

Guidelines to completing various fields in the web-based QN system:

Corrective Action Activities Required by the Supplier Quality Manager or Engineer

Containment Required (Y/N): Is there a need for the supplier needed to perform containment?

Respond to containment: Provide date when the containment activities will need to be completed.

Corrective Action: Is there a need for the supplier to provide corrective action for this problem?

Respond to Corrective Action: Provide date when the corrective action will need to be completed?

Suppliers Acceptance of Quality Notice

Accept QN (Y/N)

If no, what is the reason: Please explain why you are not accepting the QN?

Additional Explanation of Rejecting QN: Use this space to further explain in detail as to why you are not accepting the QN (for example it is not your part)

Is this QN a repeat failure or previous QN: This information is very important and must be provide to EMD with previous related QN numbers? The suppliers will be judged based on this information. This will provide EMD with evidence that the supplier corrective action was effective or not.

If yes: What was the QN number(s): See above for explanation.

Containment

Accept Containment Activity (Y/N): Does the supplier agree with EMD's request for containment?

If no, why the containment is not necessary: Provide an explanation on why containment is not necessary

Describe the results of the containment activities: The supplier needs to provide details to the containment activities and the results of their activities.

Non Conformance Analysis

Describe the Non-Conformance Failure: The supplier needs to provide a description of the nonconformance.

Summarize the Root Cause: The supplier needs to provide a summary of the root cause(s).

Date failed material received: The supplier needs to enter the date the nonconforming material was received.

Non-Conformance Permanent Corrective Action (PCA) Summary

Describe the Non-Conformance Permanent Corrective Action: The supplier needs to provide their permanent corrective action to prevent recurrence.

Summarize your plan to verify effectiveness: The supplier needs to provide their plan to verify the effectiveness of the corrective actions taken.

Date of PCA Implementation: The supplier needs to provide a date as to when the PAC will be implemented.

Next available serial number with corrective action implemented: Communicate to EMD as to which serial number will be built with the newly implemented corrective actions.

Detection System Failure Analysis Summary

Describe detection system failure: Describe where in the inspection process the nonconformance did not get detected.

Summarize the root cause: Describe why the inspection process did not detect the nonconformance.

Detection System Permanent Corrective Action (PCA) Summary

Describe the permanent correctives to detection system: The supplier needs to provide their permanent corrective action to prevent recurrence.

Summarize your plan to validate the effectiveness of the improvement: The supplier needs to provide a plan on how it will prove that the change will be able to detect the nonconformance

Detection System Implementation and Validation

Date of Implementation: The supplier needs to provide the date on which the inspection process has been updated

Next available serial number with the corrective actions: The supplier needs to provide the serial number of the first unit that will go through the improved inspection process

Summarize the validation results: The supplier needs to provide the results of validation plan.

Management or Systemic Failure Analysis Summary

Describe systemic failure: Described what failed in the quality management system that allowed the failure to occur.

Summarize Root Cause: Describe why the quality management system allowed the failure to occur or escape.

Management or Systemic Permanent Corrective Action (PCA) Summary

Describe the management or systemic PCA: The supplier needs to provide their permanent corrective action to prevent recurrence.

Summarize PCA verification plan: The supplier needs to provide a plan on how it will prove that the change in the quality management system will be able to detect the nonconformance

Management or Systemic Implementation and Validation

Date of Implementation: The supplier needs to provide the date on which the inspection process has been updated

Summarize validation results: The supplier needs to provide the results of validation plan.

Prevent Reoccurrence and Lessons Learned

Describe methods used to apply lessons learned: The supplier needs to consider the following questions: How could this problem been foreseen? How will this information be implemented?

Describe changes to process control documentation: The supplier needs to provide what is being updated on the control plan?

Suggestions for improving the QN process: Does the supplier have any suggestions on how EMD can improve the QN process?

Has the process control is updated? Yes or No

Has the process failure modes and effects analysis been updated? Yes or No

Has the control drawing been changed? Yes or No

Has any other control documentation been changed? Yes or No

All Attachments

The supplier needs to attach the necessary documents for review by EMD SQE.

Supplier QA Review Closure Checklist

This is for EMD supplier quality engineers' before final closure of the QN.

For any questions or concerns please contact: ABC