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## Procedure

### 1. Batch Record Comments

#### 1.1. Definition

Batch record comment is a minor event, which is something that is expected to occur, is usually isolated to a single batch, the cause is known with certainty, no follow-up action is required and is non-recurring within a short period of time. For example line stoppages at certain time, etc.

#### 1.2. Timelines

Batch Record comments must be documented immediately when event occurs.

#### 1.3. Investigation Steps

Define the problem, be specific about who, what, when, where, how and why

#### 1.4. Reporting

1.4.1. Batch Record Comments must be documented within the comments section of the Manufacturing Instruction Sheet.

1.4.2. Batch Record Comments are reviewed by a Quality Assurance Staff at the time of batch record review for batch release.

### 2. Deviation Report (DR)

#### 2.1. Definition

Deviation Report is a documentation system for recording, investigating and analysing of materials and processes that do not comply with in-house requirements and are raised for events that require investigation. DRs are relatively minor, usually isolated events or deviations from agreed/approved procedures or processes that usually result in rapid implementation of corrective action and are unlikely to have any impact on product quality, safety or efficacy. DRs are also raised for serious and standard audit observations.

#### 2.2. Timelines

2.2.1. A Deviation Report (DR) should be documented within a maximum of 2 working days from the event being observed and submitted to QA Management Review.

2.2.2. A Deviation Report (DR) should be analysed, appropriate follow-up actions defined. Management response tasks should be completed within 5 working days, if possible.

 

- Quality Aspects such as product safety and integrity, product purity and efficacy, product stability, customer perception and potential complaints.
- Regulatory Aspects such as deviations from product registration commitments.
- Compliance Aspects such as violation of cGMPs, or deviations from revalidation / re-qualification requirements.

3.3.8. Develop corrective/preventive actions (CAPA); determine need for new data.

- Develop corrective actions to support affected batch or batches. Corrective actions relating to batch disposition are documented in the Management Response Tasks of the DR (i.e. confirm rejection of the batch).
- Develop preventive actions to avoid recurrence.
- Corrective and preventive actions must be monitored to completion.
- All other Corrective actions and Preventive actions are documented in the follow up tasks of the DR and tracked to completion as per section 3.2.7 of this SOP.

3.3.9. Document and approve.

3.3.10. Track actions to completion.

3.3.11. Trend causes – add all the investigation outcomes including the root cause/s, corrective and preventive actions on a spreadsheet for the current year to facilitate in trending the repetitive issues.

### 3.4. Reporting

3.4.1. The report must be documented on Incident/Investigation Report Form **Form-455.**

3.4.2. The report must be organised, detailed, include all attachments and be written for the outside reader.

3.4.3. The report should include the following:

- Data in tables or traceability matrix where applicable. It should avoid checklist approach.
- A brief description of process/testing and identify materials used in batch.
- Problem description, problem discovery (who, what, when, where, why, how) and include test specifications for each pertinent test result.
- Documentation of each probable cause.
- Documentation of the investigation findings relative to each probable cause.
- Evaluation of each probable cause.
- Elaboration on actual or suspect causes(s).
- Documentation of the logic used, cite the data being used.
- Evaluation and documentation of whether other batches are potentially involved.
- Provision of the rationale for investigation conclusions.
- Corrective and preventive actions; short term, long term, global

 

# Deviation Report Form

(Ref. SOP QMS-035; MAN-080)

| **DR Number:** | **DRX-YYYY** | **Priority** | |
|---|---|---|---|

| Author (Reported by) | | Date Reported | | Area/Team Responsible | |
|---|---|---|---|---|---|
| **DR Type:** (fill in applicable information) | | | | | |
| **DR5 Customer Complaint Deviation** | | | | | |
| Customer No.: | | Delivery Doc. No.: | | | |
| Sales Order No.: | | Customer Material No.: | | | |
| Sold to Party No: | | | | | |
| **DR8 Material Complaint Deviation** | | | | | |
| Vendor No. or Vendor Name: | | Purchasing Doc. Number: | | | |
| Material Doc. No.: | | Vendors Material No.: | | | |
| **DR1 Process / Procedural Deviation** | | | | | |
| Product code: | | Equipment No. | | | |
| MI Sheet No.: | | Batch (BPN): | | | |
| **DR4 Audit Deviation** | | | | | |
| Audit Ref. No. | | Audit Type | | | |
| **DR2 EHS Deviation** | | | | | |
| **Deviation Title** | | | | | |
| **Description (Must be filled in for all deviation types)** | | | | | |

 

Incident / Investigation Report (Ref. SOP QMS120)
Report No. – YY-INI-XXX or YY-INV-XXX

| DR Number: |
|---|

## Investigation Type

*This should list the type of investigation (eg. Process Failure, Operator Error, etc.).*

## Executive Summary

*The executive summary should contain a brief description of the event, root cause found during the investigation and a final summary on product disposition.*

| Name (Position) | Signature | Date |
|---|---|---|
| **Prepared by:** | | |
| **Checked by:** | | |
| **Authorised by:** | | |
| **Approved by:** | | |

 

# Incident / Investigation Report (Ref. SOP QMS120)

Report No. – YY-INI-XXX or YY-INV-XXX

| DR Number: |
|---|

### 9.1. Attachment – Summary of Investigation Tasks

| **Task Description** | Responsible | Date Due | Date Completed |
|---|---|---|---|
| *Enter tasks here* | | | |
| | | | |
| | | | |

### 9.2. Attachment – Summary of Corrective Actions Tasks

| **Task Description** | Responsible | Date Due | Date Completed |
|---|---|---|---|
| *Enter tasks here* | | | |
| | | | |
| | | | |

### 9.3. Attachment – Summary of Preventative Actions Tasks

| **Task Description** | Responsible | Date Due | Date Completed |
|---|---|---|---|
| *Enter tasks here* | | | |
| | | | |
| | | | |

**Note: Batch release may occur prior to the preventative items being completed**

Attachment - Investigation meeting minutes

### 9.4. Meeting Minutes

If there are multiple meetings or discussions these should be listed on this page

### 9.5. Attachment - Supporting batch documentation

### 9.6. Attachment – Deviation Report/s

If there are multiple DR associated with this event then these should be listed on this page.

### 9.7. Attachment - Supporting Batch Documentation / Log Books

If there are exerts from the batch documentation or copies of log book pages associated with this event then these should be listed on this page.

### 9.8. Attachment - Supporting Facilities Data

 