

Document VOP 21 Risk, Risk Management and Risk Analysis Revision ID75935

Suggested Upload Document Name: **Risk Assessment For Updating Document ID75935**

Completed by [Derek Lamb](#) 03 Mar 2025

Reason for Risk Assessment

added VM3COP24.01 reference

Document VOP 21 Risk, Risk Management and Risk Analysis Revision ID75935 Is linked to the Following Standards and processes

Risk Assessment Question ID75935	Does Update Affect	Risk on Update	Notes On Risk / Benefits statement if required
75935Q0 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 if required
75935Q1 Viamed Ltd ISO13485:2016 Section: 4.1.2 Quality management system The organization shall: a) determine the processes needed for the quality management system and the application of these processes throughout the organization taking into account the roles undertaken by the organization; b) apply a risk based approach to the control of the appropriate processes needed for the quality management system; c) determine the sequence and interaction of these processes.	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 if required
75935Q2 Viamed Ltd ISO13485:2016 Section: 5.4.2 Quality management system planning Top management shall ensure that: a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives; b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.	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 if required
75935Q3 Viamed Ltd ISO13485:2016 Section: 7.4.1 Purchasing process The organization shall document procedures (see 4.2.4) to ensure that purchased product conforms to specified purchasing information. The organization shall establish criteria for the evaluation and selection of suppliers. The criteria shall be: a) based on the supplier's ability to provide product that meets the organizations' requirements; b) based on the performance of the supplier; c) based on the effect of the purchased product on the quality of the medical device; d) proportionate to the risk associated with the medical device. The organization shall plan the monitoring and re-evaluation of suppliers. Supplier performance in meeting requirements for the purchased product shall be monitored. The results of the monitoring shall provide an input into the supplier re-evaluation process. Non-fulfilment of purchasing requirements shall be addressed with the supplier proportionate to the risk associated with the purchased product and compliance with applicable regulatory requirements. Records of the results of evaluation, selection, monitoring and re-evaluation of supplier capability or performance and any necessary actions arising from these activities 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 if required
75935Q4 ProcessProcess 11 Distribution Of Post Distibuting incoming post to correct person Current Known Risk Royal Mail fail to deliver post Current Likly 3 Current Frequency 1	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update	Notes On Risk / Benefits statement if required

			3.Serious Action Required: No Action Required	
75935Q5	<p>ProcessProcess 5882 Send Post To Humanmed Humanmed post is received, it needs to be forwarded to Humanmed UK Sales Manager</p> <p>HumanMed has Gone, tasks no longer required Current Known Risk Post is not sent Current Likly 4 Current Frequency 1</p>	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 4.Critical Action Required: No Action Required	Notes On Risk / Benefits statement if required
75935Q6	<p>ProcessProcess 7743 Customer Complaints Paper File Major Customer Complaints get escalated to Paper Customer Complaints file.</p> <p>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</p>	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement if required
75935Q7	<p>ProcessProcess 5855 Purchase Order Requirements Teledyne To contact Teledyne and confirm the purchase orders we have outstanding for them Current Known Risk That good that are required will not be available. Current Likly 2 Current Frequency 1</p>	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement if required
75935Q8	<p>ProcessProcess 8030 Purchase Order Invoice Review Confirm the Price on our purchase order matches the price charged by the supplier Current Known Risk We over pay for products or services Current Likly 1 Current Frequency 2</p>	Does Update Affect? No	Risk Frequency due to Update 2.Remote Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required
75935Q9	<p>Final Notes No ISO Procedures or Process are negativly affected by updating this document with the new document proposed, only adding refereence to VM3C0P24.01 refe</p>			

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