Complaint Number: 101613

Report 8D

Generated By: Christine Hulme
Generated On: 04 Nov 2011

I. COMPLAINT INFORMATION

Origination Date	17 Oct 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

2) Problem Description

PO 7000055606
Batch no: 1012060
Material 10114206
During inspection the dimensional tolerances were not met by controlled samples
Total width (dimension no 1)
acceptable range 91.75-92.25mm
32 samples checked 32 >92.25-93.3mm

Width of battery slot (dimension no 20)
acceptable range 3.0-3.5mm
Measurement result for the affected batch 22/32 <3.0mm (measurement value 2.9mm)

Actions Requested From The Customer

3) Containment Actions

II. EVALUATION AND ACTION

Sample/photo Received	Yes				
Date	19 Oct 2011				
Process Owner	Christine Hulme				
Team Leader					
Is Complaint Valid?	No	Return The Goods		Dispose The Goods	

Comments

1) Analysis

The parts submitted under complaint were among those first supplied using the original set of tools purchased for this product and were known not to match the demands on the revised drawings to which these parts have been compared or later revised drafts issued to correspond with the change of supply format.

The two dimensions listed on the enclosed letter (overall width and battery slot width) were known at the time of supply to be slightly out of suggested specification but this was highlighted on the CofA supplied with the goods as instructed by Andreas Fuhrer as a means of securing release by concession. His thoughts then were that the two dimensions in question were not likely to cause any issue in use, or in processing particularly as the final design remained to be defined.

It should also be noted that all deliveries to date are not to the very latest drawings (body sensor hole and battery slot) but that will be addressed with the latest round of tool purchases made this week. We perhaps need to seek confirmation of concession for all materials supplied for machine trials up to the change over point to ensure we don’t see a repeat of this complaint.

I can confirm that the latest tools to be ordered have been done so against the current design demands, capturing in particular changes to body sensor hole and battery slot width.

Author	Jon Kitcher	Date	28 Oct 2011

2) Root Causes

Author		Date	

3) Possible Solutions

Author		Date	

4) Implemented Perm Corrective Actions

Author		Date	
Estimated Date		Implementation Date	

Validation Date

5) Corrective Actions Validation

Author | Date

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