

Internal Audit Check list

Audit of Audits

Created:	17/May 1995	Audit No 21	
Revised:	28 December 2023		Page 1 of 9
Audit Date	28/12/23	Auditor Derek Lamb	

Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
VST Ltd ISO9001:2015 5.3	Organizational roles, responsibilities and authorities Top management shall ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization. Top management shall assign the responsibility and authority for: 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 ISO9001:2015 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.	
VST Ltd ISO9001:2015 9.2.2	The organization shall: 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. NOTE See ISO 19011 for guidance.	
Viamed Ltd	General	

Internal Audit Check list

Audit of Audits

Created:	17/May 1995	Audit No 21	
Revised:	28 December 2023		Page 2 of 9
Audit Date		Auditor	

ISO 13485:2016 5.6.2 Review input	<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>Roles + titles Route map Doc index QA forms QC 21 form</p>
Viamed Ltd ISO 13485:2016 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. 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>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>Audit calendar Route map Doc index Roles + titles.</p>
Viamed Ltd	General	

via med

Internal Audit Check list

Audit of Audits

Created:	17/May 1995	Audit No 21		
Revised:	28 December 2023		Page 3 of 9	
Audit Date		Auditor		

ISO13485:2016 8.5.1	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, post market surveillance, analysis of data, corrective actions, preventive actions and management review.	management Review Issues
---------------------	--	--------------------------

TO BE COMPLETED LAST IN THE ANNUAL AUDIT CALENDAR

	QUESTION:	RESPONSE:	Y/N
1	Are there any audits outstanding.	NO	N
2	Are there any related issues outstanding to the audits.	no related outstanding	N
3	Are there any corrective actions not signed off.		N
4	Are there any follow up actions not completed.	HL	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.		Y

Internal Audit Check list				
Audit of Audits				
Created:	17/May 1995	Audit No 21		
Revised:	28 December 2023		Page 4 of 9	
Audit Date		Auditor		

9	Is there evidence that the frequency of audits should be changed.			
---	---	--	--	--

List Processes Per Title

Share Holder					
Process Scope PROCESSID 7862 Review The Audit Calendar Screen	Roll Task 313879 in terms	Roll Audit 173 Managing Director	Risk Freq 1 Risk 1 Overall 1	Action Audit 12M	Referenced in Document
Managing Director					
Process Scope 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. Ensure Audits performed indendantly of audit area Ensure All ISO Sections linked to an Audit - QC 17 Route Map	Roll Task 730 Managing Director 282039✓	Roll Audit	Risk Freq 1 Risk 1 Overall 1	Action Task 12M	Referenced in Document
ISO Controller					
Process Scope PROCESSID 7093 Review of outstanding Audits	Roll Task 725 Managing Director 282037✓	Roll Audit	Risk Freq 1 Risk 1 Overall 1	Action Task 12M	Referenced in Document
Humanmed Controller					
Process Scope	Roll Task	Roll Audit	Risk	Action	Referenced in Document

Internal Audit Check list

Audit of Audits

Created:	17/May 1995	Audit No 21	
Revised:	28 December 2023		Page 5 of 9
Audit Date		Auditor	

PROCESSID 7670 Review of Humanmed sales and orders and clear any duplicates or problems.	611		Freq 3 Risk 1 Overall 3		
Audits					
Process Scope	Roll Task	Roll Audit	Risk	Action	Referenced in Document
PROCESSID 7731 To carry out Audit 21 Audit Of Audit Viamed	313879 Viamed Audit	173 Managing Director	Freq 1 Risk 2 Overall 2	Audit 12M	
PROCESSID 7779 To carry out Audit 21 Audit Of Audit VST	313881 VST Audit	192 Managing Director	Freq 1 Risk 2 Overall 2	Audit 12M	

Internal Audit Check list

Audit of Audits

Created:	17/May 1995	Audit No 21	
Revised:	28 December 2023		Page 6 of 9
Audit Date		Auditor	

Month	Description	TaskID	ProcessID	Date	Signed off	Issues outstanding
-------	-------------	--------	-----------	------	------------	--------------------

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			
-----	--	-----------	----------------	--	--	--

Internal Audit Check list

Audit of Audits

Created:	17/May 1995	Audit No 21	
Revised:	28 December 2023		Page 7 of 9
Audit Date		Auditor	

Apr Audit 07 Handling And Storage TaskID ProcessID 7719
Viamed 25

Apr Audit 07 Handling And Storage TaskID ProcessID 7767
VST 178

Apr Audit 22 Post Market Surveillance TaskID ProcessID 7780
VST 180

May

May Audit 06 Calibration Viamed TaskID ProcessID 7718
20

May Audit 15 Production Viamed TaskID ProcessID 7727
28

May Audit 15 Production VST TaskID ProcessID 7775
175

May Audit 06 Calibration VST TaskID ProcessID 7766
182

Jun

Jun Audit 08 Training Viamed TaskID ProcessID 7720
10

Jun Audit 10 Documentation Control TaskID ProcessID 7722
Viamed 27

Jun Audit 10 Documentation Control TaskID ProcessID 7770
VST 183

Jun Audit 08 Training VST TaskID ProcessID 7768
184

Jul

Jul Audit 23 Analysis Of Data TaskID ProcessID 7733
Viamed 43

Jul Audit 11 Repairs And Service TaskID ProcessID 7724
Viamed 171

Jul Audit 11 Repairs And Service TaskID ProcessID 7772
VST 179

Jul Audit 23 Analysis Of Data VST TaskID ProcessID 7781
185

Internal Audit Check list

Audit of Audits

Created:	17/May 1995	Audit No 21	
Revised:	28 December 2023		Page 8 of 9
Audit Date		Auditor	

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 Managment Viamed	TaskID 172	ProcessID 7730
Nov	Audit 20 Process Verification To Managment VST	TaskID 181	ProcessID 7778
Nov	Audit 14 Complaints And	TaskID	ProcessID 7774

Internal Audit Check list			
Audit of Audits			
Created:	17/May 1995	Audit No 21	
Revised:	28 December 2023		Page 9 of 9
Audit Date		Auditor	

Corrective Actions VST

189

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