

Document Viamed Top Level Quality Objectives Revision ID22429

Suggested Upload Document Name: Risk Assesment For Updating Document ID22429

Completed by Derek Lamb 27 Sep 2023











Reason for Risk Assessment

No risk required, as just updating to current objectives for the files

Document Viamed Top Level Quality Objectives Revision ID22429 Is linked to the Following Standards and processes

Risk Assessment Question ID22429	Does Update Affect	Risk on Update	Notes On Risk / Benefits statement if required	Further Action Required on Issue
22429Q0 Does this Update warrant updating Any External Parties due to any <b>Terms and Conditional Agreements</b> 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	Further Action Required on Issue
22429Q1 Viamed Ltd ISO13485:2016 Section: 5.1 Management commitment Top management shall provide evidence of its commitment to the development and implementation of the quality management system and maintenance of its effectiveness by: a) communicating to the organization the importance of meeting customer as well as applicable regulatory requirements; b) establishing the quality policy; c) ensuring that quality objectives are established; d) conducting management reviews; e) ensuring the availability of resources.	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	Further Action Required on Issue
22429Q2 Viamed Ltd ISO13485:2016 Section: 5.4.1 Quality objectives Top management shall ensure that quality objectives, including those needed to meet applicable regulatory requirements and requirements for product, are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.	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	Further Action Required on Issue
22429Q3 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	Further Action Required on Issue
22429Q4 VST Ltd ISO9001:2015 Section: 5.1.1 General Top management shall demonstrate leadership and commitment with respect to the quality management system by: a) taking accountability for the effectiveness of the quality management system; b) ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of the organization; c) ensuring the integration of the quality management system requirements into the organization's business processes; d) promoting the use of the process approach and risk-based thinking; e) ensuring that the resources needed for the quality management system are available; f) communicating the importance of effective quality management and of conforming to the quality management system requirements; g) ensuring that the quality management system achieves its intended results; h) engaging, directing and supporting persons to contribute to the effectiveness of the quality management system; i) promoting improvement; j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility. NOTE Reference to business in this International Standard can be interpreted broadly to mean those activities that are core to the purposes of the organization's existence, whether the organization is public, private, for profit or not for profit.	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	Further Action Required on Issue
22429Q5 Process23 Company Objectives Ensure the company Objects are still current and upto date	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	Further Action Required on Issue

22429Q6	Process 11 Distribution Of Post Distributing 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 3.Serious Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
22429Q7	Process 22 Company Polycys Ensure the company polycys are still current and upto date Current Known Risk Company shoots of in directions that are not laid out in its polycys or does not meet its objectives Current Likly 1 Current Frequency 1	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	Further Action Required on Issue
22429Q8	Process 23 Company Objectives Ensure the company Objects are still current and upto date Current Known Risk Company shots of in directions that are not laid out in its objectives Current Likly 1 Current Frequency 1	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	Further Action Required on Issue
22429Q9	Process 26 Company Resources Overview of the Company using various data Reporting Screens Current Known Risk Not enough resources to complete tasks 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 if required	Further Action Required on Issue
22429Q10	Process 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	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 if required	Further Action Required on Issue
22429Q11	Process 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	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 if required	Further Action Required on Issue
22429Q12	Process 5882 Send Post To Humanmed Humanmed post is received, it needs to be forwarded to Humanmed UK Sales Manager HumanMed has Gone, tasks no longer required Current Known Risk Post is not sent Current Likly 4 Current Frequency 1	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	Further Action Required on Issue
22429Q13	Process 6931 Customer Complaints Review the Customer Complaints Heading Current Known Risk things are not followed up in a timely manner or are missed 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 if required	Further Action Required on Issue
22429Q14	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? 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	Further Action Required on Issue
22429Q15	Process 7093 BSI Audits Calander Review of outstanding Audits Current Known Risk Audits dont get completed Current Likly 1 Current Frequency 1	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	Further Action Required on Issue
22429Q16	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 Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue

22429Q17	 ProcessProcess 7670 Humanmed general Issues Review of Humanmed sales and orders and clear any duplicates or problems. Current Known Risk That there are duplicate orders o the system due to errors. 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 if required	Further Action Required on Issue
22429Q18	 ProcessProcess 7686 Thorough Checking Of Awaiting Action Tray - Priority 8s Check that outstanding orders with unresolved issues are being followed up and addressed Current Known Risk Computer/network breakdown Current Likly 2 Current Frequency 1	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	Further Action Required on Issue
22429Q19	 ProcessProcess 7697 Yearly Pricing Review To review the current pricing and impact of increases Current Known Risk Getting this wrong can interfere with sales. Current Likly 1 Current Frequency 2	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	Further Action Required on Issue
22429Q20	 ProcessProcess 7739 Intrastats Amendment Log Intrastat Changes updates. Logging system to enable roll back should anything break Current Known Risk None, The updates are automatically logged and stored for easy retrieval. This process is simply to add notes to new updates Current Likly 2 Current Frequency 1	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	Further Action Required on Issue
22429Q21	 ProcessProcess 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 Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
22429Q22	 ProcessProcess 7744 FDA Device Establishment Registration And Listing FDA registration and the CMDCAS products  In order to sell in the USA / Canada Markets products need to be registered with the FDA.  Current Known Risk Its harder to initially get on teh register than maintaining it.  Inability to sell products in North America Current Likly 1 Current Frequency 1	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	Further Action Required on Issue
22429Q23	 ProcessProcess 7750 Meeting With Management Meeting between management and office team leader to discuss improvement of systems and address any issues Current Known Risk Staff being unavailable 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 if required	Further Action Required on Issue
22429Q24	 ProcessProcess 7753 Management Meeting Warehouse To discuss any problems, to assess work load and staffing. To review issues with regard the Warehouse. Current Known Risk Meetings not carried out regularly. 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 if required	Further Action Required on Issue
22429Q25	 ProcessProcess 7791 Price List Check Changing of the prices lists. Issue to check these are current  *Vandagraph is not an ISO company Current Known Risk That people will quote the wrong price to the customer.  Current Likly 1 Current Frequency 2	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	Further Action Required on Issue
22429Q26	 ProcessProcess 7827 Review The Quality Policy VST To review the Quality policy and check it is still valid and upto date. Current Known Risk that policy will go out of date Current Likly 1 Current Frequency 1	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	Further Action Required on Issue
22429Q27	 ProcessProcess 7828 Review The Quality Policy Viamed To review the Quality policy and check it is still valid and upto date. Current Known Risk That the policy will go out of date Current Likly 1 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	Further Action Required on Issue

		<div>1.Negligible</div> <div>Action Required:</div> <div>No Action Required</div>			
22429Q28	<div>ProcessProcess 7830</div> <div>Review Q.A. Failures Report</div> <div>To review the Quantities of Failed product per Stock reference Passing through the Q.A. system</div> <div>Current Known Risk No risk</div> <div>Current Likly 3 Current Frequency 1</div>	<div>Does Update Affect?</div> <div>No</div>	<div>Risk Frequency due to Update</div> <div>1.Improbable</div> <div>Risk Likly Due to Update</div> <div>3.Serious</div> <div>Action Required:</div> <div>No Action Required</div>	<div>Notes On Risk / Benefits statement if required</div>	<div>Further Action Required on Issue</div>
22429Q29	<div>ProcessProcess 7833</div> <div>Importance Of Effective Quality Management</div> <div>To Remind Staff of the Importance of the ISO systems and they should be following the procedures</div> <div>Current Known Risk people may become careless</div> <div>Current Likly 2 Current Frequency 1</div>	<div>Does Update Affect?</div> <div>No</div>	<div>Risk Frequency due to Update</div> <div>1.Improbable</div> <div>Risk Likly Due to Update</div> <div>2.Minor</div> <div>Action Required:</div> <div>No Action Required</div>	<div>Notes On Risk / Benefits statement if required</div>	<div>Further Action Required on Issue</div>
22429Q30	<div>ProcessProcess 7834</div> <div>Financial Review</div> <div>The review the Financial requirements</div> <div>Current Known Risk Non</div> <div>Current Likly 1 Current Frequency 1</div>	<div>Does Update Affect?</div> <div>No</div>	<div>Risk Frequency due to Update</div> <div>1.Improbable</div> <div>Risk Likly Due to Update</div> <div>1.Negligible</div> <div>Action Required:</div> <div>No Action Required</div>	<div>Notes On Risk / Benefits statement if required</div>	<div>Further Action Required on Issue</div>
22429Q31	<div>ProcessProcess 7848</div> <div>Review ISO Scopes</div> <div>To Review the Scope of the ISO 9001 / ISO 13485 Standards</div> <div>Current Known Risk No risks Rolling issue to perform task</div> <div>Current Likly 1 Current Frequency 1</div>	<div>Does Update Affect?</div> <div>No</div>	<div>Risk Frequency due to Update</div> <div>1.Improbable</div> <div>Risk Likly Due to Update</div> <div>1.Negligible</div> <div>Action Required:</div> <div>No Action Required</div>	<div>Notes On Risk / Benefits statement if required</div>	<div>Further Action Required on Issue</div>
22429Q32	<div>Final Notes</div> <div>No ISO Procedures or Process are negativly affected by updating this document with the new document proposed</div>				

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