

Results of internal audits / Mini Audits

Issue/Linked Docs	Date Signed Off	
135113 Audit 03 Design Control Viamed (22)	43588	137048
Audit 03 Design Viamed, VST no design. Jan 2019		
135114 Audit 01 Picking Packing Viamed (24)	43588	
Audit 01 Order processing Picking Packing and despatch Viamed VS		
135125 Audit 03 Design Control VST (193)	43588	
Audit 03 Design Viamed, VST no design. Jan 2019		
135126 Audit 01 Picking Packing VST (194)	43588	
Audit 01 Order processing Picking Packing and despatch Viamed VS		
Audit 01 Order processing Picking Packing and despatch Viamed VS	43588	'137979,137980
Audit 01 Order processing Picking Packing and despatch Viamed VS		
137812 Audit 27 Software Validation (821)		
Audit 27 Software validation Viamed VST Jan 2019	Not Signed Off	
139994 Audit 09 Goods Inward And Product Identity Viamed (170)	43588	'143155,143157
139996 Audit 09 Goods Inward And Product Identity VST (174)		
Audit 09 Goods inward and product identity Viamed VST March 2019	43588	
140821 Audit 12 CE Files Viamed (16)		
Audit 12 Technical Files Viamed May 19	Not Signed Off	
140823 Audit 12 CE Files VST (176)		
Audit 12 Technical Files Viamed May 19	Not Signed Off	
142483 Audit 07 Handling And Storage Viamed (25)		
Audit 07 Handling and Stock Control Viamed VST April 2019	43588	
142489 Audit 07 Handling And Storage VST (178)		
Audit 07 Handling and Stock Control Viamed VST April 2019	43588	
143623 Audit 22 Post Market Surveillance Viamed (14)		
Audit 22 Post Marketing Viamed VST May 2019	43588	
143627 Audit 22 Post Market Surveillance VST (180)		
Audit 22 Post Marketing Viamed VST May 2019	43588	
143690 Audit 15 Production Viamed (28)		
Audit 15 Production Viamed, VST May 2019	43588	
143694 Audit 15 Production VST (175)		
Audit 15 Production Viamed, VST May 2019	43588	
145274 Audit 06 Calibration Viamed (20)		
Audit 06 Calibration Viamed VST June 2019	Not Signed Off	148652
145278 Audit 06 Calibration VST (182)		
Audit 06 Calibration Viamed VST June 2019	Not Signed Off	
146850 Audit 10 Documentation Control Viamed (27)		
Audit 10 Document Control Viamed VST June 2019	Not Signed Off	
146855 Audit 10 Documentation Control VST (183)		
Audit 10 Document Control Viamed VST June 2019	Not Signed Off	
148465 Audit 08 Training Viamed (10)		
148471 Audit 11 Repairs And Service Viamed (171)	Not Signed Off	
148474 Audit 11 Repairs And Service VST (179)	Not Signed Off	
148475 Audit 08 Training VST (184)	Not Signed Off	
149442 Audit 23 Analysis Of Data Viamed (43)	Not Signed Off	
149449 Audit 23 Analysis Of Data VST (185)	Not Signed Off	

Total of 6 Follow On issues on Audits so far this year

Output Actions:

COMPLETED ISSUE 31 Jan 2019 Helen Lamb

Audit 03 Design Control Viamed (22) Non Conformance :Issue Visable to: **Helen Lamb AND Derek Lamb**

 *Non Conformance Issues*

[137048](#)   - Created: 28 Jan 2019 12:50:52 PM By Helen Lamb

.Added by Helen Lamb sent to Derek Lamb

During 2018 audit a corrective action not fully completed.

Section 7.3.6 was to be added to the audit.

not showing on the paperwork, but is linked to the audit digitally.

the paper work need updating to reflect the changes

28 Jan 2019 Derek Lamb

done.

COMPLETED ISSUE 07 Mar 2019 Helen Lamb

Audit 01 Picking Packing VST (194) :Issue Visable to: **Helen Lamb AND Derek Lamb**

 *VST Audits Calander Audit Picking and Packing*

[137979](#)   - Created: 12 Feb 2019 05:12:27 PM By Helen Lamb

Set to User: **Derek Lamb**

Added by Helen Lamb sent to Derek Lamb

trying to check if goods are scanned to order. No easy way of doing this, in Viamed i can click ORD and it brings it up. But no link in VST for this.

12 Feb 2019 Helen Lamb

think its partly because there is little reference to invoice number and its hard to find. Can do it from invoice number

04 Mar 2019 Derek Lamb

Done

COMPLETED ISSUE 22 Mar 2019 Helen Lamb

Audit 01 Picking Packing VST (194) :Issue Visable to: **Helen**

Lamb AND Derek Lamb

 *VST Audits Calander Audit Picking and Packing*

[137980](#)   - Created: 12 Feb 2019 05:27:59 PM By Helen Lamb

Set to User: **Derek Lamb**

VST Audit

Orders VSORD1056 and VSORD1052 do not have order details / paperwork in the file for it to be checked against.

VSORD1052 does not seem to be in intrastats ORD checking in CRM, unable to find.

VSORD1056 unable to find in intrastats and not able to see if goods scanned to this order.

13 Mar 2019 Derek Lamb

have we got invoice numbers, struggling to find records in intrastats too,

24 Apr 2019 Helen Lamb

scanned blank first time re added.

COMPLETED ISSUE 24 Apr 2019 Helen Lamb

Audit 09 Goods Inward And Product Identity Viamed (170) :Issue Visable to: Helen Lamb AND Robert Connor

 *Audits Calander Audit Goods Inwards and Product Identity*

[143155](#)   - Created: 23 Apr 2019 05:30:05 PM By Helen Lamb

Set to User: **Robert Connor**

Added by Helen Lamb sent to Robert Connor

Can you have a look at the location of 1114017 NeoMask - Small. Pk 20.

found on shelf 837850 Stock Room 15 Main Office Block 2, Row 3, Shelf 3.

intrastats says on 837857 Stock Room 15 Main Office Block 2, Row 1, Shelf 3

24 Apr 2019 Robert Connor

837857 is the correct main box for booking in stock, but there will be some located on 837850 as that is the quick picking location for neomasks. There is one container for each size on the shelf for easy access for Cathy.

COMPLETED ISSUE 24 Apr 2019 Helen Lamb

Audit 09 Goods Inward And Product Identity Viamed (170) :Issue Visable to: Helen Lamb AND Derek Lamb

 **Audits Calander Audit Goods Inwards and Product Identity**
[143157](#)   - Created: 23 Apr 2019 05:32:23 PM By Helen Lamb
Set to User: **Derek Lamb**

Added by Helen Lamb sent to Derek Lamb
question 15 says Check meeting in Intrastats is completed monthly by MD.
But does not specify what the meeting heading is. So i am unsure which
meeting I am checking

24 Apr 2019 Derek Lamb

need to update the question to quarterly,
and it will be the stock meeting, last held January the 4th

COMPLETED ISSUE 09 Jul 2019 Helen Lamb

Document Update Request (23185) Audit 06 Calibration :Issue Visable
to: **Helen Lamb AND Derek Lamb**

 **BS EN ISO 13485:2003 Document Control Amendments needed**
[148652](#)   - Created: 02 Jul 2019 01:24:50 PM By Helen Lamb

Set to User: **Derek Lamb**

Added by Helen Lamb sent to Derek Lamb
Controlled Document (23185) Audit 06 Calibration Requires Updating

please change NAMAS to UKAS, page 5

05 Jul 2019 Derek Lamb

05 Jul 2019 Derek Lamb

Created Related Issue #148945

Added by Derek Lamb sent to Helen Lamb

INFORMATION ONLY ISSUE DO NOT ADD NOTES!

when creating an issue from audit, would it be possible to do them as related
issue from the audit issue,

holds them all together.

hard to prove at end of year if all followup issues have been dealt with