Internal Audit Check list

Viamed Ltd Purchasing

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Audit Date	17-10-24	Auditor Helen Lamb	

SCOPE

Company / ISO Section	Criteria of ISO Section	Auditor Comments Issues
Viamed Ltd ISO13485:2016 4.1.5	**Quality management system** For each quality management system process, the organization shall: When the organization chooses to outsource any process that affects product conformity to requirements, it shall monitor and ensure control over such processes. The organization shall retain responsibility of conformity to this International Standard and to customer and applicable regulatory requirements for outsourced processes. The controls shall be proportionate to the risk involved and the ability of the external party to meet the requirements in accordance with 7.4. The controls shall include written quality agreements.	Supplier Renew Route map Doc index Roles + titles
Viamed Ltd ISO13485:2016 7.3.4	**Design and development outputs** Design and development outputs shall: a) meet the input requirements for design and development; b) provide appropriate information for purchasing, production and service provision; c) contain or reference product acceptance criteria; d) specify the characteristics of the product that are essential for its safe and proper use. The outputs of design and development shall be in a form suitable for verification against the design and development inputs and shall be approved prior to release. Records of the design and development outputs shall be maintained (see 4.2.5).	Tech files Doc index management Renew
Viamed Ltd ISO13485:2016 7.4.1	**Purchasing process** The organization shall document procedures (see 4.2.4) to ensure that purchased product conforms to specified purchasing information. The organization shall establish criteria for the evaluation and selection of suppliers. The criteria shall be: a) based on the supplier's ability to provide product that meets the organizations' requirements; b) based on the performance of the supplier; c) based on the effect of the purchased product on the quality of the medical device; d) proportionate to the risk associated with the medical device. The organization shall plan the monitoring and re-evaluation of suppliers. Supplier performance in meeting requirements for the purchased product shall be monitored. The results of the monitoring shall provide an input into the supplier re-evaluation process. Non-fulfilment of purchasing requirements shall be addressed with the supplier proportionate to the risk associated with the purchased product and compliance with applicable regulatory requirements.	Supplier Renew Doc index Procedure Roles + titles

	Records of the results of evaluation, selection, monitoring and re-evaluation of supplier capability or performance and any necessary actions arising from these activities shall be maintained (see 4.2.5).	
Viamed Ltd ISO13485:2016 7.4.2	**Purchasing information** Purchasing information shall describe or reference the product to be purchased, including as appropriate: a) product specifications; b) requirements for product acceptance, procedures, processes and equipment; c) requirements for qualification of supplier personnel; d) quality management system requirements. The organization shall ensure the adequacy of specified purchasing requirements prior to their communication to the supplier. Purchasing information shall include, as applicable, a written agreement that the supplier notify the organization of changes in the purchased product prior to implementation of any changes that affect the ability of the purchased product to meet specified purchase requirements. To the extent required for traceability given in 7.5.9, the organization shall maintain relevant purchasing information in the form of documents (see 4.2.4) and records (see 4.2.5).	procedure Supplier Renew Doc index Purchasing System Roles + titles
Viamed Ltd ISO13485:2016 7.4.3	**Verification of purchased product** The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchasing requirements. The extent of verification activities shall be based on the supplier evaluation results and proportionate to the risks associated with the purchased product. When the organization becomes aware of any changes to the purchased product, the organization shall determine whether these changes affect the product realization process or the medical device. When the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification activities and method of product release in the purchasing information. Records of the verification shall be maintained (see 4.2.5).	Purchasing System Procedures supplier Renew Roles + titles
Viamed Ltd ISO13485:2016 7.5.2	**Cleanliness of product** The organization shall document requirements for cleanliness of product or contamination control of product if: a) product is cleaned by the organization prior to sterilization or its use; b) product is supplied non-sterile and is to be subjected to a cleaning process prior to sterilization or its use; c) product cannot be cleaned prior to sterilization or its use, and its cleanliness is of significance in use; d) product is supplied to be used non-sterile, and its cleanliness is of significance in use; e) process agents are to be removed from product during manufacture. If product is cleaned in accordance with a) or b) above, the requirements contained in 6.4.1 do not apply prior to the cleaning process.	Doc index Tech files

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Viamed Ltd ISO13485:2016 7.5.3	**Installation activities** The organization shall document requirements for medical device installation and acceptance criteria for verification of installation, as appropriate. If the agreed customer requirements allow installation of the medical device to be performed by an external party other than the organization or its supplier, the organization shall provide documented requirements for medical device installation and verification of installation. Records of medical device installation and verification of installation performed by the organization or its supplier shall be maintained (see 4.2.5).	Doc index Tech files Procedures
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.	Doc index Audit calendar Route map Manage-ment Review Rdest titles.
Viamed Ltd ISO13485:2016 8.4	**Analysis of data** The organization shall document procedures to determine, collect and analyse appropriate data to demonstrate the suitability, adequacy and effectiveness of the quality management system. The procedures shall include determination of appropriate methods, including statistical techniques and the extent of their use. The analysis of data shall include data generated as a result of monitoring and measurement and from other relevant sources and include, at a minimum, input from: a) feedback; b) conformity to product requirements; c) characteristics and trends of processes and product including opportunities for improvement; d) suppliers; e) audits;	Doc index Procedures Audit calendar QA systems Supplier Review

	f) service reports, as appropriate. If the analysis of data shows that the quality management system is not suitable, adequate or effective, the organization shall use this analysis as input for improvement as required in 8.5. Records of the results of analyses shall be maintained (see 4.2.5).	

	Question	Response/Answer	Y/N
1	Review Last years Audit. Update processes if required. Are all follow on Issue resolved satisfactory.	Nothing outstanding	Y
2	Check Rolling Task ID 15 to make sure it is up to date. ✓ # 336693 ✓		Y
3	When was the Approved Supplier List last completed. Purchase orders cannot be placed without	Task Id 15 annual review Dynamic list	Y
4	Verify that there is an up to date suppliers used list.		Y
5	Is the List up to date and reviewed annually.	Task Id 15	Y
6	Check that this list is monitored on a regular basis. Task 15 #336693 ✓	See responsibilities and roles in Intrastats	Y
7	Are individual suppliers graded and reviewed on Intrastats.		Y
8	Do our Purchasing documents clearly describe requirements, i.e. quantity, price, description. Check that purchase orders (PO) are committed by a Director. From the Purchase orders page. Check the PO matches to the items delivered. Check the PO matches to the items on the supplier invoice/s. Check 5 purchase orders at random 1. PVM 4051 ✓ ✓ 2. PVM 4048 ✓ ✓ 3. PVM 4043 ✓ ✓ 4. PVM 4039 ✓ ✓ 5. PVM 4035 ✓ ✓		Y

9	Are COSH Safety data sheets saved in Intrastats and linked to stock part numbers where required. Use the stock on the above PO's, in question 8.		Y

Sub Processes Linked to Audit 05
Review the below processes tasks and audits and ensure they are completed in a timely manner.

List Processes Per Title

Managing Director

Process Scope	Roll Task Roll Audit	Risk	Action	*	Notes
PROCESSID **34** Ensure the latest version of our Insurance / master indemnity letters are up to date	Task: 33 3336720 Managing Director Audit :	Freq 1 Risk 1 Overall 1	Task 12M		

ISO Controller

Process Scope	Roll Task Roll Audit	Risk	Action	*	Notes
PROCESSID **28** Check our supplier are still certified to ISO 9001 or ISO 13485, and do a review of their internal grading.	Task: 15 3366935 Managing Director Audit :610 3202590 Company Secretary	Freq 1 Risk 1 Overall 1	Task 12M Audit 12M		

Maintenance Controller

Process Scope	Roll Task Roll Audit	Risk	Action	*	Notes
PROCESSID **8039** Weee Report Due Vandagraph Annual	Task: 77 3163135 Managing Director Audit :	Freq 1 Risk 1 Overall 1	Task 12M		
PROCESSID **8040** Weee Report Due Vandagraph Qtr	Task: 78 3430175 Managing Director Audit :	Freq 1 Risk 1 Overall 1	Task 3M		

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Warehouse Team Leader

Process Scope	Roll Task Roll Audit	Risk	Action	*	Notes
PROCESSID **5855** To contact Teledyne and confirm the purchase orders we have outstanding for them	Task: 220 343737 + in terms Director 3 (Steve) Audit :375 Managing Director 341268✓	Freq 2 Risk 1 Overall 2	Task 1W Audit 1M		
PROCESSID **5866** UPS surcharges change on a monthly basis. The internal system requires updating so the postage rates can be calculated by anyone correctly. *PROCESS REPLACED WITH WORLDSHIP	~~Task: 64~~ ~~Audit~~ :376	Freq 1 Risk 2 Overall 2			
PROCESSID **5868** To get Returns numbers from suppliers with return shipments pending.	Task: 66 343608✓ Goods Out Audit :69 Managing Director 339080✓	Freq 2 Risk 1 Overall 2	Task 1W Audit 2M		
PROCESSID **6829** Orders that have not been supplied in the time scale provided.	Task: 616 344070+ in terms Director 3 (Steve) Audit :942 Managing Director 339172✓	Freq 2 Risk 2 Overall 4	Task 1M Audit 3M		
PROCESSID **6832** Orders that will be placed in the future.	Task: 483 341 3914 in terms Director 3 (Steve) Audit :964 344212✓ Managing Director	Freq 2 Risk 1 Overall 2	Task 1M Audit 12M		
PROCESSID **7679** To check that we have stock in for customer proformas and orders. Or review if any stock needs to be ordered.	Task: 479 343360✓ Director 3 (Steve) Audit :	Freq 2 Risk 1 Overall 2	Task 2W		
PROCESSID **7680** To check that we have stock in for customer proformas and orders. Or review if any stock needs to be ordered.	Task: 480 343201✓ Director 3 (Steve) Audit :916 344077✓ Managing Director	Freq 2 Risk 1 Overall 2	Task 2W Audit 1M		
PROCESSID **7681** To check that we have stock in for customer proformas and orders. Or review if any stock needs to be ordered.	Task: 481 343489✓ Goods In Audit :	Freq 2 Risk 1 Overall 2	Task 2W		
PROCESSID **7682** To check that we have stock in for customer proformas and orders. Or review if any stock needs to be ordered.	Task: 482 343618✓ Director 3 (Steve) Audit :	Freq 2 Risk 1 Overall 2	Task 2W		
PROCESSID **7683** To check that we have stock in for customer proformas. Or review if any stock needs to be ordered.	Task: 484 344182+ in terms Director 3 (Steve) Audit :	Freq 2 Risk 1 Overall 2	Task 1W		
PROCESSID **7784** Supplier returns to Envitec,	Task: 622 343638✓ Goods In	Freq 2 Risk 1	Task 1W Audit 1M		

return any products waiting to be returned	Audit :625 Managing Director 341817✓	Overall 2			
PROCESSID **7785** Supplier returns to Teledyne, return any products waiting to be returned	Task: 624 Goods In 342879✓ Audit :625 Managing Director 341817✓	Freq 2 Risk 1 Overall 2	Task 2W Audit 1M		
PROCESSID **7786** Supplier returns to Maxtec, return any products waiting to be returned	Task: 623 Goods In 342878✓ Audit :625 Managing Director 341817✓	Freq 2 Risk 1 Overall 2	Task 2W Audit 1M		
PROCESSID **7787** Review the returns that are present in the duckets, for each supplier as per the issues.	Task: 626 Goods In 341818✓ Audit :625 Managing Director 341817✓	Freq 3 Risk 1 Overall 3	Task 1M Audit 1M		
PROCESSID **7956** Internal Process for Vandagraph to request teledyne stock for ordering via Viamed	Task: 1045 EX Sales Controller 342459✓ Audit :1046 Managing Director 342460✓	Freq 1 Risk 1 Overall 1	Task 1M Audit 12M		
PROCESSID **7975** Arranging Teledyne failed sensors for credits and / or return. Teledyne do not want us to return Medical Sensors that have been sent out to the customer and then failed. They will be crediting these without us sending back Automotive sensors are not to be returned either and will be credited unseen.	Task: 1097 Director 3 (Steve) 336882 in date. Audit :	Freq 1 Risk 1 Overall 1	Task 3M		
Office Team Leader					
Process Scope	**Roll Task** **Roll Audit**	**Risk**	**Action**	*	Notes
PROCESSID **8051** Purchase Order log Viamed ensure the purchase order log is up to date	Task: 264 Director 3 (Steve) 339684 in terms Audit :	Freq 1 Risk 1 Overall 1	Task 3M		
Audits					
Process Scope	**Roll Task** **Roll Audit**	**Risk**	**Action**	*	Notes
PROCESSID **7717** To carry out Audit 05 Purchasing Suppliers Viamed	Task: Audit :37 Company Secretary 339671 + in terms	Freq 1 Risk 2 Overall 2	Audit 12M		
PROCESSID **7765** To carry out Audit 05 Purchasing Suppliers VST	Task:	Freq 1 Risk 2	Audit 12M		

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	Audit :190 339679 ✓ in terms Company Secretary	Overall 2			
Accounts Processes					
Process Scope	**Roll Task** **Roll Audit**	**Risk**	**Action**	*	Notes
PROCESSID **7745** Go on to the UPS web site and download the unpaid invoices. Working from the accounts package to find the date that these need to go back to. These are then entered on to the accounts package and paid.	Task: 572 342871 ✓ Company Secretary Audit :	Freq 1 Risk 2 Overall 2	Task 1M		
PROCESSID **7746** Go on to the UPS web site and download the unpaid invoices. Working from the accounts package to find the date that these need to go back to. These are then entered on to the accounts package and paid.	Task: 573 342872 ✓ Company Secretary Audit :	Freq 1 Risk 2 Overall 2	Task 1M		
PROCESSID **7747** Go on to the UPS web site and download the unpaid invoices. Working from the accounts package to find the date that these need to go back to. These are then entered on to the accounts package and paid.	Task: 571 343927 ✓ Company Secretary Audit :930 344079 ✓ in terms Office Processes	Freq 1 Risk 2 Overall 2	Task 1W Audit 1M		
PROCESSID **7790** A invoice is generate at the end of each month to charges Humanmed for the admin fee, carriage charges and any special carriage charges.	Task: ~~635~~ Audit ~~:~~688	Freq 3 Risk 1 Overall 3			
PROCESSID **7794** To review the payments of commisions for the v1000 Product line	Task: 641 342443 ✓ in terms Director 3 (Steve) Audit :	Freq 2 Risk 1 Overall 2	Task 3M		
PROCESSID **7882** Pay suppliers within terms	Task: 811 343783 ✓ Company Secretary Audit :812 341673 ✓ Office Processes	Freq 2 Risk 2 Overall 4	Task 1W Audit 3M		
PROCESSID **7984** Check the Viking Web site for invoices. As they only come in to Info@viamed.co.uk and not to accounts.	Task: 1113 342728 ✓ Company Secretary Audit :1114 332533 ✓ Office Processes	Freq 1 Risk 1 Overall 1	Task 1M Audit 6M		
Office Processes					
Process Scope	**Roll Task** **Roll Audit**	**Risk**	**Action**	*	Notes
PROCESSID **5850** Check the PO log is up to date with confirmations and expected shipping dates	Task: 616 324070 ✓ in terms Director 3 (Steve) Audit :942 339912 ✓ Managing Director	Freq 2 Risk 1 Overall 2	Task 1M Audit 3M		
PROCESSID **6972** task no longer required, WE switched toups online	Task: ~~64~~	Freq 1 Risk 2			

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WITH LIVE PRICES Update the UPS rates to ensure we charge the correct amount of carriage	Audit :467	Overall 2			
PROCESSID **7707** Emailing purchase orders to suppliers	Task: 520 344187X in terms Office Processes Audit :521 344188✓ Company Secretary	Freq 1 Risk 1 Overall 1	Task 1D Audit 1W		
PROCESSID **7751** Check the VST PO log is up to date with confirmations and expected shipping dates	Task: 584 343773✓ Office Processes Audit :585 344067X in terms Office Processes	Freq 2 Risk 1 Overall 2	Task 1W Audit 1W		
PROCESSID **8030** Confirm the Price on our purchase order matches the price charged by the supplier	Task: 1219 343797✓ Office Processes Audit :1220 339453✓ Office Processes	Freq 1 Risk 2 Overall 2	Task 1W Audit 6M		
PROCESSID **8034** Stage 2 of checking supplier prices against our Purchase orders.	Task: 1229 Managing Director 343099✓ Audit :	Freq 1 Risk 2 Overall 2	Task 2W		
Goods In					
Process Scope	**Roll Task** **Roll Audit**	**Risk**	**Action**	*	Notes
PROCESSID **7991** Verification of our purchasing documents.	Task: 1128 326857✓ Company Secretary Audit :	Freq 1 Risk 2 Overall 2	Task 12M		
PROCESSID **8003** Verify the supplier delivery notes to the ordering documents and goods in deliveries is being done correctly	Task: 1151 32[illegible]55✓ Office Processes Audit :1152 331268✓ Company Secretary	Freq 1 Risk 2 Overall 2	Task 12M Audit 12M		

Rolling Tasks Linked to Document :Task (37) Task (616) Task (64) Task (520) Task (584) Task (190) Task (641) Task (572) Task (573) Task (571) Task (635) Task (15) Task (220) Task (66) Task (483) Task (479) Task (480) Task (481) Task (482) Task (622) Task (624) Task (623) Task (626) Task (33) Task (484) Task (811) Task (1045) Task (1097) Task (1113) Task (1128) Task (1151) Task (1219) Task (1229) Task (77) Task (78) Task (264)