

Viamed + VST
Internal Audit Check list

Audit of Audits

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Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
VST Ltd ISO9001:20 15.5.3	<p>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.</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; <i>Part of MAP</i> b) ensuring that the processes are delivering their intended outputs; <i>Task Actions</i> 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. 	<i>✓ Audited</i>
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; <i>✓</i> 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>	

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Review input	<p>a) feedback; 15.1 b) complaint handling; 15.0 c) reporting to regulatory authorities; 16.9 d) audits; 16.13 e) monitoring and measurement of processes; 13.3 f) monitoring and measurement of product; 13.3 g) corrective action; 15.4 h) preventive action; 15.4 i) follow-up actions from previous management reviews; 2.0 j) changes that could affect the quality management system; 16.6 k) recommendations for improvement; 16.6 l) applicable new or revised regulatory requirements. 16.1</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> <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; ✓ 17</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>	✓ <i>where possible</i>
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>	✓

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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.		NO
2	Are there any related issues outstanding to the audits.	2020 audits All issues 2021 issues complete	✓
3	Are there any corrective actions not signed off.	3 from 2021 - But underway	✓
4	Are there any follow up actions not completed.	AS per 3	✓
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.		Yes
7	Is each audit correctly signed off.	where completed	Y
8	Have results of audits been brought to the attention of the person responsible where appropriate.		Y
9	Is there evidence that the frequency of audits should be changed.		N

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List Processes Per Title

Share Holder						
Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues	
PROCESSID 7862 Review The Audit Calendar Screen		173 Managing Director <i>243794</i>	Freq 1 Risk 1 Overall 1	Audit 12M		
		<i>This Audit</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 <i>209561</i>		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 <i>209565</i>		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 <i>244770</i>	<i>n terms</i>	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	<i>243794</i>	173 Managing Director	Freq 1 Risk 2 Overall 2	Audit 12M		
PROCESSID 7779 To carry out Audit 21 Audit Of Audit VST	<i>243798</i>	192 Managing Director	Freq 1 Risk 2 Overall 2	Audit 12M		
	<i>this Audit</i>					

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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

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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**

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**

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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**

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Dec Audit 17 Internal Audits VST TaskID 191 ProcessID **7776**

Dec Audit 21 Audit Of Audit VST TaskID 192 ProcessID **7779**