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:

Index

Incident / Investigation Report (Ref. SOP QMS120)

Report No. – YY-INI-XXX or YY-INV-XXX

DR Number:

1.0 Event

Description of event and details to be added here.

Process Line(s), Product Name(s), Product Code(s) and Batch No.(s) to be added here.

Initial Scope of the investigation and any immediate action/segregation/blocking of stock for sale should be listed here.

2.0 Batch Chronology

This table is an example of events that may need to be documented in a batch investigation chronology. Table can be customised (or even omitted) to fit the sequence of events in an investigation.

Date (dd/mm/yyyy)	Time (24 hrs)	Description
dd/mm/yyyy	00:00	Example – Batch planned / scheduled
dd/mm/yyyy	00:00	Example – Batch commenced filling
	00:30	Example – Shipper No at time of event
	05:00	Example – Line Clearance performed after event
	06:00	Example – DR raised at this point

3.0 Suspect Causes and Rationales

No.	Cause Description	Primary / Contributing / Unlikely
3.1	**Enter suspect cause here**	**Choose one type from above**
	Rationale: This is where you enter your rationale as to why a suspect cause is likely to be correct or why you have discounted this particular cause	

Incident / Investigation Report (Ref. SOP QMS120)

Report No. – YY-INI-XXX or YY-INV-XXX

DR Number:	

3.2	Enter suspect cause here	Primary / Contributing / Unlikely
	Rationale: This is where you enter your rationale as to why a suspect cause is likely to be correct or why you have discounted this particular cause	

3.3	Enter suspect cause here	Primary / Contributing / Unlikely
	Rationale: This is where you enter your rationale as to why a suspect cause is likely to be correct or why you have discounted this particular cause	

4.0 Corrective and Preventive actions to be taken

State corrective and preventive actions, which need to be taken and the reasoning behind decisions made.

5.0 Risk Analysis – Potential impact on other processes

Here is where you outline whether this event could have an impact on any other equipment or processes and your rational as to why you have made this conclusion.

You should also explore whether this is a repeat event or the first time this has occurred.

6.0 Product Disposition

6.1 Product made prior to the event

Here is where you outline the risk assessment and impact to product made prior to the event and rationale as to why it is either acceptable or not.

6.2 Product made during the event

DR Number:

Here is where you outline the risk assessment and impact to product made during the event and rationale as to why it is either acceptable or not.

6.3 Product made after the event

Here is where you outline the risk assessment and impact to product made after the event and rationale as to why it is either acceptable or not.

7.0 Summary

Here is where you write your conclusion to the investigation, you must summarise the overall root cause found during the investigation, the impact on this batch and any other batches and the overall batch disposition.

7.1 Root Cause

State the root cause or suspect cause if root cause was not determined.

7.2 Repeat Event

State if a similar event occurred in the last 12 months and DR reference.

7.3 Batch Disposition

State final batch disposition and reasoning behind the decision.

7.4 Impact on other batches / processes

State if other batches/processes are impacted and reasoning behind the decision.

Incident / Investigation Report (Ref. SOP QMS120)

Report No. – YY-INI-XXX or YY-INV-XXX

DR Number:

8.0 List of Attachments

Brief list of attachments to be added here

8.1.1 Attachment – Summary of Investigation Tasks

Task Description	Responsible	Date Due	Date Completed
Enter tasks here			

8.1.2 Attachment – Summary of Corrective Actions Tasks

Task Description	Responsible	Date Due	Date Completed
Enter tasks here			

8.1.3 Attachment – Summary of Preventative Actions Tasks

Task Description	Responsible	Date Due	Date Completed
Enter tasks here			

Incident / Investigation Report (Ref. SOP QMS120)

Report No. – YY-INI-XXX or YY-INV-XXX

DR Number:

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

8.2 Attachment - Investigation meeting minutes

8.2.1 Meeting Minutes

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

8.3 Attachment - Supporting batch documentation

8.3.1 Attachment – Deviation Report/s

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

8.3.2 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.

8.3.4 Attachment - Supporting Facilities Data

List copies of in-process checks printed from the production lines.

8.3.5 Attachment - Supporting Analytical Data

Copies of Analytical data associated with this event.

8.3.6 Attachment – Validation Data

Copies of Validation data associated with this event.

8.4 Attachment - Evidence of actions completed

8.4.2 Attachment - Employee Awareness Forms

Employees counselled as a result of this event should sign a form to say that they understand the nature of their involvement and be filed behind this attachment.

8.4.3 Attachment - SOP Updates

Evidence of critical updates to SOPs to be filed behind this attachment.

8.4.4 Attachment - Training / Assessment Updates

Evidence of critical updates to training and assessment be filed behind this attachment.