

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 Assessment

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	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 Significant change to any ISO Certifications	Does Risk Frequency Update due to 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
41422Q1 Viamed Ltd ISO13485:2016 Section: 4.1 Quality management system	Does Risk Frequency Update due to 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
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 Risk Frequency Update 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 Risk Frequency
Update due to 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

verification results.

NOTE Further information can be found in ISO 19011.

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

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? <input type="button" value="1.Improbable"/> <input type="button" value="No"/> <input type="button" value="Risk Likly Due to Update"/> <input type="button" value="1.Negligible"/> <input type="button" value="Action Required: No Action Required"/>	required	on Issue
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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 Risk Frequency Update due to Update Affect? <input type="button" value="1.Improbable"/> <input type="button" value="No"/> <input type="button" value="Risk Likly Due to Update"/> <input type="button" value="1.Negligible"/> <input type="button" value="Action Required: No Action Required"/>	Notes On Risk / Benefits statement if required	Further Action Required on Issue
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41422Q9 Process7093
BSI Audits Calander
Review of outstanding Audits

Does Risk Frequency Update due to Update Affect? <input type="button" value="1.Improbable"/> <input type="button" value="No"/> <input type="button" value="Risk Likly Due to Update"/> <input type="button" value="1.Negligible"/> <input type="button" value="Action Required: No Action Required"/>	Notes On Risk / Benefits statement if required	Further Action Required on Issue
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41422Q10 Process7670
Humanmed general Issues
Review of Humanmed sales and orders and clear any duplicates or problems.

Does Risk Frequency Update due to Update Affect? <input type="button" value="1.Improbable"/>	Notes On Risk / Benefits statement if required	Further Action Required on Issue
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		Affect? Risk Likly Due No <input type="button" value="▼"/> to Update 3.Serious <input type="button" value="▼"/> Action Required: No Action Required	
41422Q11	ProcessProcess 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 Risk Frequency Update due to Update Affect? 3.Occasional <input type="button" value="▼"/> No <input type="button" value="▼"/> Risk Likly Due to Update 1.Negligible <input type="button" value="▼"/> Action Required: No Action Required	Notes On Risk / Benefits statement if required Further Action Required on Issue
41422Q12	ProcessProcess 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 Risk Frequency Update due to Update Affect? 1.Improbable <input type="button" value="▼"/> No <input type="button" value="▼"/> Risk Likly Due to Update 2.Minor <input type="button" value="▼"/> Action Required: No Action Required	Notes On Risk / Benefits statement if required Further Action Required on Issue
41422Q13	ProcessProcess 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 Risk Frequency Update due to Update Affect? 2.Remote <input type="button" value="▼"/> No <input type="button" value="▼"/> Risk Likly Due to Update 1.Negligible <input type="button" value="▼"/> Action Required: No Action Required	Notes On Risk / Benefits statement if required Further Action Required on Issue
41422Q14	ProcessProcess 7713 Review Roles And Responsibilities	Does Risk Frequency Update 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 an appropriate way.

Risk of being over faced.

Current Likly 2 Current Frequency 2

Affect? 2.Remote
No Risk Likely Due to Update
2.Minor
Action Required:
No Action Required

41422Q15 Process 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 Risk Frequency Update due to Update
Affect? 1.Improbable
No Risk Likely Due to Update

1.Negligible
Action Required:
No Action Required

Notes On Risk / Benefits statement if required

Further Action Required on Issue

41422Q16 Process 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 Risk Frequency Update due to Update
Affect? 1.Improbable
No Risk Likely Due to Update

1.Negligible
Action Required:
No Action Required

Notes On Risk / Benefits statement if required

Further Action Required on Issue

41422Q17 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 File.

Current Known Risk Customer Complaints could be missed or not filed correctly

Current Likly 2 Current Frequency 1

Does Risk Frequency Update due to Update
Affect? 1.Improbable
No Risk Likely Due to Update

2.Minor
Action Required:
No Action Required

Notes On Risk / Benefits statement if required

Further Action Required on Issue

41422Q18 Process 7744

Does Risk Frequency

Notes On Risk / Benefits statement if

Further Action Required

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

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

on Issue

41422Q19 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 Risk Frequency
Update due to Update
Affect? 1.Improbable
No Risk Likly Due to Update
3.Serious
Action Required:
No Action Required

Notes On Risk / Benefits statement if required

Further Action Required on Issue

41422Q20 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 Risk Frequency
Update due to 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

41422Q21 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 Risk Frequency
Update due to Update
Affect? 1.Improbable
No Risk Likly Due to Update
3.Serious
Action Required:

Notes On Risk / Benefits statement if required

Further Action Required on Issue

		No Action Required	
41422Q22	Process 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	<p>Does Risk Frequency Update due to Update Affect? <input type="checkbox"/> 1.Improbable <input checked="" type="checkbox"/> 2.Likely <input type="checkbox"/> 3.Serious</p> <p>No <input type="checkbox"/> Risk Likly Due to Update</p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div style="border: 1px solid black; height: 100px; width: 100%;"></div> <p>Further Action Required on Issue</p> <div style="border: 1px solid black; height: 100px; width: 100%;"></div>
41422Q23	Process 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 ISIssue, No Risk Current Likly 3 Current Frequency 1	<p>Does Risk Frequency Update due to Update Affect? <input type="checkbox"/> 1.Improbable <input checked="" type="checkbox"/> 2.Likely <input type="checkbox"/> 3.Serious</p> <p>No <input type="checkbox"/> Risk Likly Due to Update</p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div style="border: 1px solid black; height: 100px; width: 100%;"></div> <p>Further Action Required on Issue</p> <div style="border: 1px solid black; height: 100px; width: 100%;"></div>
41422Q24	Process 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	<p>Does Risk Frequency Update due to Update Affect? <input type="checkbox"/> 1.Improbable <input checked="" type="checkbox"/> 2.Likely <input type="checkbox"/> 3.Serious</p> <p>No <input type="checkbox"/> Risk Likly Due to Update</p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div style="border: 1px solid black; height: 100px; width: 100%;"></div> <p>Further Action Required on Issue</p> <div style="border: 1px solid black; height: 100px; width: 100%;"></div>
41422Q25	Process 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>Does Risk Frequency Update due to Update Affect? <input type="checkbox"/> 1.Improbable <input checked="" type="checkbox"/> 2.Likely <input type="checkbox"/> 3.Serious</p> <p>No <input type="checkbox"/> Risk Likly Due to Update</p> <p>Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p> <div style="border: 1px solid black; height: 100px; width: 100%;"></div> <p>Further Action Required on Issue</p> <div style="border: 1px solid black; height: 100px; width: 100%;"></div>

	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 Risk Frequency Update due to Update Affect? 3.Occasional <input type="checkbox"/> No <input checked="" type="checkbox"/> 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 Risk Frequency Update due to Update Affect? 1.Improbable <input type="checkbox"/> No <input checked="" type="checkbox"/> 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			

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 preferable), go back to document upload and upload to risk assesment button