Document Audit 17 Internal Audits Revision ID41240

Suggested Completed Reason fo r					
	1 processes. No new risk or significant change				
Document Risk Assesment ID41240	Audit 17 Internal Audits Revision ID41240 Is linked to the Following Standards t Question	Does	cesses 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	Update Affect?	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	Update Affect?	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		Risk Frequency 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? Risk Likly Due No v to Update 1.Negligible v 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 so own requirements for its quality management system;
- 2) the requirements of this International Standard;
- b) is effectively implemented and maintained.

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

Notes On Risk / Benefits statement if required

Further Action Required on Issue

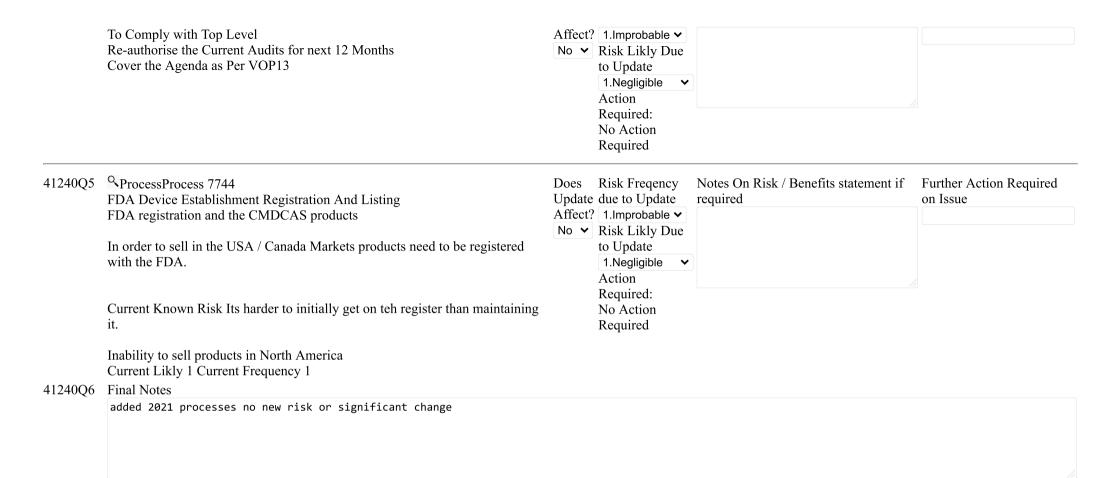
ISO System Management Review Vst

Does Risk Frequency Update due to Update

Required

Notes On Risk / Benefits statement if required

Further Action Required on Issue



SAVE FORM