Process Data Collection Form
(Ref. SOP QMS-055)

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: