Internal Audit Check list

Audit of Audits

Viamed/VST

Created:	17/May 1995	**Audit No 21**	
Revised:	23 October 2017		Page 1 of 4
Audit Date	2/2/2018 2-2-18	Auditor DLAMB HLAMB	

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	N
Are there any corrcetive actions not signed off All upto date	N
Are there any follow up actions not completed	N
Is each audit properly numbered and dated few errors on old style Audit all been Redone for New ISO clauses	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	*

frequency Same moved Dates in Audit Review

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 Managing Director		Freq 1 Risk 0 Overall	Task 12M	111243

ISO Controller

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID **7093** Review of outstanding Audits	725 Managing Director		Freq 1 Risk 1 Overall 1	Task 12M	111241

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		Freq 3 Risk 1 Overall 3	Task 1M	111911

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	?
PROCESSID **7779** To carry out Audit 21 Audit Of Audit VST		192 Managing Director	Freq 1 Risk 2 Overall 2	Audit 12M	?

List All other Audits Here
follow issue 113695