

Internal Audit Check list			
Audit of Audits			
Created:	17/May 1995	Audit No 21	
Revised:	06 August 2020		Page 1 of 9
Audit Date	13/10/21	Auditor <u>DLAMB</u>	

Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
VST Ltd ISO9001:20 15.5.3	<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. 	
VST Ltd ISO9001:20 15.9.2.1	<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: <ul style="list-style-type: none"> 1) the organization's own requirements for its quality management system; 2) the requirements of this International Standard; b) is effectively implemented and maintained. 	
VST Ltd ISO9001:20 15.9.2.2	<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>	
Viamed Ltd ISO13485:2 016 5.6.2	<p>General</p> <p>The input to management review shall include, but is not limited to, information arising from:</p>	

Internal Audit Check list		
Audit of Audits		
Created:	17/May 1995	Audit No 21
Revised:	06 August 2020	Page 2 of 9
Audit Date		Auditor

Review input	<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. 	
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. 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> <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>	
Viamed Ltd ISO13485:2016 8.5.1	<p>General</p> <p>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</p>	

Internal Audit Check list

Audit of Audits

Created:	17/May 1995	Audit No 21	
Revised:	06 August 2020		Page 3 of 9
Audit Date		Auditor	

results, post market surveillance, analysis of data, corrective actions, preventive actions and management review.

TO BE COMPLETED LAST IN THE ANNUAL AUDIT CALENDAR

	QUESTION:	RESPONSE:	Y/N
1	Are there any audits outstanding.	2020 all complete. Agreed Board meeting	
2	Are there any related issues outstanding to the audits.	18 follow on's 17 completed 1 outstanding - * 196545	Y
3	Are there any corrective actions not signed off.		N
4	Are there any follow up actions not completed.	Issue 196545 Needed closing.	N
5	Is each audit properly numbered and dated.		Y
6	Has each audit got the current years processes linked to it. Are audit processes updated annually.		Y
7	Is each audit correctly signed off.		Y
8	Have results of audits been brought to the attention of the person responsible where appropriate.	Reviewed in Board meeting	Y
9	Is there evidence that the frequency of audits should be changed.		N

* 196545 - task finished issue just required closing.

Internal Audit Check list					
Audit of Audits					
Created:	17/May 1995	Audit No 21			
Revised:	06 August 2020			Page 4 of 9	
Audit Date		Auditor			

Sub Processes Linked to Audit

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

List Processes Per Title

Share Holder					
Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID 7862 Review The Audit Calendar Screen	206385 X	173 Managing Director	Freq 1 Risk 1 Overall 1	Audit 12M	<i>2020 Audit Cal Adjusted Due to Covid. now complete</i>
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 fulfilled and completed.	730 Managing Director	209567 ✓	Freq 1 Risk 1 Overall 1	Task 12M	
ISO Controller					
Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID 7093 Review of outstanding Audits	725 Managing Director	209565 ✓	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	238343 ✓	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	
		206385	X	<i>This Audit</i>	

Internal Audit Check list		
Audit of Audits		
Created:	17/May 1995	Audit No 21
Revised:	06 August 2020	Page 5 of 9
Audit Date		Auditor

PROCESSID 7779
 To carry out Audit 21 Audit Of
 Audit VST

192 Freq 1 Audit 12M
 Managing Director Risk 2
 Overall 2

206391 this Audit
 X

Internal Audit Check list			
Audit of Audits			
Created:	17/May 1995	Audit No 21	
Revised:	06 August 2020		Page 6 of 9
Audit Date		Auditor	

Month	Description	TaskID	ProcessID	Date	Signed off	Issues outstanding
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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

Internal Audit Check list			
Audit of Audits			
Created:	17/May 1995	Audit No 21	
Revised:	06 August 2020		Page 7 of 9
Audit Date		Auditor	

Apr Audit 07 Handling And Storage TaskID 178 ProcessID 7767
VST

Apr Audit 22 Post Market Surveillance TaskID 180 ProcessID 7780
VST

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

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

Internal Audit Check list		
Audit of Audits		
Created:	17/May 1995	Audit No 21
Revised:	06 August 2020	Page 8 of 9
Audit Date		Auditor

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 Managment Viamed TaskID 172 ProcessID 7730
 Nov Audit 20 Process Verification To Managment VST TaskID 181 ProcessID 7778
 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

Internal Audit Check list			
Audit of Audits			
Created:	17/May 1995	Audit No 21	
Revised:	06 August 2020		Page 9 of 9
Audit Date		Auditor	

Dec Audit 17 Internal Audits VST TaskID 191 ProcessID 7776
 Dec Audit 21 Audit Of Audit VST TaskID 192 ProcessID 7779