Document VM3COP27.11 Performing a Technical File PMS and risk assessment Revision ID17824

Suggested Upload Document Name: **Risk Assesment For Updating Document ID17824**
Completed by Derek Lamb 17 Nov 2021
Reason for Risk Assesment

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Updated reference link from 14971:2012 to
Risk Admin Core Questions.
See Issue 241900 for more information
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Document VM3COP27.11 Performing a Technical File PMS and risk assessment Revision ID17824 Is linked to the Following Standards and processes

Risk Assesment ID17824	Question	Does Update Affect	Risk on Update	Notes On Risk / Benefits statement if required	Further Action Required on Issue
17824Q0	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 Freqency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required		
17824Q1	Viamed Ltd ISO13485:2016 Section: 7.1 Planning of product realization The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system. The organization shall document one or more processes for risk management in product realization. Records of risk management activities shall be maintained (see 4.2.5). In planning product realization, the organization shall determine the following, as appropriate:	Does Update Affect? Yes	Risk Freqency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: Needs Setting	Risk Admin Core Questions. this does not change or cause a risk to this process	

a) quality objectives and requirements for the product;
b) the need to establish processes and documents (see 4.2.4) and to provide resources specific to the
product, including infrastructure and work environment;
c) required verification, validation, monitoring, measurement, inspection and test, handling,
storage, distribution and traceability activities specific to the product together with the criteria
for product acceptance;
d) records needed to provide evidence that the realization processes and resulting product meet
requirements (see 4.2.5).
The output of this planning shall be documented in a form suitable for the organization's method of
operations.
NOTE Further information can be found in ISO 14971.

17824Q2 Viamed Ltd ISO13485:2016 Section: 7.3.2

Design and development planning
The organization shall plan and control the design and development of product. As appropriate,
design and development planning documents shall be maintained and updated as the design and
development progresses.
During design and development planning, the organization shall document:
a) the design and development stages;
b) the review(s) needed at each design and development stage;
c) the verification, validation, and design transfer activities that are appropriate at each design and
development stage;
d) the responsibilities and authorities for design and development;
e) the methods to ensure traceability of design and development outputs to design and
development inputs;
f) the resources needed including necessary competence of personnel

Does Update Affect? No

Risk Freqency 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

17824Q3 Viamed Ltd ISO13485:2016 Section: 8.1

General
The organization shall plan and implement the monitoring, measurement, analysis and improvement
processes needed to:
a) demonstrate conformity of product;
b) ensure conformity of the quality management system;
c) maintain the effectiveness of the quality management system.
This shall include determination of appropriate methods, including statistical

Does Update Affect? No

Risk Freqency due to Update 1.Improbable

Risk Likly Due to Update 1.Negligible

Action Required:

Notes On Risk / Benefits statement if required

Further Action Required on Issue

techniques, and the extent of their use.

No Action Required

17824Q4 Viamed Ltd ISO13485:2016 Section: 8.2.1

Feedback

As one of the measurements of the effectiveness of the quality management system, the organization shall gather and monitor information relating to whether the organization has met customer requirements. The methods for obtaining and using this information shall be documented.

The organization shall document procedures for the feedback process. This feedback process shall include provisions to gather data from production as well as post-production activities.

The information gathered in the feedback process shall serve as potential input into risk management for monitoring and maintaining the product requirements as well as the product realization or improvement processes.

If applicable regulatory requirements require the organization to gain specific experience from postproduction activities, the review of this experience shall form part of the feedback process.

Does Update Affect? No

Risk Freqency 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

17824Q5 VST Ltd ISO9001:2015 Section: 8.1

Operational planning and control

The organization shall plan, implement and control the processes (see 4.4) needed to meet the requirements for the provision of products and services, and to implement the actions determined in Clause 6, by:

a) determining the requirements for the products and services;

b) establishing criteria for:

1) the processes;

2) the acceptance of products and services;

c) determining the resources needed to achieve conformity to the product and service requirements;

d) implementing control of the processes in accordance with the criteria;

e) determining, maintaining and retaining documented information to the extent necessary:

1) to have confidence that the processes have been carried out as planned;

2) to demonstrate the conformity of products and services to their requirements.

The output of this planning shall be suitable for the organizations operations.

The organization shall control planned changes and review the consequences of unintended changes,

Does Update Affect? No

Risk Freqency 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

taking action to mitigate any adverse effects, as necessary.
The organization shall ensure that outsourced processes are controlled (see 8.4).

17824Q6 ProcessProcess 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 Freqency 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

17824Q7 ProcessProcess 5877
Review Company Data
To review the numbers of various departments.
Showing increasing / reducing staff requirements
Current Known Risk incorrect staff levels
Current Likly 3 Current Frequency 1

Does Update Affect? No
Risk Freqency 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

17824Q8 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 Update Affect? No
Risk Freqency 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

17824Q9 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

Does Update Affect? No
Risk Freqency due to Update 1.Improbable
Risk Likly Due to Update 3.Serious

Notes On Risk / Benefits statement if required

Further Action Required on Issue

Action Required: No Action Required

17824Q10 ProcessProcess 7834
Financial Review
The review the Financial requirements
Current Known Risk Non
Current Likly 1 Current Frequency 1

Does Update Affect? No

Risk Freqency 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

17824Q11 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

Does Update Affect? No

Risk Freqency 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

17824Q12 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

Does Update Affect? No

Risk Freqency 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

17824Q13 ProcessProcess 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 Freqency due to Update 1.Improbable

Risk Likly Due to Update

Notes On Risk / Benefits statement if required

Further Action Required on Issue

			3.Serious Action Required: No Action Required		

17824Q14	ProcessProcess 7840 Review VST Feedback - Customer 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 Freqency 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

17824Q15	ProcessProcess 7841 Review VST Feedback - Customer Complaints To review Customer Complaints see if Non Conformance need to be raised Current Known Risk Rolling ISsue, No Risk Current Likly 3 Current Frequency 1	Does Update Affect? No	Risk Freqency 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

17824Q16	ProcessProcess 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 Freqency 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

17824Q17	ProcessProcess 7843 Review VST Product Feedback Negative To review Negative feedback form Products see if Non Conformance or customer Complaints need to be raise	Does Update Affect? No	Risk Freqency due to Update 1.Improbable Risk Likly Due	Notes On Risk / Benefits statement if required	Further Action Required on Issue

Current Known Risk Rolling ISsue, No Risk
Current Likly 3 Current Frequency 1

to Update
3.Serious
Action Required:
No Action Required

17824Q18 ProcessProcess 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 Freqency 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

17824Q19 ProcessProcess 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 Freqency 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

17824Q20 ProcessProcess 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 Freqency 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

17824Q21 ProcessProcess 7874
Review For Latest Version Med Dev 2.12.
To Ensure we have the latest version of Med Dev 2.12.

Does Update
Risk Freqency due to Update
1.Improbable

Notes On Risk / Benefits statement if required

Further Action Required on Issue

and update management if its been updated
Current Known Risk Using out of date Med Dev
Current Likly 1 Current Frequency 1

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

17824Q22 ProcessProcess 7876
Maintain Update Of ISO Route Maps
To review
Route map VIAMED 13485:2016
and VST 9001:2015

See if a new Summary sheet needs producing,
print new PDF, and upload on top of the old summary

Current Known Risk Summary sheet gets out of date.
Current Likly 2 Current Frequency 1

Does Update Affect? No
Risk Freqency 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

17824Q23 ProcessProcess 7877
Disaster Planning
To Plan for disaster
Current Known Risk Total failure
Current Likly 1 Current Frequency 3

Does Update Affect? No
Risk Freqency 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

17824Q24 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 Freqency 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

17824Q25	Does Bluepoint Capnograph Technical file #47 Of type 5 require any Notificaions and/or Risk assesment updates	Does Update Affect? No Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Risk Freqency due to Update 1.Improbable	Notes On Risk / Benefits statement if required	Further Action Required on Issue

17824Q26 Final Notes

No ISO Procedures or Process
are negativly affected by updating this document with the new document proposed

SAVE FORM