**Document approval**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Name** | **Date** | **Signature** |
| **Author’s designation****{{ QualityDesignee2 }}** |  |  |  |
| **Reviewer’s designation****{{ QualityDesignee1 }}** |  |  |  |
| **Approver’s designation****{{ QualityOrganizationHead }}** |  |  |  |

|  |  |
| --- | --- |
| **Effective Date** | **{{ EffectiveDate }}** |

**Table of Contents**

[1 Purpose 3](#_Toc125736884)

[2 Scope 3](#_Toc125736885)

[3 Responsibilities 3](#_Toc125736886)

[4 Definitions, terms, and abbreviations 4](#_Toc125736887)

[5 Workflow 5](#_Toc125736888)

[5.1 Complaint maintenance 5](#_Toc125736889)

[5.1.1 Acceptance of Complaint 5](#_Toc125736890)

[5.1.2 Investigation of Complaint 6](#_Toc125736891)

[5.1.3 Complaint investigation results reporting 7](#_Toc125736892)

[5.2 Product Recall 8](#_Toc125736893)

[5.2.1 Quality Defects Classification 8](#_Toc125736894)

[5.2.2 Recall Levels 9](#_Toc125736895)

[5.2.3 Recall process 10](#_Toc125736896)

[5.2.4 Mock Recall trials 11](#_Toc125736897)

[6 Applicable documents 12](#_Toc125736898)

[7 Appendices 12](#_Toc125736899)

[8 Document revision history 12](#_Toc125736900)

# Purpose

The purpose of this Standard Operating Procedure (SOP) is to provide a guideline for handling and management of Complaints related to the quality of a medicinal productor distribution operations and for the handling of products Recall.

# Scope

This SOP is valid at {{ CompanyName }} for the whole Organization. The respective training shall be given in accordance with **{{ TrainingCode }} {{ TrainingTitle }}**.

This SOP is applicable for all oral and written Complaints received, and for the prompt and effective Recall of products known or suspected to be defective.

This SOP is not applicable for processing cases related to adverse events and pharmacovigilance processes.

# Responsibilities

Responsible for the content of this SOP is {{ QualityOrganizationHead }}.

| **Role** | **Definition/Task** |
| --- | --- |
| All employees | * Acceptance and conveying of any product quality Complaints to the Quality Organization within twenty-four (24) hours.
 |
| Quality Organization | * conducts {{ ComplaintPrelimAssess }}
* initiates Complaint investigation
* maintains {{ ComplaintsLog }}
* organizes, facilitates, and supports the investigation of Complaints
* prepares, distributes, agrees, {{ Complaint\_Investigation\_Plan }}
* coordinates, and takes an active part in Complaint investigating
* collects, reviews, and provides investigation-supportive data and documents
* maintains List of {{ RCC\_Members }}
* stores records and other documents related to Complaints investigations, Recalls, Mock Recalls
 |
| Subject Matter Experts (SMEs) | * take an active part in Complaints investigating
* collects, reviews, and provides investigation-supportive data and documents
* investigate potential defect root case
* assess the risk and Qualify Defect classification
* propose CAPA measures to eliminate the product defect associated with the Complaint
* prepare {{ Complaint\_Investigation\_Report }}
 |
| Marketing Department | * sends formal Complaint response to the Customer
 |
| Operation Department, specifically the Warehouse and Supply Team | * takes an active part in Complaints investigating
* collects, reviews, and provides investigation-supportive data and documents
* determines product distribution chain, and provides product Complaint distribution records and other related data for any investigation, Recall, and Mock Recall purposes
* sends {{ Recall\_Statement }} to all identified clients for the particular product distribution chain
* monitors on daily basis Recall steps performance and updates product Recall status
 |
| {{ QualityOrganizationHead }} | * approves {{ ComplaintPrelimAssess }}, {{ Complaint\_Investigation\_Plan }}, {{ Complaint\_Investigation\_Report }}
* appoints {{ RCC\_Members }}
* acts as Recall Coordinator or appointed employee in this role
* shares investigation and other related data as required by any authority/Contract Giver/Qualified Person etc.
 |
| Recall Coordinator (RC) | * Organizes, coordinates, supports, and facilitates, all Recall activities and Mock Recalls
* monitors product Recall status and Mock Recall status
* prepares {{ Recall\_Statement }}, {{ Recall\_Report }} drafts.
* Initiates rapid alert notifications, if required
* Defines Mock Recall design and its legend (class, depth, particular batch numbers, etc.)
 |
| {{ RCC\_Members }} | * decide on the need for a Recall, determine Quality Defect Class, depth, and all necessary actions related to the Recall
* review, approve {{ Recall\_Statement }}
* reviews, approve {{ Recall\_Report }}
* allocate required resources, if needed.
 |

# Definitions, terms, and abbreviations

| **Term/abbreviation** | **Definition at {{ CompanyName }}** |
| --- | --- |
| Adverse drug experience (ADE) | Any adverse experience associated with the use of a drug product in humans, whether or not considered drug-related, includes the following:* adverse experience occurring from the use of a drug product in professional practice,
* adverse experience occurring from drug overdose whether accidental or intentional,
* adverse experience occurring from drug abuse,
* adverse experience occurring from drug withdrawal,
* any failure of expected pharmacological action.
 |
| Class 1 Quality Defect | Quality Defect is potentially life-threatening and could pose a serious health risk. |
| Class 2 Quality Defect | Quality Defect may result in illness or inappropriate treatment and does not come under Class 1. |
| Class 3 Quality Defect | Quality Defect does not pose a significant health risk (Recall not essential). |
| CRN | Complaint Reference Number |
| MAH | Marketing Authorization Holder |
| RCC | Recall Coordinator Comittee |
| WSC | Warehouse and Supply Chain (WSC) |

# Workflow

## Complaint maintenance

### Acceptance of Complaint

The process is initiated with the receipt of a Complaint. A Complaint may be received from consumers, healthcare professionals, government / regulatory agencies, trade sources, or from any other source, in any form (written or verbal, post, fax, email, or through the website and social networks).

A distinction should be made between complaints related to the quality of a medicinal product and those related to distribution. In the event of a complaint about the quality of a medicinal product and a potential product defect, the manufacturer and/or marketing authorization holder should be informed without delay. Any product distribution complaint should be thoroughly investigated to identify the origin of or reason for the complaint.

Complaints are taken by all employees and conveyed to Quality Organization within twenty-four (24) hours. The employee must request all relevant information about the product under Complaint from the Customer, i.e.:

* name of the product,
* size/strength of package,
* lot/batch number,
* manufacturing date,
* expiry date,
* description of Complaint,
* product packaging details
* product samples availability for return, and complainant contact details.

The employee who receives the Complaint fills out the **{{ ComplaintNotification }} Form** and sends it to Quality Organization.

Quality Organization representative reviews completeness of **{{ ComplaintNotification }}** record and assigns Complaint Reference Number (CRN) number.

Further CRN numbering assignment principle is applied as follows:

MC-YY-ZZZ

where MC stands for Market Complaint, and YY stands for the last two digits of the year. 23 for 2023 and 24 for 2024 and so on, ZZZ stands for Serial number starting from 001 for each calendar year.

The first Complaint for the year 2023 shall be numbered MC-23-001 and for the year 2024 shall be numbered MC-24-001, and so on.

Quality Organization logs all received Complaints into **{{ ComplaintsLog }}** according to **{{ ComplaintsLog }} Form**, whether they are justified or not.

Quality Organization conducts a preliminary assessment according to **{{ ComplaintPrelimAssess }} Form** within twenty-four (24) hours. {{ QualityOrganizationHead }} approves **{{ ComplaintPrelimAssess }}** and preliminary proposalsfor the furtheraction plan**.**

The purposes of preliminary assessment are:

* Complaint categorization,
* decide whether the Complaint is justified or not,
* determine a preliminary action plan,
* decision for further Complaint investigation.

The Complaint may be dismissed, and the procedure completed if there are compelling reasons for doing so.

### Investigation of Complaint

{{ CompanyName }} initiates investigation only for complaints related to distribution operations. In case of complaint about the quality of a medicinal product and a potential product defect, {{ CompanyName }} informs the manufacturer and/or marketing authorization and/or importer without delay according to mutual quality agreements.

When **{{ ComplaintPrelimAssess }}** is done and Quality Organization confirms the founded Complaint, Quality Organization initiates a Complaint investigation. Investigation scope and goals shall be formalized according to **{{ Complaint\_Investigation\_Plan }} Form**. For purposes of the investigation, Subject Matter Experts (SMEs) from different departments may be involved, depending on the areas and scope of the investigation. If necessary, internal communication should be held with all stakeholders to discuss and agree on **{{ Complaint\_Investigation\_Plan }}**.

The most important objectives of the investigation are:

* identification of Root Cause,
* risk assessment, measure risk level,
* determine the real size of the problem (particular batch/lot, tray of batches/lots),
* take immediate actions to isolate the problem and mitigate the associated risks.

Quality Organization prepares and distributes proposed **{{ Complaint\_Investigation\_Plan }}** to all involved Departments within twenty-four (24) hours.

Department Heads or designated SMEs shall apply and review **{{ Complaint\_Investigation\_Plan }}**.

All rational and reasonable proposals shall be discussed and agreed upon. Any additional activities and actions that have arisen since the approval of the **{{ Complaint\_Investigation\_Plan }}** must be reflected in the **{{ Complaint\_Investigation\_Report }}**.

All involved Departments and SMEs are responsible for investigating the Complaint according to **{{ Complaint\_Investigation\_Plan }}**. All time delays and other problems shall be communicated and approved by Quality Organization prior.

**Appropriate containment measures (quarantine) should be taken if current risks to the product are identified.**

The Complaint case is investigated by Quality Organization and Operations Department. This may include the following points:

* visual examination of the Complaint sample,
* comparison with previous, similar Complaints,
* resulting Corrective Actions and Preventive Actions (CAPAs), if applicable,
* further measures which may help to clarify the respective facts,
* reasoning or investigation of the cause.

### Complaint investigation results reporting

Any Operational Complaint received shall be closed within thirty (30) days after receiving the Complaint.

When **{{ Complaint\_Investigation\_Plan }}** was realized, associated Root Cause Analysis and CAPA measures, and associated risks were defined, SMEs finalize **{{ Complaint\_Investigation\_Report }}** **{{ Complaint\_Investigation\_Report }} Form**. Affected Departments Heads review **{{ Complaint\_Investigation\_Report }}** and{{ QualityOrganizationHead }} approves final **{{ Complaint\_Investigation\_Report }}.**

All defined CAPA measures are carried out in accordance with **{{ CAPA\_Code }} {{ CAPA\_Title }}**.

The Operations Department sends the Customer a formal Complaint response in three (3) days. This response shall contain the company’s decisions regarding:

* decision for Complaint foundation (founded or unfounded),
* proposed corrections and resolutions.

## Product Recall

{{ CompanyName }} facilitates and supports any Recall decisions made by product owner or regulatory body according to mutual or legal public obligations.

{{ CompanyName }} It promptly provides any information and data related to the recalled product (distribution protocols, current product stocks / disposition) and also performs related activities such as quarantine, returns in accordance with obligations.

### Recall process

#### Assembling Recall Management Team

{{ QualityOrganizationHead }} shall designate Recall Coordinator and {{ RCC\_Members }}. {{ RCC\_Members }} shall represent the organization’s key functions and stakeholders such as: Quality Organization, Operations, Legal. All Recall Coordinator Committee (RCC) members shall be listed in the actual list **{{ RCC\_Members }}** according to **{{ RCC\_Members }} Form.**

#### Recall initiation

Product Recall might be initiated by:

* Manufacturer/MAH/Importer/product owner
* local or overseas health authorities, or from information received directly from such authorities

The Recall Coordinator ({{ QualityOrganizationHead }} or designated person in this role) organizes and coordinates all Recall activities. If there is a need to initiate a Recall, Recall Coordinator arranges a meeting of the RCC immediately.

RCC shall decide

* what are the Recalled products (lots/batches),
* what are the Recall related actions,
* who shall be notified and how,
* what information should be collected, reviewed, provided, if requested

After discussion and assessment, RCC Members approve **{{ Recall\_Statement }}** according to **{{ Recall\_Statement }} Form**.

#### Recall Notification

The Operation Department sends approved **{{ Recall\_Statement }}** to all identified Customers for the particular product distribution chain. The product distribution chain is determined based on the product distribution records. Operational Department shall provide to Recall Coordinator and {{ RCC\_Members }} product related distribution records summary for all affected products and Customer contact details.

Distribution records shall contain further sufficient Customer information:

* addresses
* phone and/or fax numbers inside and outside working hours
* product Lots/Batches numbers
* delivered product amounts/dates

#### Recall performance

Recall Coordinator monitors Recall performance and status for each particular product distribution chain. Recall Coordinator this status daily until its completion and reporting. If there are difficulties or delays in providing information or taking any actions by distribution stakeholders, Recall Coordinator escalates this to {{ RCC\_Members }} for appropriate decision-making.

#### Recall completion and reporting

After Recall completion, Recall Coordinator prepares a **{{ Recall\_Report }}** according to **{{ Recall\_Report }} Form**. {{ RCC\_Members }} review, discuss and approve final **{{ Recall\_Report }}.** Other forms and formats of reports may also be used in accordance with the requirements of suppliers and health authorities.

The **{{ Recall\_Report }}** shall be supported by appropriate evidence (communication evidence, stock transactions, disposal/destruction records, distribution records, etc.). Full product reconciliation shall be done and explained in the report.

In case of Deviations, or Nonconformities detected during Recall execution, process participants shall follow **{{ DevMng\_Code }} {{ DevMng\_Title }} and {{ CAPA\_Code }} {{ CAPA\_Title }}**.

### Mock Recall trials

This test shall be carried out once a year and cover both within office-hour situations as well as after-hours office situations.

If any product is Recalled as per the above-mentioned procedure in the current year, there is no need to carry out Mock Recalls as the effectiveness of the arrangements of the Recall procedure shall be established from the records of the actual Recalled product.

Recall Coordinator plans and organizes annual Mock Recall. Recall Coordinator shall select any batch of any product that should be a fast-moving item with the farthest distribution chain. The Wholesale level of Recall shall be assigned. The batch selected shall have been distributed.

This exercise shall be performed only to verify the effectiveness of the Recall, but an actual product Recall will not be performed. All affected Customers, Clients and other stakeholders shall be informed that it is not a real Recall, but a mock Recall process intended for the evaluation of the Recall system.

The Mock Recall is considered successful if all the records are accurate and the tracing back to the stock level is completed.

After completion of Mock Recall, Recall Coordinator shall circulate the **{{ Recall\_Report }}** to {{ RCC\_Members }} for review and assessment.

In case of Deviations, or Nonconformity detected during Recall execution, process participants shall follow **{{ DevMng\_Code }} {{ DevMng\_Title }} and {{ CAPA\_Code }} {{ CAPA\_Title }}**.

Mock Recall outputs shall be taken into consideration during **{{ ManagementReviewTitle }}.**

# Applicable documents

{{ DocMngmtCode }} {{ DocMngmtTitle }}

{{ ManagementReviewCode }} {{ ManagementReviewTitle }}

{{ DevMng\_Code }} {{ DevMng\_Title }}

{{ CAPA\_Code }} {{ CAPA\_Title }}

{{ QRM\_Code }} {{ QRM\_Title }}

{{ TrainingCode }} {{ TrainingTitle }}

# Appendices

The following appendices are an integral part of this SOP:

Appendix {{ ComplaintNotification }} Form

Appendix {{ ComplaintsLog }} Form

Appendix {{ ComplaintPrelimAssess }} Form

Appendix {{ Complaint\_Investigation\_Plan }} Form

Appendix {{ Complaint\_Investigation\_Report }} Form

Appendix {{ RCC\_Members }} Form

Appendix {{ Recall\_Statement }} Form

Appendix {{ Recall\_Report }} Form

# Document revision history

|  |  |  |  |
| --- | --- | --- | --- |
| **Version** | **Valid from** | **Description of the revision** | **Reason for the revision** |
| 1 | See header | Document created | QMS implementation |