

Document VM3COP24.01 Definitions of Risk Revision ID51885

Suggested Upload Document Name: **Risk Assesment For Updating Document ID51885**

Completed by [Derek Lamb](#) 19 Nov 2021

Reason for Risk Assesment

Fixed word unlikely to Improbable. To make it consistent.Risk Assesment For Updating Document ID51885





Document VM3COP24.01 Definitions of Risk Revision ID51885 Is linked to the Following Standards and processes

Risk Assesment Question ID51885	Does Update Risk on Update Affect	Risk Frequency due to Update	Notes On Risk / Benefits statement if required	Further Action Required on Issue
51885Q0 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	Further Action Required on Issue
51885Q1 Viamed Ltd ISO13485:2016 Section: 4.1.4 Quality management system For each quality management system process, the organization shall: The organization shall manage these quality management system processes in accordance with the requirements of this International Standard and applicable regulatory requirements. Changes to be made to these processes shall be: a) evaluated for their impact on the quality management system; b) evaluated for their impact on the medical devices produced under this quality management system c) controlled in accordance with the requirements of this International Standard and applicable regulatory requirements.	Does Update Affect? Yes ▾	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 fixed wording wording, no inherent risk to rest of system	Further Action Required on Issue

51885Q2 VST Ltd ISO9001:2015 Section: 4 Context of the organization	Does Update Affect? <input type="button" value="No"/> Risk Frequency due to Update <input type="button" value="1.Improbable"/> Risk Likly Due to Update <input type="button" value="1.Negligible"/> Action Required: No Action Required	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>
51885Q3 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? <input checked="" type="button" value="Yes"/> Risk Frequency due to Update <input type="button" value="1.Improbable"/> Risk Likly Due to Update <input type="button" value="1.Negligible"/> Action Required: No Action Required	Notes On Risk / Benefits statement if required fixed wording wording, no inherent risk to rest of system	Further Action Required on Issue <div></div>





51885Q4	VST Ltd ISO9001:2015 Section: 6.1 When planning for the quality management system, the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to: a) give assurance that the quality management system can achieve its intended result(s); b) enhance desirable effects; c) prevent, or reduce, undesired effects; d) achieve improvement.	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 if required	Further Action Required on Issue
51885Q5	Process 22 Company Policies Ensure the company policies are still current and upto date Current Known Risk Company shoots of in directions that are not laid out in its policies or does not meet its objectives 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 if required	Further Action Required on Issue
51885Q6	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 Likely Due to Update 1.Negligible ▾ Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
51885Q7	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 Likely Due to Update 3.Serious ▾ Action Required:	Notes On Risk / Benefits statement if required	Further Action Required on Issue

No Action
Required

51885Q8	 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? <div>No ▾</div>	Risk Frequency due to Update <div>1.Improbable ▾</div> Risk Likly Due to Update <div>3.Serious ▾</div> Action Required: No Action Required	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>
51885Q9	 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? <div>No ▾</div>	Risk Frequency due to Update <div>3.Occasional ▾</div> Risk Likly Due to Update <div>1.Negligible ▾</div> Action Required: No Action Required	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>
51885Q10	 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? <div>No ▾</div>	Risk Frequency due to Update <div>1.Improbable ▾</div> Risk Likly Due to Update <div>1.Negligible ▾</div> Action Required: No Action Required	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>
51885Q11	 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.	Does Update Affect? <div>Yes ▾</div>	Risk Frequency due to Update <div>2.Remote ▾</div> Risk Likly Due to Update <div>2.Minor ▾</div>	Notes On Risk / Benefits statement if required fixed wording wording, no inherent risk to rest of system <div></div>	Further Action Required on Issue <div></div>

Current Known Risk Non conformances go unfixed
Current Likly 2 Current Frequency 2

Action
Required:
No Action
Required

51885Q12	 Process 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 <div></div>	Further Action Required on Issue <div></div>
51885Q13	 Process 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 <div></div>	Further Action Required on Issue <div></div>
51885Q14	 Process 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 <div></div>	Further Action Required on Issue <div></div>
51885Q15	 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	Does Update Affect? No ▾	Risk Frequency due to Update 1.Improbable ▾ Risk Likly Due to Update	Notes On Risk / Benefits statement if required <div></div>	Further Action Required on Issue <div></div>

File.
Current Known Risk Customer Complaints could be missed or not filed correctly
Current Likly 2 Current Frequency 1

2.Minor
Action
Required:
No Action
Required

51885Q16	<a>Process Process 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 <div></div>	Further Action Required on Issue <div></div>
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51885Q17	<a>Process Process 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 <div></div>	Further Action Required on Issue <div></div>
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51885Q18	<a>Process Process 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 <div></div>	Further Action Required on Issue <div></div>
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51885Q19	<a>Process Process 7791	Does	Risk Frequency	Notes On Risk / Benefits statement if	Further Action Required
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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

Update due to Update
Affect? 2.Remote
No Risk Likly Due
to Update
1.Negligible
Action
Required:
No Action
Required

required

on Issue

51885Q20 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? 1.Improbable
No Risk Likly Due
to Update
1.Negligible
Action
Required:
No Action
Required

Notes On Risk / Benefits statement if
required

Further Action Required
on Issue

51885Q21 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? 1.Improbable
No Risk Likly Due
to Update
1.Negligible
Action
Required:
No Action
Required

Notes On Risk / Benefits statement if
required

Further Action Required
on Issue

51885Q22 ProcessProcess 7833

Importance Of Effective Quality Management
To Remind Staff of the Importance of the ISO systems and they should be
following the procedures
Current Known Risk people may become careless
Current Likly 2 Current Frequency 1

Does Update
Affect? 1.Improbable
No Risk Likly Due
to Update
2.Minor
Action
Required:
No Action
Required

Notes On Risk / Benefits statement if
required

Further Action Required
on Issue

51885Q23

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ProcessProcess 7834

Financial Review

The review the Financial requirements

Current Known Risk Non

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

51885Q24

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ProcessProcess 7878

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

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

51885Q25

Final Notes

Fixed wording wording,
no inherent risk to rest of system

SAVE FORM