



Process Data Collection Form

(Ref. SOP QMS-055)

Insert Picture (if any) of Complaint here if required.

Complaint Reference Number: XXX-YYY-ZZ-AA

QA staff investigating complaint- Write short Description of Complaint and any specific questions to be answered by line manager.

PART ONE: CAUSALITY INVESTIGATION (To be done by authorised production person)

Logbooks, Maintenance, DRs and MI Sheets.
(Print/Photocopy relevant documentation and attach)

- Have the Production logbooks been checked? _____
- Is there any information related to the complaint in the logbook?

- Were there any maintenance related to this BPN? _____
- List the Maintenance Work Order Numbers _____
- If so, what adjustments to equipment/machinery were made?

- Were there any DR related to this BPN? (Check the batch Document)
- List the DR Numbers _____
- Were any applicable to this issue?

- Have the MI Sheet been reviewed? _____
- Was there any information related to the complaint in the MI Sheet Comments?

Consultation with technician/Process Engineer.

- Consult the Process Technician / Process Engineer. Describe the complaint and show the complaint picture. Use the space below to record the answers to the following information.



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- Q1. Have they seen this problem before? If so, what did they do to rectify this?
- Q2. Do they have any ideas as to what the problem was caused by?
- Q3. Do they have any ideas as to how to prevent this problem from occurring again? (Process improvements)

Collate all of the above information and determine a causality of the defective product. Describe below:

PART 2. CURRENT PROCESS CONTROLS

Current Practices.

- Describe the current process controls that would normally prevent this defective product from reaching the customer.

- Describe how this control could be by-passed, thus allowing the defective product to reach the customer?

Process Improvements.

- What are possible process improvements to prevent this problem from reoccurring?

- Has the Production Manager been consulted regarding the Process Improvement? ____
- What are the timelines for implementation of the Process Improvement

Sign Investigation Complete:

Date:

Sign Production Manager:

Date: