Viamed + VST

Internal Audit Check list			
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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.	

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Viamed Ltd ISO13485:2016 5.6.2 Review input	**General** The input to management review shall include, but is not limited to, information arising from: 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	**Internal audit** The organization shall conduct internal audits at planned intervals to determine whether the quality management system: 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). 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. NOTE Further information can be found in ISO 19011.

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Viamed Ltd ISO13485:2016 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 corrcetive actions not signed off	No
Are there any follow up actions not completed GDPR - Audit Required	Yes
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	Y
Is there evidence that the frequency of audits should be changed	N

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 111263 ✓ Managing Director		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 111241 ✓ Managing Director		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 133914 Office Processes		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 133312 within terms Managing Director	Freq 1 Risk 2 Overall 2	Audit 12M	
PROCESSID **7779** To carry out Audit 21 Audit Of Audit VST		192 Managing Director 133315 within terms	Freq 1 Risk 2 Overall 2	Audit 12M	

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Month	Description	TaskID	ProcessID	Date
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 Survellance 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 Survellance 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 Managment Viamed	TaskID 172 ProcessID **7730**
Nov	Audit 20 Process Verification To Managment 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**