

Internal Audit Check list

Viamed Ltd Training

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Audit Date		Auditor Michael Lamb Derek Lamb	

Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
Viamed Ltd ISO13485:2016 5.5.1	<p>Responsibility and authority Top management shall ensure that responsibilities and authorities are defined, documented and communicated within the organization. Top management shall document the interrelation of all personnel who manage, perform and verify work affecting quality and shall ensure the independence and authority necessary to perform these tasks.</p>	Roles + titles Doc index Management Review
Viamed Ltd ISO13485:2016 6.2	<p>Human resources Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience. The organization shall document the process(es) for establishing competence, providing needed training, and ensuring awareness of personnel. The organization shall: a) determine the necessary competence for personnel performing work affecting product quality; b) provide training or take other actions to achieve or maintain the necessary competence; c) evaluate the effectiveness of the actions taken; d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives; e) maintain appropriate records of education, training, skills and experience (see 4.2.5). NOTE The methodology used to check effectiveness is proportionate to the risk associated with the work for which the training or other action is being provided.</p>	Doc index Training Record Review meetings Issues
Viamed Ltd ISO13485:2016 6.4.1	<p>Work environment The organization shall document the requirements for the work environment needed to achieve conformity to product requirements. If the conditions for the work environment can have an adverse effect on product quality, the organization shall document the requirements for the work environment and the procedures to monitor and control the work environment. The organization shall: a) document requirements for health, cleanliness and clothing of personnel if contact between such personnel and the product or work environment could affect medical device safety or performance; b) ensure that all personnel who are required to work temporarily under special environmental conditions within the work environment are competent or supervised by a competent person. NOTE Further information can be found in ISO 14644 and ISO 14698</p>	CPM Training manual & Reviews Review meetings
Viamed Ltd ISO13485:2016 7.3.2	<p>Design and development planning The organization shall plan and control the design and development of product. As appropriate, design and development planning documents shall be maintained and updated as the design and development progresses. During design and development planning, the organization shall document: a) the design and development stages; b) the review(s) needed at each design and development stage; c) the verification, validation, and design transfer activities that are appropriate at each design and development stage; d) the responsibilities and authorities for design and development;</p>	Technical files Doc issues marketing index

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	<p>e) the methods to ensure traceability of design and development outputs to design and development inputs;</p> <p>f) the resources needed including necessary competence of personnel</p>	
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.</p> <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. 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>	<p><i>Audit Calendar</i></p> <p><i>Route map</i></p> <p><i>Roles + titles.</i></p> <p><i>management Renew</i></p>

	Question	Response/Answer	Y/N
1	<p>Review Last years Audit</p> <p>Are all follow on Issue resolved satisfactory?</p>	<i>Nothing waiting completion</i>	<i>Y</i>
2	<p>Each new employee must have the Induction recorded on there own training record.</p> <p>Check any staff that have been employed since the last Audit.</p>	<i>Sherralee Lamb</i> <i>Yes has induction.</i>	<i>Y</i>
3	<p>The requirement for every member of staff to re-evaluate there own training record is automatically generated as an Issue in Intrastats annually. Check Task ID 314.</p>	<i>✓ 339090</i> <i>all up to date</i>	<i>Y</i>

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4	Review the last Management meeting for review of capability/ competence of staff.	No staff issues Renewed Staff ok	Y
5	Review the last Management meeting for the identification of training is discussed at management meetings.	Training Renewed No problems	Y
6	Check any actions or follow ups are completed in a timely manner.		Y
7	Training records are now held electronically. Task IDs 316 and 303. Check the tasks are carried out in a timely manner. ✓ 560, 380 ✓ 339717 327370 ✓	341266 ✓ Issue sent to update Audit 341265 Sent	Y
8	Are arrangements for training personnel satisfactory. Check courses over last year.	Internal Systems + Products .	Y
9	Check that personnel have updated their training records with any in-house training undertaken. Check recent training that has been carried out, is present on the training record.		Y

Sub Processes Linked to Audit 08

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

List Processes Per Title

Clone from Docid

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	Task: 730 Managing Director Audit : 316372	Freq 1 Risk 1 Overall 1	Task 12M		

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Ensure All ISO Sections linked to an Audit - QC 17 Route Map	Task: 83 Managing Director Audit : 336815 ✓	Freq 2 Risk 1 Overall 2	Task 3M		
PROCESSID 7070 To discuss any problems, to assess work load and staffing. To review issues.	Task: 548 Managing Director 338620 ✓ Audit :1218 Company Secretary	Freq 2 Risk 2 Overall 4	Task 1M Audit 6M		
PROCESSID 7713 Ensure All tasks allocated to active Members of staff,					
IT Controller		334107 ✓			
Process Scope	Roll Task Roll Audit	Risk	Action	*	Notes
PROCESSID 7951 Check the Server space and Size of important files	Task: 139 Office Processes 340139 ✓ Audit :1033 Managing Director	Freq 1 Risk 2 Overall 2	Task 1M Audit 3M		
Documentation And Records Controller		333886 ✓			
Process Scope	Roll Task Roll Audit	Risk	Action	*	Notes
PROCESSID 7907 To review which employees have Access to sensitive areas of Intrastats	Task: 887 Company Secretary 336463 ✓ Audit :888 Office Processes	Freq 1 Risk 1 Overall 1	Task 12M Audit 12M		
Human Resources		338381 ✓			
Process Scope	Roll Task Roll Audit	Risk	Action	*	Notes
PROCESSID 5881 Keep Staff Training records upto date See if any records need updating, also see if any records need signing off	Task: 314 Company Secretary 339090 ✓ Audit :380 Managing Director	Freq 2 Risk 1 Overall 2	Task 6M Audit 12M		
PROCESSID 5904 Check all new staff in the last 12 months have an Induction form filled in	Task: 1117 Managing Director 322254 ✓ Audit :	Freq 1 Risk 1 Overall 1	Task 12M		
PROCESSID 5934 To check that any training that has been done is valid and then checked off the training record. Including	Task: 316 Company Secretary 341266 ✓	Freq 4 Risk 1 Overall 4	Task 1W Audit 3M		

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enough detail to describe what has been covered in the training and any material used.	Audit :560 Office Processes 339717 ✓	Freq 2 Risk 2 Overall 4	Task 1M	
PROCESSID 5936 To print the time sheets and add any extras, overtime, sick days, or commissions.	Task: 448 Company Secretary 341127 ✓	Audit :	Task 1M	
PROCESSID 6837 Keep Staff Training records upto date	Task: 314 Company Secretary 339090 ✓	Freq 2 Risk 1 Overall 2	Task 6M	
PROCESSID 6851 To look through the accident book and make sure there were no breaches of Health and Safety that were not reported.	Task: 287 Managing Director 33534 ✓	Freq 2 Risk 2 Overall 4	Task 6M	
PROCESSID 6877 those that have keys and use the intruder alarm	Task: 771 Company Secretary 325678 ✓	Freq 2 Risk 3 Overall 6	Task 6M	
PROCESSID 6928 EYE TESTS Create new MOTD with the following	Task: 38 Managing Director 305384 ✓	Freq 1 Risk 1 Overall 1	Task 24M	
PROCESSID 7759 Information from the staff that would be used in case of emergency health issue. These are filled in by staff and filled securely.	Task: 606 Company Secretary 318528 ✓	Freq 1 Risk 3 Overall 3	Task 12M	
PROCESSID 7883 to review the staff, give feedback and discuss issues	Task: 813 Company Secretary 321180 ✓	Freq 1 Risk 1 Overall 1	Task 12M Audit 24M	
PROCESSID 7884 Review the staff pay, ensure its above minimum living wage and at a level appropriate to the work	Task: 815 Company Secretary 331655 ✓	Freq 1 Risk 1 Overall 1	Task 12M Audit 24M	
	Audit :816 Managing Director 338242 ✓	in terms.		
PROCESSID 7908 remind staff about private information data and that it needs to be looked after and securely.	Task: 889 Company Secretary 336464 ✓	Freq 1 Risk 1 Overall 1	Task 12M Audit 12M	
	Audit :890 Office Processes 340750 ✓			
PROCESSID 7937 Diversity Impact Assessment	Task: 992 Managing Director 333687 ✓	Freq 1 Risk 1 Overall 1	Task 12M	
PROCESSID 7982 To Check online and see if there have been any	Task: 1107 Company Secretary 321593 ✓	Freq 1 Risk 1	Task 12M Audit 24M	

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changes to Minimum wage or employment law we need to be aware of.	288809 ✓ Audit :1109 Managing Director	Overall 1		
PROCESSID 7983 To Check online and see if there have been any changes to GDPR we need to be aware of. Check web site for GDPR https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/whats-new/	Task: 1110 Company Secretary 323095 ✓ Audit :1111 Office Processes 292069 ✓	Freq 1 Risk 2 Overall 2	Task 12M Audit 24M	
PROCESSID 8054 Team Building Event - June	Task: 334 Marketing Processes 328125 ✓ Audit :	Freq 1 Risk 1 Overall 1	Task 12M	
PROCESSID 8055 Christmas/Team Building Event - December	Task: 336 341386 Marketing Processes Audit : in terms.	Freq 1 Risk 1 Overall 1	Task 12M	
PROCESSID 8067 Training Refresh Issues to Send / Questions to Write Send issue to staff to re-read training material for the following - month dependant (if nothing has changed) and CH to issue new questions for completion.	Task: 1225 Marketing Processes Audit : 333843	Freq 1 Risk 1 Overall 1	Task 1M	
1. Temperature Probes 2. TOF 3D 3. Phototherapy 4. Posey/Tidi 5. Envitec Oxygen Monitoring 6. Maxtec Oxygen Monitoring 7. Radiant Warmers 8. Finger Pulse Oximeters 9. Handheld Pulse Oximeters 10. Flow Sensors 11. Oxygen Sensors - Automotive 12. Medical Oxygen Sensors 13. AlcoTrue 14. Blenders IHC 15. Blenders Maxtec 16. V1000				

Audits

Process Scope	Roll Task Roll Audit	Risk	Action	*	Notes
PROCESSID 7720 To carry out Audit 08 Training Viamed	Task: 333809 ✓ in terms Audit :10 Managing Director	Freq 1 Risk 2 Overall 2	Audit 12M		

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PROCESSID 7768 To carry out Audit 08 Training VST	Task: Audit :184 Managing Director	Freq 1 Risk 2 Overall 2	Audit 12M			
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Rolling Tasks Linked to Document :Task (10) Task (314) Task (1117) Task (448) Task (287) Task (771) Task (38) Task (606) Task (184) Task (316) Task (83) Task (548) Task (815) Task (813) Task (889) Task (887) Task (992) Task (139) Task (1110) Task (1107) Task (730) Task (334) Task (336) Task (1225)