

Internal Audit Check list			
MANAGEMENT REVIEW			
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SCOPE

Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
VST Ltd ISO9001:2015 10.3	Continual improvement The organization shall continually improve the suitability, adequacy and effectiveness of the quality management system. The organization shall consider the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities that shall be addressed as part of continual improvement.	
VST Ltd ISO9001:2015 4.1	Understanding the organization and its context The organization shall determine external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system. The organization shall monitor and review information about these external and internal issues. NOTE 1 Issues can include positive and negative factors or conditions for consideration. NOTE 2 Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, market, cultural, social and economic environments, whether international, national, regional or local. NOTE 3 Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge and performance of the organization.	
VST Ltd ISO9001:2015 4.2	Understanding the needs and expectations of interested parties Due to their effect or potential effect on the organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, the organization shall determine: a) the interested parties that are relevant to the quality management system; b) the requirements of these interested parties that are relevant to the quality management system. The organization shall monitor and review information about these interested parties and their relevant requirements.	
VST Ltd ISO9001:2015 4.3	Determining the scope of the quality management system The organization shall determine the boundaries and applicability of the quality management system	

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	<p>to establish its scope.</p> <p>When determining this scope, the organization shall consider:</p> <ul style="list-style-type: none"> a) the external and internal issues referred to in 4.1; b) the requirements of relevant interested parties referred to in 4.2; c) the products and services of the organization. <p>The organization shall apply all the requirements of this International Standard if they are applicable within the determined scope of its quality management system.</p> <p>The scope of the organization's quality management system shall be available and be maintained as documented information. The scope shall state the types of products and services covered, and provide justification for any requirement of this International Standard that the organization determines is not applicable to the scope of its quality management system.</p> <p>Conformity to this International Standard may only be claimed if the requirements determined as not being applicable do not affect the organization's ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction.</p>	
VST Ltd ISO9001:2015 5.1.1	<p>General</p> <p>Top management shall demonstrate leadership and commitment with respect to the quality management system by:</p> <ul style="list-style-type: none"> a) taking accountability for the effectiveness of the quality management system; b) ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of the organization; c) ensuring the integration of the quality management system requirements into the organization's business processes; d) promoting the use of the process approach and risk-based thinking; e) ensuring that the resources needed for the quality management system are available; f) communicating the importance of effective quality management and of conforming to the quality management system requirements; g) ensuring that the quality management system achieves its intended results; h) engaging, directing and supporting persons to contribute to the effectiveness of the quality management system; i) promoting improvement; j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility. <p>NOTE Reference to "business" in this International Standard can be</p>	

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	interpreted broadly to mean those activities that are core to the purposes of the organization's existence, whether the organization is public, private, for profit or not for profit.	
VST Ltd ISO9001:2015 6.1	When planning for the quality management system, the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to: a) give assurance that the quality management system can achieve its intended result(s); b) enhance desirable effects; c) prevent, or reduce, undesired effects; d) achieve improvement.	
VST Ltd ISO9001:2015 6.1.2	The organization shall plan: a) actions to address these risks and opportunities; b) how to: 1) integrate and implement the actions into its quality management system processes (see 4.4); 2) evaluate the effectiveness of these actions. Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services. NOTE 1 Options to address risks can include avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision. NOTE 2 Opportunities can lead to the adoption of new practices, launching new products, opening new markets, addressing new customers, building partnerships, using new technology and other desirable and viable possibilities to address the organization's or its customers' needs.	
VST Ltd ISO9001:2015 7.1.1 General	General The organization shall determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system. The organization shall consider: a) the capabilities of, and constraints on, existing internal resources; b) what needs to be obtained from external providers.	
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	

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	<p>into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits;</p> <p>b) define the audit criteria and scope for each audit;</p> <p>c) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;</p> <p>d) ensure that the results of the audits are reported to relevant management;</p> <p>e) take appropriate correction and corrective actions without undue delay;</p> <p>f) retain documented information as evidence of the implementation of the audit programme and the audit results.</p> <p>NOTE See ISO 19011 for guidance.</p>	
VST Ltd ISO9001:2015 9.3.2	<p>Management review inputs</p> <p>9.3.2 Management review inputs</p> <p>The management review shall be planned and carried out taking into consideration:</p> <p>a) the status of actions from previous management reviews;</p> <p>b) changes in external and internal issues that are relevant to the quality management system;</p> <p>c) information on the performance and effectiveness of the quality management system, including trends in:</p> <ol style="list-style-type: none"> 1) customer satisfaction and feedback from relevant interested parties; 2) the extent to which quality objectives have been met; 3) process performance and conformity of products and services; 4) nonconformities and corrective actions; 5) monitoring and measurement results; 6) audit results; 7) the performance of external providers; <p>d) the adequacy of resources;</p> <p>e) the effectiveness of actions taken to address risks and opportunities (see 6.1);</p> <p>f) opportunities for improvement.</p>	
VST Ltd ISO9001:2015 9.3.3	<p>Management review outputs</p> <p>The outputs of the management review shall include decisions and actions related to:</p> <p>a) opportunities for improvement;</p> <p>b) any need for changes to the quality management system;</p> <p>c) resource needs.</p> <p>The organization shall retain documented information as evidence of the results of management reviews.</p>	
Viamed Ltd ISO13485:2016 4.1.1	<p>Quality management system</p> <p>The organization shall document a quality management system and maintain its effectiveness in accordance with the requirements of this International Standard and applicable regulatory requirements.</p>	

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	<p>The organization shall establish, implement and maintain any requirement, procedure, activity or arrangement required to be documented by this International Standard or applicable regulatory requirements.</p> <p>The organization shall document the role(s) undertaken by the organization under the applicable regulatory requirements.</p> <p>NOTE Roles undertaken by the organization can include manufacturer, authorized representative, importer or distributor.</p>	
Viamed Ltd ISO13485:2016 4.1.3	<p>Quality management system</p> <p>For each quality management system process, the organization shall:</p> <ul style="list-style-type: none"> a) determine criteria and methods needed to ensure that both the operation and control of these processes are effective; b) ensure the availability of resources and information necessary to support the operation and monitoring of these processes; c) implement actions necessary to achieve planned results and maintain the effectiveness of these processes; d) monitor, measure as appropriate, and analyse these processes; e) establish and maintain records needed to demonstrate conformance to this International Standard and compliance with applicable regulatory requirements (see 4.2.5). 	
Viamed Ltd ISO13485:2016 4.1.4	<p>Quality management system</p> <p>For each quality management system process, the organization shall:</p> <p>The organization shall manage these quality management system processes in accordance with the requirements of this International Standard and applicable regulatory requirements. Changes to be made to these processes shall be:</p> <ul style="list-style-type: none"> a) evaluated for their impact on the quality management system; b) evaluated for their impact on the medical devices produced under this quality management system c) controlled in accordance with the requirements of this International Standard and applicable regulatory requirements. 	
Viamed Ltd ISO13485:2016 5.1	<p>Management commitment</p> <p>Top management shall provide evidence of its commitment to the development and implementation of the quality management system and maintenance of its effectiveness by:</p> <ul style="list-style-type: none"> a) communicating to the organization the importance of meeting customer as well as applicable regulatory requirements; b) establishing the quality policy; c) ensuring that quality objectives are established; 	

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	<p>d) conducting management reviews;</p> <p>e) ensuring the availability of resources.</p>	
<p>Viamed Ltd</p> <p>ISO13485:2016 5.3</p>	<p>Quality policy</p> <p>Top management shall ensure that the quality policy:</p> <p>a) is applicable to the purpose of the organization;</p> <p>b) includes a commitment to comply with requirements and to maintain the effectiveness of the quality management system;</p> <p>c) provides a framework for establishing and reviewing quality objectives;</p> <p>d) is communicated and understood within the organization;</p> <p>e) is reviewed for continuing suitability.</p>	
<p>Viamed Ltd</p> <p>ISO13485:2016 5.6.1</p>	<p>General</p> <p>The organization shall document procedures for management review. Top management shall review the organization's quality management system at documented planned intervals to ensure its continuing suitability, adequacy, and effectiveness. The review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.</p> <p>Records from management reviews shall be maintained</p>	
<p>Viamed Ltd</p> <p>ISO13485:2016 5.6.2</p> <p>Review input</p>	<p>General</p> <p>The input to management review shall include, but is not limited to, information arising from:</p> <p>a) feedback;</p> <p>b) complaint handling;</p> <p>c) reporting to regulatory authorities;</p> <p>d) audits;</p> <p>e) monitoring and measurement of processes;</p> <p>f) monitoring and measurement of product;</p> <p>g) corrective action;</p> <p>h) preventive action;</p> <p>i) follow-up actions from previous management reviews;</p> <p>j) changes that could affect the quality management system;</p> <p>k) recommendations for improvement;</p> <p>l) applicable new or revised regulatory requirements.</p>	
<p>Viamed Ltd</p> <p>ISO13485:2016 5.6.3</p>	<p>Review output</p> <p>The output from management review shall be recorded (see 4.2.5) and include the input reviewed and any decisions and actions related to:</p> <p>a) improvement needed to maintain the suitability, adequacy, and effectiveness of the quality management system and its processes;</p> <p>b) improvement of product related to customer requirements;</p> <p>c) changes needed to respond to applicable new or revised regulatory requirements;</p>	

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	d) resource needs.	
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.</p> <p>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 results, postmarket surveillance, analysis of data, corrective actions, preventive actions and management review.</p>	

Extra Questions?

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Question	Response	Y/N
Check the Review is carried out timely. Task 746 Meeting Minutes should be Attached to Latest Issue #		
Verify that all relevant persons were present. See minutes at the bottom		
Check that the review was carried out to the preset agenda. As per Vop 13		
Is this agenda adequate? See any other business see if other sections should be added?		
Check that an action plan is generated from the review. Check Section g Recommendations or improvement , and if there any further linked issues to the primary issue.		
Check that actions are completed in a timely manner.		
Are minutes retained from the review? Are the minutes attached to the issue		
Can these minutes be accessed readily?		

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Sub Processes Linked to Audit 18

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

Share Holder

Process Scope	Roll Task	Roll Audit	Risk/Freq/Overall	Action	Notes / Issues
PROCESSID 7834 Shareholder review of the Financial position of the Companies	733 Share Holder	769 Managing Director	Risk 3 Freq: 1 Overall 3	Task 1M Audit 3M	
PROCESSID 7862 Review The Audit Calendar Screen		173 Managing Director	Risk 1 Freq: 1 Overall 1	Audit 12M	

Managing Director

Process Scope	Roll Task	Roll Audit	Risk/Freq/Overall	Action	Notes / Issues
PROCESSID 22 Ensure the company polycys are still current and upto date	300 Managing Director		Risk 1 Freq: 1 Overall 1	Task 12M	
PROCESSID 23 Ensure the company Objects are still current and upto date	300 Managing Director		Risk Freq: Overall	Task 12M	
PROCESSID 26 Overview of the Company using various data Reporting Screens	114 Managing Director		Risk 3 Freq: 1 Overall 3	Task 1M	
PROCESSID 27 To review and Close all automatic rolling Issues. Including all rolling tasks and audits	290 Managing Director	775 Company Secretary	Risk 4 Freq: 1 Overall 4	Task 1W Audit 6M	
PROCESSID 55 Business Continuity Plan	266 Managing Director		Risk 1 Freq: 1 Overall 1	Task 12M	
PROCESSID 6861 Non Minuted Management discussions on issues	456 Managing Director		Risk 4 Freq: 0 Overall	Task 1W	

IT Controller

Process Scope	Roll Task	Roll Audit	Risk/Freq/Overall	Action	Notes / Issues
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PROCESSID 6813	459	460	Risk 3	Task 1M
Ensure the turnover report is accurate	Managing Director	Company Secretary	Freq: 1	Audit 12M
			Overall 3	

ISO Controller

Process Scope	Roll Task	Roll Audit	Risk/Freq/Overall	Action	Notes / Issues
PROCESSID 29	49		Risk	Task 12M	
	Managing Director		Freq:		
			Overall		
PROCESSID 5889	290		Risk 4	Task 1W	
To Review the Rolling Tasks and Mini Audits,	Managing Director		Freq: 1		
Look for High number outstanding tasks and audits.			Overall 4		
Locate the reason for High number outstanding tasks and audits.					
Decide on course of action to reduce / redistribute the tasks and audits					
PROCESSID 6871	748		Risk 1	Task 12M	
Not yet Applied	Managing Director		Freq: 1		
Rolling Issue to see if we should apply this standard in the future			Overall 1		
PROCESSID 7744	565		Risk 1	Task 12M	
FDA registration and the CMDCAS products	Managing Director		Freq: 1		
			Overall 1		
In order to sell in the USA / Canada Markets products need to be registered with the FDA.					
PROCESSID 7829	726		Risk 1	Task 12M	
Complete Systems Review	Managing Director		Freq: 1		
			Overall 1		
PROCESSID 7833	732		Risk 2	Task 6M	
To Remind Staff of the Importance of the ISO systems and they should be following the procedures	Managing Director		Freq: 1		
			Overall 2		

Warehouse Team Leader

Process Scope	Roll Task	Roll Audit	Risk/Freq/Overall	Action	Notes / Issues
PROCESSID 7753	589	590	Risk 3	Task 1M	

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To discuss any problems, to assess work load and staffing. To review issues.

Managing Director

Company Secretary

Freq: 1
Overall 3

Audit 3M

Office Processes

Process Scope	Roll Task	Roll Audit	Risk/Freq/Overall	Action	Notes / Issues
PROCESSID 7750 Meeting between management and office team leader to discuss improvement of systems and address any issues	275 Managing Director		Risk 3 Freq: 1 Overall 3	Task 1M	
PROCESSID 7793 A meeting is arranged between the office team leader and their team either as a group or individually when necessary	639 Office Processes		Risk 3 Freq: 1 Overall 3	Task 1M	