Document Audit 17 Internal Audits Revision ID41240

Suggested Upload Document Name: **Risk Assesment For Updating Document ID41240**
Completed by Helen Lamb 08 Dec 2021
Reason for Risk Assesment

added 2021 processes. No new risk or significant change

Document Audit 17 Internal Audits Revision ID41240 Is linked to the Following Standards and processes

Risk Assesment Question ID41240		Does Update Affect	Risk on Update	Notes On Risk / Benefits statement if required	Further Action Required on Issue
41240Q0	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	Notes On Risk / Benefits statement if required	Further Action Required on Issue
41240Q1	Viamed Ltd ISO13485:2016 Section: 4.1 Quality management system	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
41240Q2	Viamed Ltd ISO13485:2016 Section: 8.2.4 Internal audit The organization shall conduct internal audits at planned intervals to determine	Does Update	Risk Freqency due to Update 1.Improbable	Notes On Risk / Benefits statement if required	Further Action Required on Issue

	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 verification results. NOTE Further information can be found in ISO 19011.	Affect? No Risk Likly Due to Update 1.Negligible Action Required: No Action Required		

41240Q3	VST Ltd ISO9001:2015 Section: 9.2.1 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.	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

41240Q4	Process7972 ISO System Management Review Vst	Does Update	Risk Freqency due to Update	Notes On Risk / Benefits statement if required	Further Action Required on Issue

To Comply with Top Level
Re-authorise the Current Audits for next 12 Months
Cover the Agenda as Per VOP13

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

41240Q5 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? 1.Improbable
No
Risk Likly Due to Update
1.Negligible
Action Required:
No Action Required

Risk Freqency due to Update

Notes On Risk / Benefits statement if required

Further Action Required on Issue

41240Q6 Final Notes

```
added 2021 processes no new risk or significant change
```

SAVE FORM