

Document VOP 10 Non Conformance, Corrective and Preventive Actions

Revision ID46915

Suggested Upload Document Name: **Risk Assessment For Updating Document ID46915**

Completed by [Derek Lamb](#) 6 May 2022

Reason for Risk Assessment

Minor non conformance from BSI
Effect on changes to system See Issue 241898
Our QC21 form did not look at or review the risks involved with the use of the form, the contents of it and any actions resulting from the use of it.

Document VOP 10 Non Conformance, Corrective and Preventive Actions Revision ID46915 Is linked to the Following Standards and processes test block

Risk	Assesment Question	Does Update Affect	Risk on Update	Notes On Risk / Benefits statement i required
46915Q0	Does this Update warrant updating Any External Parties due to any Terms and Conditional Agreements E.G. Notified Body or is the update a Significate change to any ISO Certifications	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement i required
46915Q1	Viamed Ltd ISO13485:2016 Section: 8.3.1 General The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The organization shall document a procedure to define the controls and related responsibilities and authorities for the identification, documentation, segregation, evaluation, and disposition of nonconforming product. The evaluation of nonconformity shall include a determination of the need for an investigation and notification of any external party responsible for the nonconformity. Records of the nature of the nonconformities and any subsequent action taken, including the evaluation, any investigation and the rationale for decisions shall be maintained (see 4.2.5)	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement i required
46915Q2	Viamed Ltd ISO13485:2016 Section: 8.5.1 General The organization shall identify and implement any changes necessary to ensure and maintain the continued suitability, adequacy and effectiveness of the quality management system as well as medical device safety and performance through the use of the quality policy, quality objectives, audit results, postmarket surveillance, analysis of data, corrective actions, preventive actions and management review.	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement i required
46915Q3	Viamed Ltd ISO13485:2016 Section: 8.5.2 Corrective action The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Any necessary corrective actions shall be taken without undue delay. Corrective actions shall be proportionate to the effects of the nonconformities encountered. The organization shall document a procedure to define requirements for: a) reviewing nonconformities (including complaints); b) determining the causes of nonconformities; c) evaluating the need for action to ensure that nonconformities do not recur; d) planning and documenting action needed and implementing such action, including, as appropriate, updating documentation; e) verifying that the corrective action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device; f) reviewing the effectiveness of corrective action taken Records of the results of any investigation and action taken shall be maintained (see 4.2.5).	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement i required
46915Q4	Viamed Ltd ISO13485:2016 Section: 8.5.3 Preventive action The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be proportionate to the effects of the	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update	Notes On Risk / Benefits statement i required

potential problems.

The organization shall document a procedure to describe requirements for:

- a) determining potential nonconformities and their causes;
 - b) evaluating the need for action to prevent occurrence of nonconformities;
 - c) planning and documenting action needed and implementing such action, including, as appropriate, updating documentation;
 - d) verifying that the action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device;
 - e) reviewing the effectiveness of the preventive action taken, as appropriate.
- Records of the results of any investigations and of action taken shall be maintained (see 4.2.5).

1.Negligible

Action Required:

No Action

Required

46915Q5	VST Ltd ISO9001:2015 Section: 7.5.2 Creating and updating 7.5.2 Creating and updating When creating and updating documented information, the organization shall ensure appropriate: a) identification and description (e.g. a title, date, author, or reference number); b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic); c) review and approval for suitability and adequacy.	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likely Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement i required
46915Q6	VST Ltd ISO9001:2015 Section: 7.5.3 Control of documented information	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likely Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement i required
46915Q7	VST Ltd ISO9001:2015 Section: 9.1.1 General The organization shall determine: a) what needs to be monitored and measured; b) the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results; c) when the monitoring and measuring shall be performed; d) when the results from monitoring and measurement shall be analysed and evaluated. The organization shall evaluate the performance and the effectiveness of the quality management system. The organization shall retain appropriate documented information as evidence of the results.	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likely Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement i required
46915Q8	VST Ltd ISO9001:2015 Section: 10.1 General The organization shall determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction. These shall include: a) improving products and services to meet requirements as well as to address future needs and expectations; b) correcting, preventing or reducing undesired effects; c) improving the performance and effectiveness of the quality management system. NOTE Examples of improvement can include correction, corrective action, continual improvement, breakthrough change, innovation and re-organization.	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likely Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement i required
46915Q9	VST Ltd ISO9001:2015 Section: 10.2 Nonconformity and corrective action	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likely Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement i required
46915Q10	VST Ltd ISO9001:2015 Section: 10.2.1 When a nonconformity occurs, including any arising from complaints, the organization shall: a) react to the nonconformity and, as applicable: 1) take action to control and correct it; 2) deal with the consequences; b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by: 1) reviewing and analysing the nonconformity; 2) determining the causes of the nonconformity;	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likely Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement i required

- 3) determining if similar nonconformities exist, or could potentially occur;
 c) implement any action needed;
 d) review the effectiveness of any corrective action taken;
 e) update risks and opportunities determined during planning, if necessary;
 f) make changes to the quality management system, if necessary.
 Corrective actions shall be appropriate to the effects of the nonconformities encountered.

46915Q11 VST Ltd ISO9001:2015 Section: 10.2.2

The organization shall retain documented information as evidence of:
 a) the nature of the nonconformities and any subsequent actions taken;
 b) the results of any corrective action.

Does Update Affect? Risk Frequency due to Update Risk Likely Due to Update Action Required: No Action Required

Notes On Risk / Benefits statement i required

46915Q12 7199

Non Conformities Review Viamed
 To review any non conformances created during the previous month, and produce a non conformance report.

Review history of non conformances and see if there has been any improvement.

Does Update Affect? Risk Frequency due to Update Risk Likely Due to Update Action Required: No Action Required

Notes On Risk / Benefits statement i required

46915Q13 7849

Review Product Failures New Codes
 Review the Customer Returns and Review Product Failures New Codes

Does Update Affect? Risk Frequency due to Update Risk Likely Due to Update Action Required: No Action Required

Notes On Risk / Benefits statement i required

46915Q14 7874

Review For Latest Version Med Dev 2.12.
 To Ensure we have the latest version of Med Dev 2.12.
 and update management if its been updated

Does Update Affect? Risk Frequency due to Update Risk Likely Due to Update Action Required: No Action Required

Notes On Risk / Benefits statement i required

46915Q15 7264

VST Management Meeting Non Conformance Issues
 To review any non conformances created during the previous month, and produce a non conformance report.

Review history of non conformances and see if there has been any improvement.

Does Update Affect? Risk Frequency due to Update Risk Likely Due to Update Action Required: No Action Required

Notes On Risk / Benefits statement i required

46915Q16 Process 6866

Internal Process Verification Complete Systems Review
 Review the Internal Process and Verification's are suitable for the current standards

PROCESS NOW CANCELLED AS REPEAT OF AUDIT 20
 Current Known Risk Review not carried out
 Current Likly 1 Current Frequency 1

Does Update Affect? Risk Frequency due to Update Risk Likely Due to Update Action Required: No Action Required

Notes On Risk / Benefits statement i required

46915Q17 Process 7091

Calibration Index
 To ensure that all equipment that requires calibration is done.
 In the correct timescale and manor.
 Current Known Risk That equipment we use to may not be calibrated when we need it.

Current Likly 1 Current Frequency 2

Does Update Affect? Risk Frequency due to Update Risk Likely Due to Update Action Required: No Action Required

Notes On Risk / Benefits statement i required

46915Q18 Process 7138

Non Conformance Issues Any New QC21 Forms
 To review any new QC 21 Forms
 Current Known Risk potential non conformances go undetected
 Current Likly 3 Current Frequency 1

Does Update Affect? Risk Frequency due to Update Risk Likely Due to Update

Notes On Risk / Benefits statement i required

			3.Serious	Action Required: No Action Required	
46915Q19	Process 7199 Non Conformities Review Viamed To review any non conformances created during the previous month, and produce a non conformance report. Review history of non conformances and see if there has been any improvement. Current Known Risk Non conformances go unfixed Current Likly 2 Current Frequency 2	Does Update Affect? No	Risk Frequency due to Update 2.Remote Risk Likely Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement i required	
46915Q20	Process 7671 Humanmed Non Conformances Humanmed Non Conformances Current Known Risk non conformations not logged. Current Likly 2 Current Frequency 2	Does Update Affect? No	Risk Frequency due to Update 2.Remote Risk Likely Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement i required	
46915Q21	Process 7676 PDFing Of Invoices Viamed Process of PDF ing Invoices into the system for easy of use in the future and the Emailing of Invoices to customers NO LONGER REQUIRED AS DONE BY THE SYSTEM AUTOMATICALLY Current Known Risk Incorrect name given to Invoice when saving the PDF. customer gets incorrect invoice. Current Likly 2 Current Frequency 1	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likely Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement i required	
46915Q22	Process 7693 Collect Repair Filing From Warehouse Collect the filing form the warehouse Current Known Risk paperwork has been missed Current Likly 1 Current Frequency 1	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likely Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement i required	
46915Q23	Process 7705 Checking For Uploaded Files Checking if a customer has uploaded an order directly to our website Current Known Risk Computer/network breakdown Current Likly 2 Current Frequency 2	Does Update Affect? No	Risk Frequency due to Update 2.Remote Risk Likely Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement i required	
46915Q24	Process 7743 Customer Complaints Paper File Major Customer Complaints get escalated to Paper Customer Complaints file. Check the File is being Maintained and any relevant documentation is in the File. Current Known Risk Customer Complaints could be missed or not filed correctly Current Likly 2 Current Frequency 1	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likely Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement i required	
46915Q25	Process 7748 Check Repair Orders Check the orders against the customer paperwork, that we have generated, for the repair we have received in. Current Known Risk That details will be incorrect and it will affect the customer. That mistakes may be missed. Current Likly 2 Current Frequency 1	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likely Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement i required	
46915Q26	Process 7782 Remove Started But Not Used Order Numbers Remove Started But Not Used Order Numbers from intrastats. Current Known Risk not clear regularly, accidental usage of an old ORDER number	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likely Due to Update	Notes On Risk / Benefits statement i required	

generated by mistake

Current Likly 2 Current Frequency 1

2.Minor ▾

Action Required:
No Action
Required

46915Q27	Process 7822 Review Oxylink Stock To check we have the stock available to supply our customer Oxylink. NOTE THIS PROCESS HAS BEEN STOPPED. Part number has been superseded Current Known Risk The we do not have the stock needed to satisfy the orders for this customer. Current Likly 3 Current Frequency 1	Does Update Affect? No ▾	Risk Frequency due to Update 1.Improbable ▾ Risk Likly Due to Update 3.Serious ▾ Action Required: No Action Required	Notes On Risk / Benefits statement i required
46915Q28	Process 7830 Review Q.A. Failures Report To review the Quantities of Failed product per Stock reference Passing through the Q.A. system Current Known Risk No risk Current Likly 3 Current Frequency 1	Does Update Affect? No ▾	Risk Frequency due to Update 1.Improbable ▾ Risk Likly Due to Update 3.Serious ▾ Action Required: No Action Required	Notes On Risk / Benefits statement i required
46915Q29	Process 7838 Review VIAMED Feedback - Customer Feedback Negative Review Customer Feedback Negative Current Known Risk Rolling Issues No risk to process Current Likly 3 Current Frequency 1	Does Update Affect? No ▾	Risk Frequency due to Update 1.Improbable ▾ Risk Likly Due to Update 3.Serious ▾ Action Required: No Action Required	Notes On Risk / Benefits statement i required
46915Q30	Process 7839 Review VIAMED Feedback - Customer Complaints To Review Viamed Customer Complaints Current Known Risk Rolling Issue No Risk Current Likly 3 Current Frequency 1	Does Update Affect? No ▾	Risk Frequency due to Update 1.Improbable ▾ Risk Likly Due to Update 3.Serious ▾ Action Required: No Action Required	Notes On Risk / Benefits statement i required
46915Q31	Process 7841 Review VST Feedback - Customer Complaints To review Customer Complaints see if Non Conformance need to be raised Current Known Risk Rolling ISSue, No Risk Current Likly 3 Current Frequency 1	Does Update Affect? No ▾	Risk Frequency due to Update 1.Improbable ▾ Risk Likly Due to Update 3.Serious ▾ Action Required: No Action Required	Notes On Risk / Benefits statement i required
46915Q32	Process 7842 Review VIAMED Product Feedback Negative To review Negative feedback form Products see if Non Conformance or customer Complaints need to be raised Current Known Risk Rolling ISSue, No Risk Current Likly 3 Current Frequency 1	Does Update Affect? No ▾	Risk Frequency due to Update 1.Improbable ▾ Risk Likly Due to Update 3.Serious ▾ Action Required: No Action Required	Notes On Risk / Benefits statement i required
46915Q33	Process 7849 Review Product Failures New Codes Review the Customer Returns and Review Product Failures New Codes Current Known Risk Product failures / returns do not get reviewed and a new Risk may occur Current Likly 1 Current Frequency 3	Does Update Affect? No ▾	Risk Frequency due to Update 3.Occasional ▾ Risk Likly Due to Update 1.Negligible ▾ Action Required: No Action Required	Notes On Risk / Benefits statement i required
46915Q34	Process 7857 Software Validation Stock Tracking Check To confirm Software Validation Stock Tracking Check, is functioning as expected Current Known Risk Stock gets mislaid in the warehouse Current Likly 2 Current Frequency 1	Does Update Affect? No ▾	Risk Frequency due to Update 1.Improbable ▾ Risk Likly Due to Update	Notes On Risk / Benefits statement i required

		<div>2.Minor</div> <div>Action Required:</div> <div>No Action</div> <div>Required</div>	
46915Q35	Document ID71643 VM3COP27.46 Non Conformance review (How Too) Is Related to this document	<div>Does Update Affect?</div> <div>No</div> <div>Risk Frequency due to Update</div> <div>1.Improbable</div> <div>Risk Likely Due to Update</div> <div>1.Negligible</div> <div>Action Required:</div> <div>No Action</div> <div>Required</div>	Notes On Risk / Benefits statement i required
46915Q36	Does Generic CE File Attached to All Technical file #2 Of type 5 require any Notificaions and/or Risk assesment updates	<div>Does Update Affect?</div> <div>No</div> <div>Risk Frequency due to Update</div> <div>1.Improbable</div> <div>Risk Likely Due to Update</div> <div>1.Negligible</div> <div>Action Required:</div> <div>No Action</div> <div>Required</div>	Notes On Risk / Benefits statement i required
46915Q37	Final Notes		
	No ISO Procedures or Process are negativly affected by updating this document with the new document proposed		

SAVE FORM

Only saves your progress in filling in above Questions - No feed back to pressing save form button

Once Form Complete Print Page to PDF (Landscape mode prefereable), go back to document upload page and upload to risk assesment button