

Internal Audit Check list

VIAMED LTD INTERNAL AUDITS

Created:	17/May 1995	Audit No 17	
			Page 1 of 3
Audit Date	30-12-25	Auditor <i>Helen Lamb</i> <i>Derek Lamb</i>	

Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
Viamed Ltd ISO13485:2016 8.2.4	<p>Internal audit</p> <p>The organization shall conduct internal audits at planned intervals to determine whether the quality management system:</p> <p>a) conforms to planned and documented arrangements, requirements of this International Standard, quality management system requirements established by the organization, and applicable regulatory requirements;</p> <p>b) is effectively implemented and maintained.</p> <p>The organization shall document a procedure to describe the responsibilities and requirements for planning and conducting audits and recording and reporting audit results.</p> <p>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.</p> <p>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).</p> <p>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.</p> <p>NOTE Further information can be found in ISO 19011.</p>	<i>Doc index</i> <i>Audit calendar</i> <i>Route map</i> <i>Management review</i> <i>Roles + tasks</i>

	<u>QUESTION:</u>	<u>RESPONSE:</u>	Y/N
1	Review Last years Audit. Update processes if required. Are all follow on Issue resolved satisfactory.	<i>Nothing outstanding</i> <i>No Non Conformances.</i>	Y
2	Verify that audits are performed independently of audit area. <i>Audits by Helen, Derek + Mike</i>		Y
3	Check that the audit programme shows every area of the system has been covered. Intrastats → ISO → Document index File Groups → Processes to Audits VOPs.	<i>Checked</i> <i>No gaps</i>	Y
4	Verify that checklists are used to conduct the audit.		Y

5	Verify that area processes have been updated for the current year and are on the bottom of each audits.		Y
6	Check that sufficient objective evidence has been taken to ascertain conformance.		Y
7	Check that an audit report issue is produced that highlights agreed corrective actions.	Issues + Non Con Issues	Y
8	Check that these actions have followed up in a timely manner.		Y
9	Check that the audit database and matrix, is updated. (route map to ISO standard, link to QC 17 Cross reference)		Y
10	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

Clone from Docid

Managing Director				
Process Scope	Roll Task Roll Audit	Risk	Action	
PROCESSID 7972 To Comply with Top Level Re-authorise the Current Audits for next 12 Months Cover the Agenda as Per VOP13 *Note was linked to Viamed management headers relinked in 2025	Task: 1094 379089 Managing Director Audit : Due Feb 26	Freq 1 Risk 1 Overall 1	Task 12M	
Audits				
Process Scope	Roll Task Roll Audit	Risk	Action	
PROCESSID 7728 To carry out Audit 17 Internal Audits Viamed Any follow on issues must be identified with Observation Issue or a Non Conformance	Task: 382120 Audit :11 Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M	

<p>PROCESSID 7776 To carry out Audit 17 Internal Audits VST Any follow on issues must be identified with Observation Issue or a Non Conformance Issue. If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.</p>	<p>Task: 382126 Audit :191 Company Secretary Audit</p>	<p>Freq 1 Risk 2 Overall 2</p>	<p>Audit 12M</p>
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Rolling Tasks Linked to Document :Task (11) Task (191) Task (1094)