA)
- Affected systems and/or lack of systems
- Impact assessment
- Impact or relation to other related processes, sites, products, equipment, procedures, etc. (as necessary)
- CAPA addressing the root cause
- Target date/time allotted for implementation of each CAPA
- CAPA effectiveness plan

Addendum to the investigation report

Create addendums when there is additional information available after the closure of the incident. Include the following details in the addendum:

- Reference of the incident report number
- The reason/requirement for the addendum
- Scope of the additional information
- A statement indicating whether there is any impact to the product due to additional information.

Notes:

- *If there is an impact due to the addendum, escalate it.*
- *Do not use the addendum for recurring, similar incidents after the closure of the incident. Handle them as new incidents.*

Interim investigation report

If needed, prepare the interim investigation report as follows:

- Title it as "Interim Investigation Report" – No._01, 02, etc.
- Refer it in the main document.
- Attach it to the "Investigation Report".
- Refer annexure GQA032/A05.

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Reporting the Incident, Continued

Preparing an investigation report

The following activities occur while preparing the investigation report:

Stage	Who	Does What
1	SIT	• Prepare the investigation report containing the relevant details, from the day of the notification to the conclusion. • Send it to HOD or Designee for review. ***Note:*** *Refer annexure GQA032/A05.*
2	HOD or Designee	• Review the investigation report. • Send it to the appropriate QA Personnel for review depending upon the incident category.
3	QA Personnel	• Verify the investigation report using the details mentioned at When approving an investigation report. • Approve it.

When approving an investigation report

Look for the following in the investigation report:

- Performed and documented impact assessment
- Impact on other related processes, sites, products, equipment, procedures, etc. (as necessary)
- Contents of the investigation report include the
  - requirement
  - documented conclusion of investigation with supporting data and trends
  - Performed Root Cause Analysis (RCA)
  - Addressed systems affected or lack of systems

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Reporting the Incident, Continued

When approving an investigation report, continued

- CAPA
  - addresses the root cause stated
  - has target date/time allotted for implementation of each
  - is adequate and feasible
  - the effectiveness plan is adequate
  - the timeline is justified, and
  - clear, succinct, logical documentation written as per good documentation practices.

Disposing the Product and Closing the Incident

Disposing the product

Dispose the product as per the established batch/product release procedures.

Closing the incident

Check for the following while closing the incident:

- Approved investigation report
- CAPA and effectiveness check plan (as applicable)
- CAPA task with appropriate timeline
- Appropriate decision on product disposition based on the investigation outcome
- All supporting documents/objective evidences available and uploaded
- Clear, succinct, logical documentation and written as per good documentation practices.

Before releasing the product

Ensure the following before releasing the product impacted:

- Identify and implement all required actions
- Verify the closure of all associated incidents.
- Released the impacted batches with the concurrence from the customer (for e.g. contract manufacturing), as per the specific requirements mentioned in the respective quality agreement.

Implementing CAPA and Checking Its Effectiveness

Implementing CAPA

The responsible personnel implement CAPA within the target completion dates assigned. They submit/upload the objective evidences for the implementation.

Checking the CAPA effectiveness

The following activities occur while checking the effectiveness of CAPA implemented:

Stage	Who	Does What
1	HOD or Designee	• Adopt the specific methodology to perform the effectiveness check as defined in the effectiveness check plan. • Upload all objective evidences in support of the effectiveness check performance
2	Plant QA Head or Designee	Verify the effectiveness check. **When the effectiveness check is...** / **Then ...** satisfactory / close the task. not satisfactory / Go back to the CAPA.

Incidents Requiring an IT Intervention

IT intervention

Do as follows for incidents requiring an IT intervention:

Step	Action
1	• Notify the IT department, or • Raise an IT Ticket.
2	Seek support from the IT team for • the investigation (wherever applicable) related to the IT aspects, and • an investigation report along with CAPA.
3	Attach, to the incident report, the • reference of IT ticket number, and/or • investigation report.

Section E: Other Related Activities

Overview

Introduction

This section describes

- when and how to track and trend incidents,
- what to do with the incident reports during the management review meetings
- when to cancel incident records, and
- when not to use the Incident Management System.

Contents

The table below lists the topics discussed in this section:

Tracking Trending and Reviewing the Incidents

Tracking and trending incidents

The PQA does as follows:

Step	Action	Timeline
1	Track the incident for its • investigations • CAPAs, and • CAPA effectiveness for use in applicable periodic reviews.	Once a month.
2	• Trend it to understand the trends. • Review it for use in the applicable review meetings. • Include, if applicable, the – repeat incidents – number of incidents in each category, and – differential trending with respect to the root cause identified.	Quarterly

Reviewing in the Management Review Meetings

Conduct reviews in the Management Review Meetings as part of quality management reviews per SOP No. GQA008 to

- provide the appropriate governance and accountability, and
- disseminate information to the organizational functions related to the nonconforming product or quality problems.

Cancelling Incident Records

Guidelines for cancelling the records

If the cancellation of a record is necessary, ensure the following:

- Provide a clear justification. Document it.
- The PQA Head, Cluster QA Head or BU Quality Head or their Designees provide the decision for the record to be cancelled based on the category of incident.

Examples

Following are some examples illustrating where a record can be cancelled (this is not an all-inclusive list):

- **Duplicate record:** Provide the details for initiating more than one applicable record.
- **Incorrect initiation** (such as market complaint registered as an incident): Provide the details for the reason leading to error in initiating.

Exceptions to the Incident Management System (SAP)

Documenting incidents without the IT (SAP) application

If the IT application is not available,

- use the forms/attachments defined in this procedure to temporarily document incidents, and
- log the information into the IT Incident Management System (SAP) as soon as it is available for use; state the rationale for using the forms/attachments for incident management.

Exceptions for electronic recording of batch execution

If the batch execution is through an electronic system such as a Manufacturing Execution system, do as follows:

- Capture the exception in the respective batch record with the details.
- Document the reason for exception along with correction details in concurrence with QA.
- Log the exceptions having an impact on the product quality, safety and/or efficacy as an incident.
- Review, monthly, the summary of exceptions in the quality review meetings.

Section F: Abbreviations and Glossary

Overview

Introduction

This section lists the abbreviations and the definitions of the terms used in this document.

Contents

The table below lists the topics discussed in this section:

Abbreviations

Full forms

The table below lists the abbreviations used in this document and their full forms:

Abbreviation	Full Form
API	Active Pharmaceutical Ingredient
BU	Business Unit
CAPA	Corrective Action and Preventive Action
cGMP	Current Good Manufacturing Practices
CIT	Central Investigation Team
CTO	Chemical Technical Operations
FTO	Formulation Technical Operations
GMP	Good Manufacturing Practice
HOD	Head of the Department
IIA	Impact Investigation Report
IT	Information Technology
NA	Not applicable
PQA	Plant Quality Assurance
QA	Quality Assurance
QP	Qualified Person
RCA	Root Cause Analysis
SAP	Systems, Applications, Products in data processing
SIT	Site Investigation Team
SME	Subject Matter Experts

Glossary

Terms and definitions

The table below lists the terms used in this document and their definitions:

Term	Definition
Approval of a record	A statement that the record • has been reviewed for technical and compliance integrity, and • is complete, thorough, clear, and concise.
Central Investigation Team	A team of subject matter experts (manufacturing, analytical quality, engineering and microbiology) involved in effective investigation.
Containment	• The action of assuring that all material that is potentially affected by an incident is withheld from release/further distribution, pending completion of an investigation or impact assessment. • Includes actions taken to immediately stop further occurrences of the unexpected incident.
Corrections	Repair, rework, reprocess, or adjustment relating to the disposition of an existing discrepancy.
Corrective Action	Actions taken to • eliminate the causes of a detected non-conformity or other undesirable situation, and • prevent the recurrence of an existing nonconformity.
Effectiveness check	An action taken to verify that the expected results of the CAPA are achieved and prevent the occurrence or recurrence of the incident.
Immediate action	• Action taken immediately to – salvage a situation, and – prevent the non-conformity to spread further. • May involve some corrections.
Impact Assessment	An assessment to evaluate the impact of an incident on other batches, processes, procedures, other sites, products already in the market, patient safety, regulatory filing, vendor qualification etc.

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Glossary, Continued

Terms and definitions, continued

Term	Definition
Incident	An unplanned occurrence where the actual outcome is different from the expected outcome, resulting in a nonconformity and/or an uncontrolled event in the form of departure from an approved system or procedures.
Incident Management System	An IT or manual system (i.e., logbooks/databases) used to record, document and manage incidents, investigations, corrections and CAPAs.
Incident observer/Identifier	An employee who • observes/identifies an incident, and • may inform the supervisor/HOD or record the incident (originator).
Incident Originator (Initiator)	An employee who documents the description of an incident in the associated record.
Investigation	A documented analysis conducted to discover the facts and clues in order to determine the root cause.
Manufacturing Execution System	A system that is equipped with an inbuilt facility to generate or log exceptions (in the event of departure from defined design/operating requirements of batch record system) on real time basis.
Non-conformity	Non-fulfilment of an established requirement.
Preventive Action	Actions taken to prevent an occurrence of a potential nonconformity or other undesirable potential situation.
Recurrence	A repeat incident that is same or similar in nature.
Site Investigation Team	A team of subject experts who operate at the site level for an investigation of incidents of all categories.