Internal Audit Check list

VIAMED LTD AUDIT OF AUDITS

Created:	17/May 1995	**Audit No 21**	
			Page 1 of 4
Audit Date	29/12/25	Auditor Derek Lunt	

Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
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.	Issues Roles + Titles Management Reviews Audit Calendar
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.	Audit calendar Route Map Management Reviews

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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, 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.		N
2	Are there any related issues outstanding to the audits.	1. 381760 Training issue	Y
3	Are there any corrective actions not signed off.		N
4	Are there any follow up actions not completed.	381760 Due to staff illness will be completed in new year	Y
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.		Y
7	Is each audit correctly signed off.	Board meeting Due for final Closure	Y
8	Have results of audits been brought to the attention of the person responsible where appropriate.		Y

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9	Is there evidence that the frequency of audits should be changed.		

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

List Processes Per Title

Clone from Docid

Share Holder				
Process Scope	**Roll Task** **Roll Audit**	**Risk**	**Action**	*
PROCESSID **7862** Review The Audit Calendar Screen	Task: 382125. Audit Audit :173 Managing Director	Freq 1 Risk 1 Overall 1	Audit 12M	
Managing Director				
Process Scope	**Roll Task** **Roll Audit**	**Risk**	**Action**	*
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 350936 ✓ Managing Director Audit :	Freq 1 Risk 1 Overall 1	Task 12M	
ISO and Compliance Controller				
Process Scope	**Roll Task** **Roll Audit**	**Risk**	**Action**	*
PROCESSID **7093** Review of outstanding Audits	Task: 725 350935 ✓ Managing Director Audit :	Freq 1 Risk 1 Overall 1	Task 12M	
Humanmed Controller				
Process Scope	**Roll Task** **Roll Audit**	**Risk**	**Action**	*

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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**
PROCESSID **7731** To carry out Audit 21 Audit Of Audit Viamed Any follow on issues must be identified with Observation Issue or a Non Conformance Issue. If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.	Task: Audit :173 382125 Audit Managing Director	Freq 1 Risk 2 Overall 2	Audit 12M
PROCESSID **7779** To carry out Audit 21 Audit Of Audit VST Any follow on issues must be identified with Observation Issue or a Non Conformance Issue. If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.	Task: Audit :192 382127 Audit Managing Director	Freq 1 Risk 2 Overall 2	Audit 12M

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