

Internal Audit Check list

Audit of Audits

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Audit Date	11-2-2020	Auditor H. Lamb + D. Lamb	

Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
VST Ltd ISO9001:2015 5.3	<p>Organizational roles, responsibilities and authorities</p> <p>Top management shall ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization.</p> <p>Top management shall assign the responsibility and authority for:</p> <ul style="list-style-type: none"> a) ensuring that the quality management system conforms to the requirements of this International Standard; b) ensuring that the processes are delivering their intended outputs; c) reporting on the performance of the quality management system and on opportunities for improvement (see 10.1), in particular to top management; d) ensuring the promotion of customer focus throughout the organization; e) ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented. 	Interstate Review meetings + issues
VST Ltd ISO9001:2015 9.2.1	<p>The organization shall conduct internal audits at planned intervals to provide information on whether the quality management system:</p> <ul style="list-style-type: none"> 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 Review issues Audit
VST Ltd ISO9001:2015 9.2.2	<p>The organization shall:</p> <ul style="list-style-type: none"> a) plan, establish, implement and maintain an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits; b) define the audit criteria and scope for each audit; c) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process; d) ensure that the results of the audits are reported to relevant management; e) take appropriate correction and corrective actions without undue delay; f) retain documented information as evidence of the implementation of the audit programme and the audit results. <p>NOTE See ISO 19011 for guidance.</p>	Audit calendar Management Meetings Related issues Regular meetings

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Viamed Ltd ISO13485:2016 5.6.2 Review input	<p>General</p> <p>The input to management review shall include, but is not limited to, information arising from:</p> <ul style="list-style-type: none"> a) feedback; b) complaint handling; c) reporting to regulatory authorities; d) audits; e) monitoring and measurement of processes; f) monitoring and measurement of product; g) corrective action; h) preventive action; i) follow-up actions from previous management reviews; j) changes that could affect the quality management system; k) recommendations for improvement; l) applicable new or revised regulatory requirements. <p><i>These are covered.</i></p>
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> <ul style="list-style-type: none"> 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. <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> <p><i>Audit calendar</i></p> <p><i>Issues + reviews</i></p>

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Viamed Ltd ISO13485:2 016 8.5.1	General The organization shall identify and implement any changes necessary to ensure and maintain the continued suitability, adequacy and effectiveness of the quality management system as well as medical device safety and performance through the use of the quality policy, quality objectives, audit results, postmarket surveillance, analysis of data, corrective actions, preventive actions and management review.	
Are there any audits outstanding		No
Are there any corrective actions not signed off		Y
Are there any follow up actions not completed #160654 still outstanding - system upgrade one issue not signed off.		N
Is each audit properly numbered and dated		Y
Is each audit correctly signed off		Y
Have results of audits been brought to the attention of the person responsible where appropriate Issues+ meetings		Y
Is there evidence that the frequency of audits should be changed		No

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Sub Processes Linked to Audit

Review the below processes tasks and audits and ensure they are completed in a timely manner.

Managing Director

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID 38 Management oversight of Internal Tasks and Audits Issue(s). Review the responses to Tasks and Audits. ensure they are being full filled and completed.	730 Managing Director	# 161537 x In terms	Freq 1 Risk 0 Overall	Task 12M	

ISO Controller

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID 7093 Review of outstanding Audits	725 Managing Director	#161536 + In terms	Freq 1 Risk 1 Overall 1	Task 12M	

Humanmed Controller

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID 7670 Review of Humanmed sales and orders and clear any duplicates or problems.	611 Office Processes	#164912 ✓	Freq 3 Risk 1 Overall 3	Task 1M	

Audits

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID 7731 To carry out Audit 21 Audit Of Audit Viamed		173 Managing Director	Freq 1 Risk 2 Overall 2	Audit 12M	This Audit
PROCESSID 7779 To carry out Audit 21 Audit Of Audit VST		192 Managing Director	Freq 1 Risk 2 Overall 2	Audit 12M	#159652 x

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Month	Description	TaskID	ProcessID	Date
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Jan

Jan	Audit 03 Design Control Viamed	TaskID 22	ProcessID 7716
Jan	Audit 01 Picking Packing Viamed	TaskID 24	ProcessID 7860
Jan	Audit 03 Design Control VST	TaskID 193	ProcessID 7764
Jan	Audit 01 Picking Packing VST	TaskID 194	ProcessID 7762

Feb

Feb	Audit 10b Process Verification Viamed	TaskID 3	ProcessID 7723
Feb	Audit 10b Process Verification VST	TaskID 177	ProcessID 7771
Feb	Audit 27 Software Validation	TaskID 821	ProcessID 7892

Mar

Mar	Audit 09 Goods Inward And Product Identity Viamed	TaskID 170	ProcessID 7721
Mar	Audit 12 CE Files Viamed	TaskID 16	ProcessID 7725
Mar	Audit 09 Goods Inward And Product Identity VST	TaskID 174	ProcessID 7769
Mar	Audit 12 CE Files VST	TaskID 176	ProcessID 7773

Apr

Apr	Audit 22 Post Market Surveillance Viamed	TaskID 14	ProcessID 7732
Apr	Audit 07 Handling And Storage Viamed	TaskID 25	ProcessID 7719
Apr	Audit 07 Handling And Storage VST	TaskID 178	ProcessID 7767
Apr	Audit 22 Post Market Surveillance VST	TaskID 180	ProcessID 7780

May

May	Audit 06 Calibration Viamed	TaskID 20	ProcessID 7718
May	Audit 15 Production Viamed	TaskID 28	ProcessID 7727
May	Audit 15 Production VST	TaskID 175	ProcessID 7775
May	Audit 06 Calibration VST	TaskID 182	ProcessID 7766

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Jun

Jun	Audit 08 Training Viamed	TaskID 10 ProcessID 7720
Jun	Audit 10 Documentation Control Viamed	TaskID 27 ProcessID 7722
Jun	Audit 10 Documentation Control VST	TaskID 183 ProcessID 7770
Jun	Audit 08 Training VST	TaskID 184 ProcessID 7768

Jul

Jul	Audit 23 Analysis Of Data Viamed	TaskID 43 ProcessID 7733
Jul	Audit 11 Repairs And Service Viamed	TaskID 171 ProcessID 7724
Jul	Audit 11 Repairs And Service VST	TaskID 179 ProcessID 7772
Jul	Audit 23 Analysis Of Data VST	TaskID 185 ProcessID 7781

Aug

Aug	Audit 19 Health And Saftey Viamed	TaskID 13 ProcessID 7729
Aug	Audit 19 Health And Saftey VST	TaskID 186 ProcessID 7777
Aug	Audit 24 Due Servicing	TaskID 288 ProcessID 7889

Sep

Sep	Audit 02 Contract Review Viamed	TaskID 36 ProcessID 7715
Sep	Audit 05 Purchasing Suppliers Viamed	TaskID 37 ProcessID 7717
Sep	Audit 02 Contract Review VST	TaskID 187 ProcessID 7763
Sep	Audit 05 Purchasing Suppliers VST	TaskID 190 ProcessID 7765

Oct

Oct	Audit 18 Management Review Viamed	TaskID 21 ProcessID 7886
Oct	Audit 18 Management Review VST	TaskID 188 ProcessID 7887
Oct	Audit 04 Accounts	TaskID 817 ProcessID 7885

Nov

Nov	Audit 14 Complaints And Corrective Actions Viamed	TaskID 30 ProcessID 7726
Nov	Audit 20 Process Verification To Management Viamed	TaskID 172 ProcessID 7730
Nov	Audit 20 Process Verification To Management VST	TaskID 181 ProcessID 7778

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Nov Audit 14 Complaints And Corrective Actions VST TaskID 189 ProcessID **7774**

Dec

Dec	Audit 17 Internal Audits Viamed	TaskID 11 ProcessID 7728
Dec	Audit 21 Audit Of Audit Viamed	TaskID 173 ProcessID 7862
Dec	Audit 17 Internal Audits VST	TaskID 191 ProcessID 7776
Dec	Audit 21 Audit Of Audit VST	TaskID 192 ProcessID 7779