

Internal Audit Check list

VIAMED LTD AUDIT OF AUDITS

Created:	17/May 1995	Audit No 21	
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Audit Date	27-12-24	Auditor <i>Derek Lamb</i>	

Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
Viamed Ltd ISO13485:2016 5.6.2 Review input	<p>General</p> <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. 	<i>Management review</i> <i>Roles and processes</i> <i>Route map</i> <i>Audit calendar</i>
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> <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. <p>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.</p> <p>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>Audit calendar</i> <i>Route map</i> <i>Management review</i> <i>Roles and processes</i>

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	NOTE Further information can be found in ISO 19011.	
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, post market surveillance, analysis of data, corrective actions, preventive actions and management review.</p>	

TO BE COMPLETED LAST IN THE ANNUAL AUDIT CALENDAR

	QUESTION:	RESPONSE:	Y/N
1	Are there any audits outstanding.	Nothing outstanding	N
2	Are there any related issues outstanding to the audits.	All Done	N
3	Are there any corrective actions not signed off.	No	N
4	Are there any follow up actions not completed.	No	✓
5	Is each audit properly numbered and dated.	Yes	Y
6	Has each audit got the current years processes linked to it. Are audit processes updated annually.	Yes	Y
7	Is each audit correctly signed off.	Yes	Y
8	Have results of audits been brought to the attention of the person responsible where appropriate.	Yes Issues	✗

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9	Is there evidence that the frequency of audits should be changed.		
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Review the below processes tasks and audits and ensure they are completed in a timely manner.

List Processes Per Title

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Share Holder	Roll Task Roll Audit	Risk	Action	*	Notes
PROCESSID 7862 Review The Audit Calendar Screen	Task: 348376 Audit :173 Managing Director	Freq 1 Risk 1 Overall 1 <i>Within terms</i>	Audit 12M		
Managing Director	Roll Task Roll Audit	Risk	Action	*	Notes
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	Task: 730 Managing Director Audit: 350936 <i>within terms</i>	Freq 1 Risk 1 Overall 1	Task 12M		
ISO Controller	Roll Task Roll Audit	Risk	Action	*	Notes
PROCESSID 7093 Review of outstanding Audits	Task: 725 350935 Managing Director Audit: <i>within terms</i>	Freq 1 Risk 1 Overall 1	Task 12M		

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Humanmed Controller						
Process Scope		Roll Task Roll Audit	Risk	Action	*	Notes
PROCESSID 7670	Review of Humanmed sales and orders and clear any duplicates or problems.	Task: 611 Audit :	Freq 3 Risk 1 Overall 3			
Audits						
Process Scope		Roll Task Roll Audit	Risk	Action	*	Notes
PROCESSID 7731	To carry out Audit 21 Audit Of Audit Viamed	Task: 348576 Audit :173 Managing Director	Freq 1 Risk 2 Overall 2 <i>within terms</i>	Audit 12M		
PROCESSID 7779	To carry out Audit 21 Audit Of Audit VST	Task: 348378 Audit :192 Managing Director	Freq 1 Risk 2 Overall 2 <i>within terms</i>	Audit 12M		

Rolling Tasks Linked to Document :Task (173) Task (192) Task (730) Task (725) Task (611)