Viamed Ltd + VST Ltd

Internal Audit Check list

INTERNAL AUDITS			
Created:	17/May 1995	**Audit No 17**	
Revised:	03 August 2020	_Derek Laws_	Page 1 of 2
Audit Date 21-9-20		Auditor _Helen Laws_	

header needs to be on every page

Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
VST Ltd ISO9001:2015 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.	_Audit Calendar infrastruct Doc index Route map_
Viamed Ltd ISO13485:2016 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 verification results. NOTE Further information can be found in ISO 19011.	_Audit Calendar Doc index_

QUESTION:	RESPONSE:	Y/N
Review Last years Audit. Update processes if required. Are all follow on Issue resolved satisfactory.	Nothing outstanding	Y
Verify that audits are performed independently of audit area.		Y
Check that the audit programme shows every area of the system has been covered. Intrastats → ISO → Document index File Groups → Processes to Audits VOPs.		Y
Verify that checklists are used to conduct the audit.		Y
Verify that area processes have been updated for the current year and are on the bottom of each audits.		Y
Check that sufficient objective evidence has been taken to ascertain conformance.		Y
Check that an audit report issue is produced that highlights agreed corrective actions.		Y
Check that these actions have followed up in a timely manner.		Y
Check that the audit database and matrix, is updated. (route map to ISO standard, link to QC 17 Cross reference)		Y
Verify that an Audit review has been undertaken. (Audit 21)		Y

Sub Processes Linked to Audit 17
Review the below processes tasks and audits and ensure they are completed in a timely manner.

List Processes Per Title

Audits

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID 7728 To carry out Audit 17 Internal Audits Viamed	#159640	11 Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M	
PROCESSID 7776 To carry out Audit 17 Internal Audits VST	#159651	191 Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M	