Internal Audit Check list			
Viamed Ltd Purchasing			
Created:	17/May 1995	**Audit No 05**	VOP 05
			Page 1 of 10
Audit Date	3-9-25	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 + tasks
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 renew meetings
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	Supplier Renew Doc index Roles + tasks Procedures

	compliance with applicable regulatory requirements. 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).	Procedures Supplier Renew Doc index Purchasing System Roles + tasks
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 + tasks
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	Doc index Tech files

	contained in 6.4.1 do not apply prior to the cleaning process.	
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 Procedures tech files
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 Doc index Roles + tasks Management Review
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	Doc index Audit Calendar QA System

	for improvement; d) suppliers; e) audits; 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 No Non Conformances.	Y
2	Check Rolling Task ID 15 to make sure it is up to date.	371304 ✓	Y
3	When was the Approved Supplier List last completed.	4/9/25	Y
4	Verify that there is an up to date suppliers used list.		Y
5	Is the List up to date and reviewed annually.		Y
6	Check that this list is monitored on a regular basis. Task 15 371304 ✓	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 4564 0110590 × 50 ✓ 2. PVM 4519 0110805 × 10 ✓ 3. PVM 4526 0110020 × 200 ✓ 4. PVM 4568 3810107 × 5 ✓ 0021014 × 1440 ✓ 5. PVM 4612 4610030 × 60 ✓		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. This question is for our products. Some of the products we supply but not all. as a distributor we are not required to have all these. ✓ ✓ ✓	3810107 } NO 0021014 } Data 4610030 } Sheets.	some.

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

Clone from Docid

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 Audit :	Freq 1 Risk 1 Overall 1			
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 371304 Managing Director Audit :610 355046 ✓	Freq 1 Risk 1 Overall 1	Task 12M Audit 12M		

	Company Secretary				
Maintenance Controller					
Process Scope	**Roll Task** **Roll Audit**	**Risk**	**Action**	*	Notes
PROCESSID **8039** Weee Report Due Vandagraph Annual	Task: 77 350823 ✓ Managing Director Audit :	Freq 1 Risk 1 Overall 1	Task 12M		
PROCESSID **8040** Weee Report Due Vandagraph Qtr	Task: 78 369016 ✓ Managing Director Audit :	Freq 1 Risk 1 Overall 1	Task 3M		
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 373974 Director 3 (Steve) ✗ in terms Audit :375 372879 ✓ Managing Director	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 373851 ✓ Goods Out Audit :69 373527 ✓ Managing Director	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 372914 ✗ Director 3 (Steve) in terms Audit :942 374340 ✗ in terms Managing Director	Freq 2 Risk 2 Overall 4	Task 1M Audit 3M		
PROCESSID **6832** Orders that will be placed in the future.	Task: 483 373046 ✗ Director 3 (Steve) in terms Audit :964 364212 ✓ 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 373635 ✓ 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 373536 ✓ Director 3 (Steve) Audit :916 372933 ✓ 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 373757 ✓ 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 373860 × Director 3 (Steve) in terms 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 374434 × Director 3 (Steve) in terms Audit :	Freq 2 Risk 1 Overall 2	Task 1W		
PROCESSID **7784** Supplier returns to Envitec, return any products waiting to be returned	Task: 622 373880 ✓ Goods In Audit :625 373492 ✓ Managing Director	Freq 2 Risk 1 Overall 2	Task 1W Audit 1M		
PROCESSID **7785** Supplier returns to Teledyne, return any products waiting to be returned	Task: 624 Goods In 373378 ✓ Audit :625 373492 ✓ Managing Director	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 373377 ✓ Goods In Audit :625 373492 ✓ Managing Director	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 373493 ✓ Goods In Audit :625 373492 ✓ Managing Director	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 374045 ✓ EX Sales Controller Audit :1046 342460 ✓ Managing Director	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 371489 × Director 3 (Steve) in terms 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 373976 × Director 3 (Steve) in Audit : terms.	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: 373965 ✓ Audit :37 Audit Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M		
PROCESSID **7765** To carry out Audit 05 Purchasing Suppliers VST	Task: 373973 ✓ Audit :190 Audit Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M		

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 374447 ✓ 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 374448 ✓ 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 374192 ✓ Company Secretary Audit :930 372935 ✓ 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 368486 ✓ Director 3 (Steve) Audit :	Freq 2 Risk 1 Overall 2	Task 3M		
PROCESSID **7882** Pay suppliers within terms	Task: 811 374029 ✓ Company Secretary Audit :812 367779 ✓ 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 374344 ✓ Company Secretary Audit :1114 367143 ✓ 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 372914 Director 3 (Steve) Audit :942 374340 in terms Managing Director in terms.	Freq 2 Risk 1 Overall 2	Task 1M Audit 3M		
PROCESSID **6972** task no longer required, WE switched toups online WITH LIVE PRICES Update the UPS rates to ensure we charge the correct amount of carriage	Task: 64 Audit :467	Freq 1 Risk 2 Overall 2			
PROCESSID **7707** Emailing purchase orders to suppliers	Task: 520 374439 Office Processes in terms Audit :521 374440 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 374013 Office Processes Audit :585 374330 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 374059 Office Processes in terms Audit :1220 374060 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 373522 Managing Director 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 362029 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 357162 Office Processes Audit :1152 365855 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)