

Document Audit 21 Audit of Audit Revision ID41422

Suggested Upload Document Name: **Risk Assesment For Updating Document ID41422**

Completed by Helen Lamb 09 Dec 2021

Reason for Risk Assesment

Updating processes for 2021 no risk associated with the update

Document Audit 21 Audit of Audit Revision ID41422 Is linked to the Following Standards and processes

Risk Assesment Question ID41422	Does Update Risk on Update Affect	Risk Frequency due to Update	Notes On Risk / Benefits statement if required	Further Action Required on Issue
41422Q0 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
41422Q1 Viamed Ltd ISO13485:2016 Section: 4.1 Quality management system	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
41422Q2 Viamed Ltd ISO13485:2016 Section: 5.6.2 Review input General The input to management review shall include, but is not limited to,	Does Update	Risk Frequency due to Update 1.Improbable ▾	Notes On Risk / Benefits statement if required	Further Action Required on Issue

information arising from:

- a) feedback;
- b) complaint handling;
- c) reporting to regulatory authorities;
- d) audits;
- e) monitoring and measurement of processes;
- f) monitoring and measurement of product;
- g) corrective action;
- h) preventive action;
- i) follow-up actions from previous management reviews;
- j) changes that could affect the quality management system;
- k) recommendations for improvement;
- l) applicable new or revised regulatory requirements.

Affect? Risk Likly Due
No ▼ to Update
1.Negligible ▼
Action
Required:
No Action
Required

41422Q3	Viamed Ltd ISO13485:2016 Section: 8.2.4 Internal audit The organization shall conduct internal audits at planned intervals to determine whether the quality management system: a) conforms to planned and documented arrangements, requirements of this International Standard, quality management system requirements established by the organization, and applicable regulatory requirements; b) is effectively implemented and maintained. The organization shall document a procedure to describe the responsibilities and requirements for planning and conducting audits and recording and reporting audit results. An audit program shall be planned, taking into consideration the status and importance of the processes and area to be audited, as well as the results of previous audits. The audit criteria, scope, interval and methods shall be defined and recorded (see 4.2.5). The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work. Records of the audits and their results, including identification of the processes and areas audited and the conclusions, shall be maintained (see 4.2.5). The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of	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

verification results.
NOTE Further information can be found in ISO 19011.

41422Q4	<p>Viamed Ltd ISO13485:2016 Section: 8.5.1</p> <p>General</p> <p>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.</p>	<p>Does Update Affect? No ▼</p>	<p>Risk Frequency due to Update</p> <p>1.Improbable ▼</p> <p>Risk Likely Due to Update</p> <p>1.Negligible ▼</p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>
41422Q5	<p>VST Ltd ISO9001:2015 Section: 5.3</p> <p>Organizational roles, responsibilities and authorities</p> <p>Top management shall ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization.</p> <p>Top management shall assign the responsibility and authority for:</p> <p>a) ensuring that the quality management system conforms to the requirements of this International Standard;</p> <p>b) ensuring that the processes are delivering their intended outputs;</p> <p>c) reporting on the performance of the quality management system and on opportunities for improvement (see 10.1), in particular to top management;</p> <p>d) ensuring the promotion of customer focus throughout the organization;</p> <p>e) ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.</p>	<p>Does Update Affect? No ▼</p>	<p>Risk Frequency due to Update</p> <p>1.Improbable ▼</p> <p>Risk Likely Due to Update</p> <p>1.Negligible ▼</p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>
41422Q6	<p>VST Ltd ISO9001:2015 Section: 9.2.1</p> <p>The organization shall conduct internal audits at planned intervals to provide information on whether the quality management system:</p> <p>a) conforms to:</p> <p>1) the organization's own requirements for its quality management system;</p> <p>2) the requirements of this International Standard;</p> <p>b) is effectively implemented and maintained.</p>	<p>Does Update Affect? No ▼</p>	<p>Risk Frequency due to Update</p> <p>1.Improbable ▼</p> <p>Risk Likely Due to Update</p> <p>1.Negligible ▼</p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>
41422Q7	<p>VST Ltd ISO9001:2015 Section: 9.2.2</p>	<p>Does</p>	<p>Risk Frequency</p>	<p>Notes On Risk / Benefits statement if</p>	<p>Further Action Required</p>

The organization shall:




- a) plan, establish, implement and maintain an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits;
- b) define the audit criteria and scope for each audit;
- c) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;
- d) ensure that the results of the audits are reported to relevant management;
- e) take appropriate correction and corrective actions without undue delay;
- f) retain documented information as evidence of the implementation of the audit programme and the audit results.

NOTE See ISO 19011 for guidance.


Update due to Update
Affect? 1.Improbable ▼
No ▼ Risk Likly Due
to Update
1.Negligible ▼
Action
Required:
No Action
Required

required

on Issue

41422Q8	 Process38 Audits Up to Date and Confirm next years Audit schedule Management oversight of Internal Tasks and Audits Issue(s). Review the responses to Tasks and Audits. ensure they are being fulfilled and completed.	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
41422Q9	 Process7093 BSI Audits Calander Review of outstanding Audits	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
41422Q10	 Process7670 Humanmed general Issues Review of Humanmed sales and orders and clear any duplicates or problems.	Does Update	Risk Frequency due to Update 1.Improbable ▼	Notes On Risk / Benefits statement if required	Further Action Required on Issue


Affect? Risk Likly Due
No ☐ to Update
3.Serious ☐
Action
Required:
No Action
Required

41422Q11  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? Risk Frequency due to Update
No ☐ 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

41422Q12  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? Risk Frequency due to Update
No ☐ 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

41422Q13  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
No ☐ 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

41422Q14  Process 7713
Review Roles And Responsibility

Does Update
Affect? Risk Frequency due to Update

















Notes On Risk / Benefits statement if required

Further Action Required on Issue



	Ensure All tasks allocated to active Members of staff, Current Known Risk That not all jobs will be allocated to a member of staff. That we may not share out jobs in a appropriate way. Risk of being over faced. Current Likly 2 Current Frequency 2	Affect? <div>No</div> 2.Remote <div>▼</div> Risk Likly Due to Update 2.Minor <div>▼</div> Action Required: No Action Required			
41422Q15	<div>🔗</div> ProcessProcess 7740 Weights Per Region Needed To Submit EC Sales List Filling in HMRC data requires Weights and dimensions per region in the EC This process ensures all the data is in place for the report Current Known Risk Fines for late submission Current Likly 1 Current Frequency 1	Does Update Affect? <div>No</div> Risk Frequency due to Update 1.Improbable <div>▼</div> Risk Likly Due to Update 1.Negligible <div>▼</div> Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue	
41422Q16	<div>🔗</div> ProcessProcess 7741 Review Ethical Policy Review the current Ethical Policy in intrastats Current Known Risk That something is missed that we would like to include Current Likly 1 Current Frequency 1	Does Update Affect? <div>No</div> Risk Frequency due to Update 1.Improbable <div>▼</div> Risk Likly Due to Update 1.Negligible <div>▼</div> Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue	
41422Q17	<div>🔗</div> 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? <div>No</div> Risk Frequency due to Update 1.Improbable <div>▼</div> Risk Likly Due to Update 2.Minor <div>▼</div> Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue	
41422Q18	<div>🔗</div> ProcessProcess 7744	Does	Risk Frequency	Notes On Risk / Benefits statement if	Further Action Required

<p>FDA Device Establishment Registration And Listing FDA registration and the CMDCAS products</p> <p>In order to sell in the USA / Canada Markets products need to be registered with the FDA.</p> <p>Current Known Risk Its harder to initially get on teh register than maintaining it.</p> <p>Inability to sell products in North America Current Likly 1 Current Frequency 1</p>	<p>Update due to Update Affect? No ▾</p>	<p>1.Improbable ▾ Risk Likly Due to Update 1.Negligible ▾ Action Required: No Action Required</p>	<p>required</p>	<p>on Issue</p>
<p>41422Q19 ↻ProcessProcess 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</p>	<p>Does Update Affect? No ▾</p>	<p>Risk Frequency due to Update 1.Improbable ▾ Risk Likly Due to Update 3.Serious ▾ Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>
<p>41422Q20 ↻ProcessProcess 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</p>	<p>Does Update Affect? No ▾</p>	<p>Risk Frequency due to Update 1.Improbable ▾ Risk Likly Due to Update 1.Negligible ▾ Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>
<p>41422Q21 ↻ProcessProcess 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</p>	<p>Does Update Affect? No ▾</p>	<p>Risk Frequency due to Update 1.Improbable ▾ Risk Likly Due to Update 3.Serious ▾ Action Required:</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>

No Action
Required

41422Q22	 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 if required	Further Action Required on Issue
41422Q23	 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 if required	Further Action Required on Issue
41422Q24	 Process 7846 ISO System Management Review Viamed To Comply with Top Level Re-authorise the Current Audits for next 12 Months Cover the Agenda as Per VOP13 Current Known Risk Failure to do may cause major non conformites in QMS System 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
41422Q25	 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	Does Update Affect? No 	Risk Frequency due to Update 1.Improbable  Risk Likly Due to Update 1.Negligible 	Notes On Risk / Benefits statement if required	Further Action Required on Issue

Action
Required:
No Action
Required

41422Q26	 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 if required	Further Action Required on Issue
41422Q27	 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 Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
41422Q28	Final Notes Updating processes for 2021 no risk associated with the update				

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

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