

Document VOP 15 Data and Information Analysis Revision ID31056

Suggested Upload Document Name: **Risk Assesment For Updating Document ID31056**
Completed by [Derek Lamb](#) 07 Sep 2022
Reason for Risk Assesment
added the objective of the vop






Document VOP 15 Data and Information Analysis Revision ID31056 Is linked to the Following Standards and processes

Risk Assesment Question ID31056	Does Update Affect	Risk on Update	Notes On Risk / Benefits statement i required
31056Q0 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
31056Q1 Viamed Ltd ISO13485:2016 Section: 7.3.6 Design and development verification Design and development verification shall be performed in accordance with planned and documented arrangements to ensure that the design and development outputs have met the design and development input requirements. The organization shall document verification plans that include methods, acceptance criteria and, as appropriate, statistical techniques with rationale for sample size. If the intended use requires that the medical device be connected to, or have an interface with, other medical device(s), verification shall include confirmation that the design outputs meet design inputs when so connected or interfaced. Records of the results and conclusions of the verification and necessary actions shall be maintained (see 4.2.4 and 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
31056Q2 Viamed Ltd ISO13485:2016 Section: 7.3.7 Design and development validation Design and development validation shall be performed in accordance with planned and documented arrangements to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use. The organization shall document validation plans that include methods, acceptance criteria, and, as appropriate, statistical techniques with rationale for sample size. Design validation shall be conducted on representative product. Representative product includes initial production units, batches or their equivalents. The rationale for the choice of product used for validation shall be recorded (see 4.2.5). As part of design and development validation, the organization shall perform clinical evaluations or performance evaluations of the medical device in accordance with applicable regulatory requirements. A medical device used for clinical evaluation or performance evaluation is not considered to be released for use to the customer. If the intended use requires that the medical device be connected to, or have an interface with, other medical device(s), validation shall include confirmation that the requirements for the specified application or intended use have been met when so connected or interfaced. Validation shall be completed prior to release for use of the product to the customer. Records of the results and conclusion of validation and necessary actions shall be maintained (see 4.2.4 and 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
31056Q3 Viamed Ltd ISO13485:2016 Section: 7.5.6 Validation of processes for production and service provision The organization shall validate any processes for production and service provision where the resulting output cannot be or is not verified by subsequent monitoring or measurement and, as a	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update	Notes On Risk / Benefits statement i required

consequence,
deficiencies become apparent only after the product is in use or the service has been delivered.
Validation shall demonstrate the ability of these processes to achieve planned results consistently.
The organization shall document procedures for validation of processes including:
a) defined criteria for review and approval of the processes;
b) equipment qualification and qualification of personnel;
c) use of specific methods, procedures and acceptance criteria;
d) as appropriate, statistical techniques with rationale for sample sizes
e) requirements for records (see 4.2.5);
f) revalidation, including criteria for revalidation;
g) approval of changes to the processes.
The organization shall document procedures for the validation of the application of computer software used in production and service provision. Such software applications shall be validated prior to initial use and, as appropriate, after changes to such software or its application. The specific approach and activities associated with software validation and revalidation shall be proportionate to the risk associated with the use of the software including the effect on the ability of the product to conform to specifications.
Records of the results and conclusion of validation and necessary actions from the validation shall be maintained (see 4.2.4 and 4.2.5).

1.Negligible
Action Required:
No Action
Required

31056Q4	<p>Viamed Ltd ISO13485:2016 Section: 8.1 General The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed to:</p> <ul style="list-style-type: none"> a) demonstrate conformity of product; b) ensure conformity of the quality management system; c) maintain the effectiveness of the quality management system. <p>This shall include determination of appropriate methods, including statistical techniques, and the extent of their use.</p>	<p>Does Update Affect? No</p> <p>Risk Frequency due to Update 1.Improbable Risk Likely Due to Update 1.Negligible Action Required: No Action Required</p>	Notes On Risk / Benefits statement i required
31056Q5	<p>Viamed Ltd ISO13485:2016 Section: 8.4 Analysis of data The organization shall document procedures to determine, collect and analyse appropriate data to demonstrate the suitability, adequacy and effectiveness of the quality management system. The procedures shall include determination of appropriate methods, including statistical techniques and the extent of their use. The analysis of data shall include data generated as a result of monitoring and measurement and from other relevant sources and include, at a minimum, input from:</p> <ul style="list-style-type: none"> a) feedback; b) conformity to product requirements; c) characteristics and trends of processes and product including opportunities for improvement; d) suppliers; e) audits; f) service reports, as appropriate. <p>If the analysis of data shows that the quality management system is not suitable, adequate or effective, the organization shall use this analysis as input for improvement as required in 8.5. Records of the results of analyses shall be maintained (see 4.2.5).</p>	<p>Does Update Affect? No</p> <p>Risk Frequency due to Update 1.Improbable Risk Likely Due to Update 1.Negligible Action Required: No Action Required</p>	Notes On Risk / Benefits statement i required
31056Q6	<p>ProcessProcess 27 Management Reviews And Quality Audits To review and close all automatic rolling Issues. Including all rolling tasks and audits Current Known Risk that the task is missed that follow ups are missed Current Likly 3 Current Frequency 1</p>	<p>Does Update Affect? No</p> <p>Risk Frequency due to Update 1.Improbable Risk Likely Due to Update 3.Serious Action Required: No Action Required</p>	Notes On Risk / Benefits statement i required
31056Q7	<p>ProcessProcess 5877 Review Company Data To review the numbers of various departments. Showing increasing / reducing staff requirements Check Audit Roles Titles and Processes in Employee Roles and Titles. Check the Page for Red Crosses and potentially missing objectives Current Known Risk incorrect staff levels Current Likly 3 Current Frequency 1</p>	<p>Does Update Affect? No</p> <p>Risk Frequency due to Update 1.Improbable Risk Likely Due to Update 3.Serious Action Required: No Action Required</p>	Notes On Risk / Benefits statement i required

31056Q8	 Process 7070 Management Review To discuss any problems, to assess work load and staffing. To review issues. Current Known Risk Meetings not carried out regularly. Current Likly 2 Current Frequency 1	Does Update Affect? <input type="button" value="No"/> Risk due to Update <input type="button" value="1.Improbable"/> Frequency Due to Update <input type="button" value="2.Minor"/> Action Required: No Action Required	Notes On Risk / Benefits statement i required
31056Q9	 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? <input type="button" value="No"/> Risk due to Update <input type="button" value="1.Improbable"/> Frequency Due to Update <input type="button" value="3.Serious"/> Action Required: No Action Required	Notes On Risk / Benefits statement i required
31056Q10	 Process 7834 Financial Review The review the Financial requirements Current Known Risk Non Current Likly 1 Current Frequency 1	Does Update Affect? <input type="button" value="No"/> Risk due to Update <input type="button" value="1.Improbable"/> Frequency Due to Update <input type="button" value="1.Negligible"/> Action Required: No Action Required	Notes On Risk / Benefits statement i required
31056Q11	 Process 7837 Review External Parties Influencing The QMS VST / Viamed To Review the External Parties Influencing The QMS VST / Viamed Checked the Scopes and Risks, Review the Underlining Processes and Tasks Current Known Risk External party has un-reviewed expectations Current Likly 1 Current Frequency 1	Does Update Affect? <input type="button" value="No"/> Risk due to Update <input type="button" value="1.Improbable"/> Frequency Due to Update <input type="button" value="1.Negligible"/> Action Required: No Action Required	Notes On Risk / Benefits statement i required
31056Q12	 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? <input type="button" value="No"/> Risk due to Update <input type="button" value="1.Improbable"/> Frequency Due to Update <input type="button" value="3.Serious"/> Action Required: No Action Required	Notes On Risk / Benefits statement i required
31056Q13	 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? <input type="button" value="No"/> Risk due to Update <input type="button" value="1.Improbable"/> Frequency Due to Update <input type="button" value="3.Serious"/> Action Required: No Action Required	Notes On Risk / Benefits statement i required
31056Q14	 Process 7840 Review VST Feedback - Customer 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? <input type="button" value="No"/> Risk due to Update <input type="button" value="1.Improbable"/> Frequency Due to Update <input type="button" value="3.Serious"/> Action Required: No Action Required	Notes On Risk / Benefits statement i required
31056Q15	 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? <input type="button" value="No"/> Risk due to Update <input type="button" value="1.Improbable"/> Frequency Due to Update <input type="button" value="3.Serious"/> Action Required: No Action Required	Notes On Risk / Benefits statement i required
31056Q16	 Process 7842 Review VIAMED Product Feedback Negative	Does Update Affect? Risk due to Update Frequency Notes On Risk / Benefits statement i required	

<p>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</p>	<p>Affect? <input type="button" value="1.Improbable"/> <input type="button" value="2.No"/> <input type="button" value="3.Serious"/> Risk Likly Due to Update Action Required: No Action Required</p>	
<p>31056Q17 Process 7843 Review VST Product Feedback Negative To review Negative feedback form Products see if Non Conformance or customer Complaints need to be raise Current Known Risk Issues could be missed Current Likly 3 Current Frequency 1</p>	<p>Does Update <input type="button" value="1.Improbable"/> <input type="button" value="2.No"/> <input type="button" value="3.Serious"/> Risk Likly Due to Update Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement i required</p>
<p>31056Q18 Process 7848 Review ISO Scopes To Review the Scope of the ISO 9001 / ISO 13485 Standards Current Known Risk No risks Rolling issue to perform task Current Likly 1 Current Frequency 1</p>	<p>Does Update <input type="button" value="1.Improbable"/> <input type="button" value="2.No"/> <input type="button" value="1.Negligible"/> Risk Likly Due to Update Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement i required</p>
<p>31056Q19 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</p>	<p>Does Update <input type="button" value="3.Occasional"/> <input type="button" value="2.No"/> <input type="button" value="1.Negligible"/> Risk Likly Due to Update Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement i required</p>
<p>31056Q20 Process 7850 Software Validation Scan Incorrect Product Test the Goods out process disabling picking of items not relating to an order Current Known Risk system allows incorrect items to be picked to customer orders Current Likly 1 Current Frequency 1</p>	<p>Does Update <input type="button" value="1.Improbable"/> <input type="button" value="2.No"/> <input type="button" value="1.Negligible"/> Risk Likly Due to Update Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement i required</p>
<p>31056Q21 Process 7851 Software Validation Scan Un-QA Product To Order To test intrastats does not allow picking of unprocessed products to live customer orders Current Known Risk Unprocessed product gets out into the field, resulting in recalls Current Likly 1 Current Frequency 1</p>	<p>Does Update <input type="button" value="1.Improbable"/> <input type="button" value="2.No"/> <input type="button" value="1.Negligible"/> Risk Likly Due to Update Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement i required Likelihood is Improbable as t process tests the actual syst preventing UN-QA stock gettin past QA.
This process itse to reduce the risk of UN-QA product getting past goods ou</p>
<p>31056Q22 Process 7852 Software Validation Expired Stock To attempt to Scan a product that has gone past its expire date. Current Known Risk Expired product leaves the building and unusable products get to customers Current Likly 1 Current Frequency 1</p>	<p>Does Update <input type="button" value="1.Improbable"/> <input type="button" value="2.No"/> <input type="button" value="1.Negligible"/> Risk Likly Due to Update Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement i required</p>
<p>31056Q23 Process 7853 Software Validation Non Sell Able Shelf Warehouse shelves can be tagged as sellable stock / unsellable stock. Either for quarantine purposes or holding items for other customer orders. Test that Order picking cannot pick unsellable stock locations to an Order Current Known Risk quarantine stock leaves the building to a customer order, or stock on hold for a customer gets shipped to another customer. Current Likly 1 Current Frequency 3</p>	<p>Does Update <input type="button" value="3.Occasional"/> <input type="button" value="2.No"/> <input type="button" value="1.Negligible"/> Risk Likly Due to Update Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement i required</p>
<p>31056Q24 Process 7854 Software Validation In Production List Software Validation of the production lists.</p>	<p>Does Update <input type="button" value="2.Remote"/> <input type="button" value="2.No"/> <input type="button" value="1.Negligible"/> Risk Likly Due</p>	<p>Notes On Risk / Benefits statement i required</p>

By confirming no extra production jobs are stuck in the system, and all listed production jobs are found. the production tracking is validated Current Known Risk Software tracking of production jobs fails. Current Likly 2 Current Frequency 2			to Update 2.Minor Action Required: No Action Required	
31056Q25	Process 7855 Software Validation - Production Lists Software Validation - Production Lists Review the current active production lists in intrastats to the actual in progress production lists Current Known Risk Software inaccuracies in production 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	
31056Q26	Process 7856 Software Validation Unchecked Orders To check order picking cannot pick against an unchecked order Current Known Risk Customer receives incorrect items due to order not being checked. 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	
31056Q27	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 Likely Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement i required	
31056Q28	Process 7858 Software Validation Attempt To QA Some Stock Test the QA System that Staff not trained for QA are unable to QA a Product. Current Known Risk Untrained staff QA/Processing Product Current Likly 1 Current Frequency 3	Does Update Affect? No Risk Frequency due to Update 3.Occasional Risk Likely Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement i required	
31056Q29	Process 7861 Software Validation Of Training Documents Forced Reading Software Validating Of Training Documents via Forced Required Reading Current Known Risk required reading not read. Current Likly 1 Current Frequency 2	Does Update Affect? No Risk Frequency due to Update 2.Remote Risk Likely Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement i required	
31056Q30	Process 7865 Software Validation Conflicting Audits Software Validation of the system: To check all process(s) tasks and audits are not clashed with the same person doing the Task as the Audit. Current Known Risk non Automatic 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	
31056Q31	Process 7870 Software Validation Non Conformance Product Risk Feedback Loop Scope to check the automatic system of tagging product non conformance and other issues to the post market surveillance review report. Current Known Risk issues not carried out 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	
31056Q32	Process 7871 Review Exclusion From Viamed 13485:2016 And VST 9001:2015 To review the Exclusions / boundaries to ISO 13485:2016 for Viamed Current Known Risk Something is missed. Current Likly 1 Current Frequency 1	Does Update Affect? No Risk Frequency due to Update 1.Improbable Risk Likely Due to Update	Notes On Risk / Benefits statement i required	

		1.Negligible	Action Required: No Action Required	
31056Q33	<p>Process 7874</p> <p>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 Current Known Risk Using out of date Med Dev Current Likly 1 Current Frequency 1</p>	<p>Does Update Affect? No</p> <p>Risk Frequency due to Update 1.Improbable</p> <p>Risk Likely Due to Update 1.Negligible</p> <p>Action Required: No Action Required</p>	Notes On Risk / Benefits statement i required	
31056Q34	<p>Process 7875</p> <p>Software Validation Document Control To test document control is working as intended. Current Known Risk If not carried out, document index is unvalidated Current Likly 1 Current Frequency 1</p>	<p>Does Update Affect? No</p> <p>Risk Frequency due to Update 1.Improbable</p> <p>Risk Likely Due to Update 1.Negligible</p> <p>Action Required: No Action Required</p>	Notes On Risk / Benefits statement i required	
31056Q35	<p>Process 7876</p> <p>Maintain Update Of ISO Route Maps To review Route map VIAMED 13485:2016 and VST 9001:2015</p> <p>See if a new Summary sheet needs producing, print new PDF, and upload on top of the old summary</p> <p>Current Known Risk Summary sheet gets out of date. Current Likly 2 Current Frequency 1</p>	<p>Does Update Affect? No</p> <p>Risk Frequency due to Update 1.Improbable</p> <p>Risk Likely Due to Update 2.Minor</p> <p>Action Required: No Action Required</p>	Notes On Risk / Benefits statement i required	
31056Q36	<p>Process 7878</p> <p>Review Possible Upcoming Regulation Changes Review possible legal / regulator changes that might affect Viamed / VST Current Known Risk Legal / Regulatory changes stop us being able to carry out our processes as per QMS Current Likly 1 Current Frequency 3</p>	<p>Does Update Affect? No</p> <p>Risk Frequency due to Update 3.Occasional</p> <p>Risk Likely Due to Update 1.Negligible</p> <p>Action Required: No Action Required</p>	Notes On Risk / Benefits statement i required	
31056Q37	<p>Process 7879</p> <p>Software Validation Scheduled Tasks And Audits To check the Scheduled Tasks and Audits is working as Intended. To also Check the Out of Date documents is working as Intended. Current Known Risk Tasks and Audit Rolling Issues Key to ISO requirements. risk of losing standards Current Likly 1 Current Frequency 1</p>	<p>Does Update Affect? No</p> <p>Risk Frequency due to Update 1.Improbable</p> <p>Risk Likely Due to Update 1.Negligible</p> <p>Action Required: No Action Required</p>	Notes On Risk / Benefits statement i required	
31056Q38	<p>Process 7880</p> <p>Software Validation Out Of Date Documents To confirm the out of documents computer software functions as expected flagging out of date items on to the list Current Known Risk Old document in the system Current Likly 1 Current Frequency 1</p>	<p>Does Update Affect? No</p> <p>Risk Frequency due to Update 1.Improbable</p> <p>Risk Likely Due to Update 1.Negligible</p> <p>Action Required: No Action Required</p>	Notes On Risk / Benefits statement i required	
31056Q39	<p>Process 7881</p> <p>Software Validation - Live Orders To compare Opera Live Orders to Intrastats Back order Active List</p> <p>NO LONGER REQUIRED Opera is now out of the system Current Known Risk no risks, confirmation back orders is working as inteneded Current Likly 1 Current Frequency 1</p>	<p>Does Update Affect? No</p> <p>Risk Frequency due to Update 1.Improbable</p> <p>Risk Likely Due to Update 1.Negligible</p> <p>Action Required: No Action Required</p>	Notes On Risk / Benefits statement i required	
31056Q40	<p>Does Generic CE File Attached to All Technical file #2 Of type 5 require any Notificaions and/or Risk assesment updates due to this update</p>	<p>Does Update Affect? No</p> <p>Risk Frequency due to Update 1.Improbable</p>	Notes On Risk / Benefits statement i required	

Affect? Risk Likly Due

No to Update

1.Negligible

Action Required:

No Action

Required

31056Q41 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