

Planned +
VST

Internal Audit Check list			
Purchasing			
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Audit Date	23-11-19	Auditor	Helen Lamb

SCOPE

Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
VST Ltd ISO9001:2015 7.1.3	Infrastructure The organization shall determine, provide and maintain the infrastructure necessary for the operation of its processes and to achieve conformity of products and services. NOTE Infrastructure can include: a) buildings and associated utilities; b) equipment, including hardware and software; c) transportation resources; d) information and communication technology.	Issues instructions Roles + Response.
VST Ltd ISO9001:2015 8.4.1	General The organization shall ensure that externally provided processes, products and services conform to requirements. The organization shall determine the controls to be applied to externally provided processes, products and services when: a) products and services from external providers are intended for incorporation into the organization's own products and services; b) products and services are provided directly to the customer(s) by external providers on behalf of the organization; c) a process, or part of a process, is provided by an external provider as a result of a decision by the organization. The organization shall determine and apply criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements. The organization shall retain documented information of these activities and any necessary actions arising from the evaluations.	Supplier Review instructions doc index
VST Ltd ISO9001:2015 8.4.2	Type and extent of control The organization shall ensure that externally provided processes, products and services do not adversely affect the organization's ability to consistently deliver conforming products and services to its customers. The organization shall: a) ensure that externally provided processes remain within the control of its quality management system; b) define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output; c) take into consideration: 1) the potential impact of the externally provided processes, products and services on the organization's ability to consistently meet customer and	Supplier Review Procedures + VOP

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	applicable statutory and regulatory requirements; 2) the effectiveness of the controls applied by the external provider; d) determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements.	Infrastructure
VST Ltd ISO9001:2015 8.4.3	Information for external providers The organization shall ensure the adequacy of requirements prior to their communication to the external provider. The organization shall communicate to external providers its requirements for: a) the processes, products and services to be provided; b) the approval of: 1) products and services; 2) methods, processes and equipment; 3) the release of products and services; c) competence, including any required qualification of persons; d) the external providers' interactions with the organization; e) control and monitoring of the external providers' performance to be applied by the organization; f) verification or validation activities that the organization, or its customer, intends to perform at the external providers' premises.	Supplier Review Infrastructure Issues
VST Ltd ISO9001:2015 8.5.1	Control of production and service provision The organization shall implement production and service provision under controlled conditions. Controlled conditions shall include, as applicable: a) the availability of documented information that defines: 1) the characteristics of the products to be produced, the services to be provided, or the activities to be performed; 2) the results to be achieved; b) the availability and use of suitable monitoring and measuring resources; c) the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met; d) the use of suitable infrastructure and environment for the operation of processes; e) the appointment of competent persons, including any required qualification; f) the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement; g) the implementation of actions to prevent human error; h) the implementation of release, delivery and post-delivery activities	Infrastructure QA Training manager

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VST Ltd ISO9001:2015 8.7.1	The organization shall ensure that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery. The organization shall take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This shall also apply to nonconforming products and services detected after delivery of products, during or after the provision of services. The organization shall deal with nonconforming outputs in one or more of the following ways: a) correction; b) segregation, containment, return or suspension of provision of products and services; c) informing the customer; d) obtaining authorization for acceptance under concession. Conformity to the requirements shall be verified when nonconforming outputs are corrected.	Internal Procedures Issues Reg Reading
VST Ltd ISO9001:2015 9.3.2	Management review inputs 9.3.2 Management review inputs The management review shall be planned and carried out taking into consideration: a) the status of actions from previous management reviews; b) changes in external and internal issues that are relevant to the quality management system; c) information on the performance and effectiveness of the quality management system, including trends in: 1) customer satisfaction and feedback from relevant interested parties; 2) the extent to which quality objectives have been met; 3) process performance and conformity of products and services; 4) nonconformities and corrective actions; 5) monitoring and measurement results; 6) audit results; 7) the performance of external providers; d) the adequacy of resources; e) the effectiveness of actions taken to address risks and opportunities (see 6.1); f) opportunities for improvement.	Management Review Internal Management meetings Non Conformance Reviews
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	Management Review

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	the requirements in accordance with 7.4. The controls shall include written quality agreements.	
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).	No Design If we did would be New Project Job Log.
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. 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).	Supplier Review Instruments Issues
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;	POR Proactive Instruments

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	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).	
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).	intra slots Received goods QA
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.	goods in intra slots procedures No sterilization we do not have our own goods any more
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.	intra slots service log

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	Records of medical device installation and verification of installation performed by the organization or its supplier shall be maintained (see 4.2.5).	
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.	Rolling tasks + schedules audit calendar
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; 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).	Instructions Doc index Reviews Instructions Analyses Data

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Task ID 15

Question	Response/Answer
When was the Approved Supplier List last completed.	done annually task (15) 31st July 19 ✓
Verify that there is an up to date suppliers used list.	Y
Is the List up to date and reviewed annually.	Y issue with suppliers not getting ISO certs through.
Check that this list is monitored on a regular basis.	See responsibilities and roles in Intrastats Y
Are individual suppliers graded and reviewed on Intrastats.	Y
Do our Purchasing documents clearly describe requirements, i.e. quantity, price, description. Check that purchase orders are countersigned by a Director. Filed correctly in order. Stamped received. Check Opera and Intrastats has been updated when booked into stock.	#130803-2018 signed + filed - Not Done by Steve. Unsure what to do as system will be gone in 3 months. Y
Check 5 purchase orders at random	#159751
11340 1. PO 12540 ✓	✓ ✓ ✓ ✓ ✓
2. VSTPO01017 ✓	✓ ✓ ✓ ✓ ✓
3. VSTPO01013 ✓	✓ ✓ ✓ ✓ ✓
11704 4. PO 12546 ✓	✓ ✓ ✓ ✓ ✓
9147 5. PO 12522 ✓	✓ ✓ ✓ ✓ ✓
Are COSH data sheets saved in intrastats and linked to stock part numbers.	Y

Sub Processes Linked to Audit 05

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

Managing Director

Process Scope	Brief Description	Responsibility/Procedure/Training	Measurable Objective	Task	Audit	Freq	Risk	Overall	Action
34 Ensure the latest version of our Insurance / master indemnity letters are up to date	Insurance Is Upto Date	27244 VOP 02 Personnel and Responsibility , Staff and Staffing Issues, Training, Roles and Tasks 26657 Employers Products and Public Liability Insurance master indemnity letter	Letter is upto date	33 Managing Director	148154	1	0		Task 12M

ISO Controller

Process Scope	Brief Description	Responsibility/Procedure/Training	Measurable Objective	Task	Audit	Freq	Risk	Overall	Action
28 - History/Details Check our supplier are still certified to ISO 9001 or ISO 13485, and do a review of their internal grading.	Supplier Review	23972 VOP 05 Supplier Control Supplier Review Purchase Orders Supplier Returns 27178 VOP 13 Process Monitoring, System Reviews, Audits, Management Review, Analysis Data	Check the supplier review page make sure none are more then a month out of date.	15 Managing Director	610 Company Secretary	1	1	1	Task 12M Audit 12M

Warehouse Team Leader

Process Scope	Brief Description	Responsibility/Procedure/Training	Measurable Objective	Task	Audit	Freq	Risk	Overall	Action
5855 - History/Details To contact Teledyne and confirm the purchase orders we have outstanding for them	Purchase Order Requirements Teledyne	23615 VOP 07 Stock Control, Handling, Control of Labelling, Storage, Movement	ensure the task is being signed off	220 Director 3 (Steve)	375 Managing Director	4	1	4	Task 1W Audit 1M
5866 - History/Details	UPS Shipping Fuel Surcharge	24730 VOP 03 Contract Review,		64 Office	376 Managing	3	1	3	Task 1M

order one not completed.

#157773

#158099

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UPS surcharges change on a monthly basis. The internal system requires updating so the postage rates can be calculated by anyone correctly.		Enquires, Office Processes	Processes	Director				Audit 3M
5868 - <i>History/Details</i> To get Returns numbers from suppliers with return shipments pending.	Return Goods To Suppliers	23615 VOP 07 Stock Control, Handling, Control of Labelling, Storage, Movement	66 Goods In	69 Managing Director	4	1	4	Task 1W Audit 2M
6829 - <i>History/Details</i> Orders that have not been supplied in the time scale provided.	Supplier Review - Outstanding orders	23615 VOP 07 Stock Control, Handling, Control of Labelling, Storage, Movement	616 Managing Director		4	1	4	Task 2W
6832 - <i>History/Details</i> Orders that will be placed in the future.	Supplier Review Future orders	23615 VOP 07 Stock Control, Handling, Control of Labelling, Storage, Movement	483 Managing Director		3	1	3	Task 1M
6952	Lost in Shipping Claims	24730 VOP 03 Contract Review, Enquires, Office Processes						
7679 - <i>History/Details</i> To check that we have stock in for customer proformas and orders. Or review if any stock needs to be ordered.	Check Stock Requirements Supplier Teledyne	23615 VOP 07 Stock Control, Handling, Control of Labelling, Storage, Movement	479 Director 3 (Steve)		4	1	4	Task 2W
7680 - <i>History/Details</i> To check that we have stock in for customer proformas and orders. Or review if any stock needs to be ordered.	Check Stock Requirements Supplier Envitec	23615 VOP 07 Stock Control, Handling, Control of Labelling, Storage, Movement	480 Director 3 (Steve)	916 Managing Director	4	1	4	Task 2W Audit 1M
7681 - <i>History/Details</i> To check that we have stock in for customer proformas and orders. Or review if any stock needs to be ordered.	Check Stock Requirements Supplier Posey	23615 VOP 07 Stock Control, Handling, Control of Labelling, Storage, Movement	481 Goods In		4	1	4	Task 2W
7682 - <i>History/Details</i>	Check Stock Requirements	23615 VOP 07 Stock Control,	482 Director 3		4	1	4	Task 2W

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To check that we have stock in for customer proformas and orders. Or review if any stock needs to be ordered.	Supplier Bluepoint	Handling, Control of Labelling, Storage, Movement	(Steve)	Completion					
7683 - History/Details To check that we have stock in for customer proformas. Or review if any stock needs to be ordered.	Check Stock For Proforma	23615 VOP 07 Stock Control, Handling, Control of Labelling, Storage, Movement	484 Director 3 (Steve)		4	1	4	Task 1W	
			#159490x in terms						
7784 - History/Details Supplier returns to Envitec, return any products waiting to be returned	Check Returns Supplier Envitec	23972 VOP 05 Supplier Control Supplier Review Purchase Orders Supplier Returns	622 Goods In	625 Managing Director	4	1	4	Task 1W Audit 1M	
			#159599x in terms	#159216					
7785 - History/Details Supplier returns to Teledyne, return any products waiting to be returned	Check Returns Supplier Teledyne	23972 VOP 05 Supplier Control Supplier Review Purchase Orders Supplier Returns	624 Goods In	625 Managing Director	4	1	4	Task 2W Audit 1M	
			#159133	#159216					
7786 - History/Details Supplier returns to Maxtec, return any products waiting to be returned	Check Returns Supplier Maxtec	23972 VOP 05 Supplier Control Supplier Review Purchase Orders Supplier Returns	623 Goods In	625 Managing Director	4	1	4	Task 2W Audit 1M	
			#159132	#159216					
7787 - History/Details Review the returns that are present in the duckets, for each supplier as per the issues.	Check Returns All Supplier	23972 VOP 05 Supplier Control Supplier Review Purchase Orders Supplier Returns	626 Goods In	625 Managing Director	3	1	3	Task 1M Audit 1M	
			#159217	#159216					

Accounts Processes

Process Scope	Brief Description	Responsibility/Procedure/Training	Measurable Objective	Task	Audit	Freq	Risk	Overall	Action
7745 - History/Details Go on to the UPS web site and download the unpaid invoices. Working from Opera to find the date that these need to go back	UPS Invoices Viamed	23381 VOP 04 Accounts, Bank, Loans, Debtors, Creditors, Accountant Processes		572 Company Secretary		3	2	6	Task 1M
				#157924					

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to. These are then entered on to Opera and paid.

7746 - History/Details Go on to the UPS web site and download the unpaid invoices. Working from Opera to find the date that these need to go back to. These are then entered on to Opera and paid.	UPS Invoices VST	23381 VOP 04 Accounts, Bank, Loans, Debtors, Creditors, Accountant Processes	573 Company Secretary	3	2	6	Task 1M	
			#157923✓					
7747 - History/Details Go on to the UPS web site and download the unpaid invoices. Working from Opera to find the date that these need to go back to. These are then entered on to Opera and paid.	UPS Invoices Vandagraph	23381 VOP 04 Accounts, Bank, Loans, Debtors, Creditors, Accountant Processes	571 Company Secretary	3	2	6	Task 1M	
			#159286✓					
7790 - History/Details A invoice is generate at the end of each month to charges Humanmed for the admin fee, carriage charges and any special carriage charges.	Humanmed Invoice them For Previous Month	23381 VOP 04 Accounts, Bank, Loans, Debtors, Creditors, Accountant Processes	635 Company Secretary	688 Managing Director	3	1	3	Task 1M Audit 12M
			#147821✓					
7794 - History/Details To review the payments of commissions for the v1000 Product line	V1000 Commissions Review	23381 VOP 04 Accounts, Bank, Loans, Debtors, Creditors, Accountant Processes	641 Director 3 (Steve)		2	1	2	Task 3M
			#155611					
7882 - History/Details Pay suppliers within terms	Purchase Payments	23381 VOP 04 Accounts, Bank, Loans, Debtors, Creditors, Accountant Processes	811 Company Secretary	812 Managing Director	2	2	4	Task 1W Audit 3M
			#159226	#154950				

Audits

Process Scope	Brief Description	Responsibility/Procedure/Training	Measurable Objective	Task	Audit	Freq Risk	Overall Action
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7717 - History/Details To carry out Audit 05 Purchasing Suppliers Viamed	Audit 05 Purchasing Suppliers Viamed	27178 VOP 13 Process Monitoring, System Reviews, Audits, Management Review, Analysis Data	37 Company Secretary	1	2	2	Audit 12M
#152745 x in terms							
7765 - History/Details To carry out Audit 05 Purchasing Suppliers VST	Audit 05 Purchasing Suppliers VST	27178 VOP 13 Process Monitoring, System Reviews, Audits, Management Review, Analysis Data	190 Company Secretary	1	2	2	Audit 12M
#152759 x in terms							

Office Processes

Process Scope	Brief Description	Responsibility/Procedure/Training	Measurable Objective	Task	Audit	Freq	Risk	Overall	Action
5850 - History/Details Check the PO log is up to date with confirmations and expected shipping dates	Purchase Order Log	20588 VM3COP20.29 Checking the Purchase Order Log 24730 VOP 03 Contract Review, Enquires, Office Processes		262 Office Processes	263 Office Processes	4	1	4	Task 1W Audit 2W
6971 To get cost of shipping from freight companies	Freight Courier Cost Request	24730 VOP 03 Contract Review, Enquires, Office Processes 24844 VM3COP20.43 Requesting Quotes from Shippers	None - this is a dynamic process and done on a ad hock basis			1	1	1	
6972 - History/Details Update the UPS rates to ensure we charge the correct amount of carriage	UPS Shipping Fuel Surcharge	23972 VOP 05 Supplier Control Supplier Review Purchase Orders Supplier Returns		64 Office Processes	467 Managing Director	3	1	3	Task 1M Audit 3M
7707 - History/Details Emailing purchase orders to suppliers	Send Purchase Orders To Suppliers	17070 VM3COP27.34 Sending Purchase Orders to Suppliers 24730 VOP 03 Contract Review, Enquires, Office Processes	should be no white lines older than 48 hours in the list in the po update log.	520 Office Processes	521 Company Secretary	5	1	5	Task 1D Audit 1W
7751 - History/Details Check the VST PO log	VST Purchase Order Log	24730 VOP 03 Contract Review, Enquires, Office		584 Office Processes	585 Office Processes	4	1	4	Task 1W Audit

#159212 #159397

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is up to date with
confirmations and
expected shipping
dates

Processes
25292
VM3COP20.66 VST
PO Log

1W