



Complaint Number: 100535

Report 8D

Generated By: Christine Hulme
Generated On: 12 Jul 2011

I. COMPLAINT INFORMATION

Origination Date	22 Jun 2011		
Sales Name	Daniel Eng	Sales Office	Dunstable
Telephone	+44 (0)1636 821494	Fax Number	+44 (0)1582 478111
Email	daniel.eng@scapa.com		
Customer Complaint Ref			
Customer Name	F Hoffmann-La Roche AG		
SAP Customer Number	134718	Customer Order N°	
Customer Part Number			

1) Invoices And Items On Complaint

(a) SAP Invoice Number	9100244616	Invoice Date	17 Jun 2011
- Material	163524	Batch	
Material Description			
9868 MyDose plaster			

2) Problem Description

Customer POEPBA1133678-G-A26
1 carton sent by DHL 17.06. Customer reported upon receipt that some perforations are torn. Carton is to be returned & material re-worked.
Customer requires confirmation of probable root cause analysis & agree process controls to avoid repeat fault.
Please pass to JK for analysis.

Actions Requested From The Customer

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3) Containment Actions

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II. EVALUATION AND ACTION

Sample/photo Received	<input type="text" value="Yes"/>				
Date	<input type="text" value="29 Jun 2011"/>				
Process Owner	<input type="text" value="Christine Hulme"/>				
Team Leader	<input type="text" value="jkitcher"/>				
Is Complaint Valid?	<input type="text" value="Yes"/>	Return The Goods	<input type="text" value="Yes"/>	Dispose The Goods	<input type="text" value="No"/>

Comments

As this product and process are still in development, this complaint was raised primarily as an observation but there was a need to provide parts for development of a processing machine at Hoffman La Roche hence the agreement to rework the parts.

1) Analysis

Box of parts returned for re-work which gave opportunity to view every perforated fold. 96mm area within the paper carrier is perforated with a 3mm cut, 1mm tie configuration. Large numbers of these has either partially or fully burst through. In no case did the non-perforated "tram line" area of the paper split.

Of note is the fact that this carton of 4200 parts was sent a) on its side to evaluate the effect of easing the load vertically through the stack of parts and b) via DHL non-palletised service. The outer carton was dirty and showed signs of light damage but the inner cartons were intact.

Author	<input type="text" value="Jon Kitcher"/>	Date	<input type="text" value="12 Jul 2011"/>
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2) Root Causes

Possible Route Causes:

- 1) perforation configuration not sufficiently robust
- 2) damage caused during hand assembly
- 3) damage caused by transit method

Author	<input type="text" value="Jon Kitcher"/>	Date	<input type="text" value="12 Jul 2011"/>
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3) Possible Solutions

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Author	<input type="text"/>	Date	<input type="text"/>
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4) Implemented Perm Corrective Actions

Implemented with immediate effect:

- 1) revised perforation design changing from a 3mm cut, 1mm tie to a 2mm cut, 2mm tie configuration
- 2) clear instruction provided during reworking of the parts to avoid excessive, repeated folding at the perforation line
- 3) reworked goods sent palletised.

Author	<input type="text" value="Jon Kitcher"/>	Date	<input type="text" value="12 Jul 2011"/>
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Estimated Date	<input type="text" value="01 Aug 2011"/>	Implementation Date	<input type="text" value="12 Jul 2011"/>
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Validation Date	<input type="text" value="01 Aug 2011"/>
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5) Corrective Actions Validation

To be carried out between July / August.

1) New design of perforation will be included in production trial run scheduled for Mid July. Feedback will be required on this asap after delivery.

2) Feedback required on reworked material during second half of July 2011.

3) Feedback required on reworked material during second half of July 2011.

Author

Jon Kitcher

Date

12 Jul 2011

6) Preventive Actions

Author

Date

Estimated Date

Implementation Date

Validation Date

7) Review Of Documentation

(a) MSR

Reviewed?

No

Reference

Date

(b) Flow chart, control plan, work inspection instructions

Reviewed?

No

Reference

Date

(c) FMEA

Reviewed?

No

Reference

Date

(d) Customer specification

Reviewed?

No

Reference

Date

8) Congratulate The Team