



Old Style View

Issue #375173: BSI Non Conformance 2700663-202509-N1

Add File

*** NON Conformance Header it must contain reasoning to explain why this is or is not a vigilance ISSUE

- Minor Internal Error i.e. not ISO Non Conformance or Complaint / No preventative or corrective actions required / No Internal Review Requested / Product Failure but no requirement to Escalate Non conformance / must state in issue if its an observation
- Reviewed Non Conformity / Complaint and determine if its a vigilance Issue requiring a corrective action plan
- Determined Cause of Non Conformity / Complaint
- Evaluated action to Ensure does not recur
- Planning and documenting action needed and implementation QC 28b
- Verify Action does not adversely affect Safety Performance or regulatory requirements
- Effectiveness of corrective action reviewed

Meeting: Non Conformance Issues Section: BSI Minor Non conformances

Created: 11 Sep 2025 12:55:40 PM By: Derek Lamb

Set to User: Helen Lamb

Additional Information:

Subject: BSI Non Conformance 2700663-202509-N1
 Link To Rolling Issue - Task ID: 1276
 Corrective Action Plan: Yes
 Next Action By: Helen Lamb

Add Update Message

Issue #375173

Enter your update message here...

Update Complete

Hide Linked Files (7)


BSI Audit SMO 30133042 Nonconformity Report 11-09-2025.pdf Ref #375173.15747 · 11/09/25 1:00 pm · Derek Lamb	[Remove] [Update/History]	Drop new version here
375173.15745 QC 21 First_11_09_25.doc Ref #375173.15750 · 11/09/25 1:07 pm ·	[Remove] [Update/History]	Drop new version here
375175.15749 375175.15746 QC 21 First_11_09_25.doc_11_09_25 HL V1.doc Ref #375173.15754 · 11/09/25 4:11 pm · Helen Lamb	[Remove] [Update/History]	Drop new version here
QC 21 HL V2.doc_15_09_25 (1).odt Ref #375173.15770 · 15/09/25 11:21 am · Derek Lamb	[Remove] [Update/History]	Drop new version here
Acceptance of Corrective Action Plan- SMO 30133042.pdf Ref #375173.15792 · 19/09/25 10:14 am · Derek Lamb	[Remove] [Update/History]	Drop new version here
VOP 13 Process Monitoring, System Reviews, Audits, Management Reviews Analysis Data PMS Post Market ID135769.doc Ref #375173.16264 · 22/09/25 10:01 am · Helen Lamb	[Remove] [Update/History]	Drop new version here
375173.16262 375173.15775 375173.15771 QC 21 final.odt_17_09_25.odt_16_02_26.odt_16_02_26.odt Ref #375173.16265 · 16/02/26 2:18 pm ·	[Remove] [Update/History]	Drop new version here

Show all

12 Sep 2025 - #375173.8 - Derek Lamb

Corrective Action Plan updated to: 1


Issue None Conf.

11 Sep 2025 - #375173.6 - Helen Lamb 

My first version is attached please review it and see if im on the right track. Once we are happy i will start doing the corrective actions

 Issue

 None Conf.

11 Sep 2025 - #375173.1 - Derek Lamb 

Added by Derek Lamb sent to Helen Lamb

The internal audit process is not fully effective as raised issues

within audit records do not clearly differentiate between

observations and non-conformities.

Audit records reviewed (Audit 15 and Audit 06) highlighted issues

and were raised within the Intrastat (eQMS system). The issues

raised did not highlight or state if the issues were an observation

or non-conformance. No investigation or CAPA related actions

were seen and the issues were cleared/completed with note

comment only.

Audit 06 – Performed 30 May 2025 – Issues 365729 Raised 26

June 2025; Issue 367474 Raised 18 June 2025 – Closed 26 June 2025

Audit 15 – Performed 21 July 2025 – Issues 370409, 370410 –

Raised 21 July 2025 – Closed 22 July 2025

 Issue

 None Conf.

System (initial record)

Added by Derek Lamb sent to Helen Lamb

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11 Sep 2025 Helen Lamb

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