Internal Audit Check list			
Purchasing			
Created:	17/May 1995	**Audit No 05**	VOP 05
Revised:	23 October 2017		Page 1 of 10
Audit Date		Auditor	

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.	
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.	
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 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.	
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.	
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	
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.	
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.	
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.	
Viamed Ltd ISO13485:20	**Design and development outputs** Design and development outputs shall:	

16 7.3.4	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).	
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).	
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).	
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).	
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.	
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).	
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.	
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).	

Task ID 15

Question	**Response/Answer**	
When was the Approved Supplier List last completed.		
Verify that there is an up to date suppliers used list.		
Is the List up to date and reviewed annually.		
Check that this list is monitored on a regular basis.		See responsibilities and roles in Intrastats
Are individual suppliers graded and reviewed on Intrastats.		
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. Check 5 purchase orders at random 1. 2. 3. 4. 5.		
Are COSH data sheets saved in intrastats and linked to stock part numbers.		

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

Managing Director

Process Scope	**Roll Task**	**Roll Audit**	**Risk**	**Action**	Notes / Issues
PROCESSID **34** Ensure the latest version of our Insurance / master indemnity letters are up to date	33 Managing Director		Freq 1 Risk 0 Overall	Task 12M	

ISO Controller

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

Warehouse Team Leader

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID **5855** To contact Teledyne and confirm the purchase orders we have outstanding for them	220 Office Processes	375 Goods In	Freq 4 Risk 1 Overall 4	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.	64 Office Processes	376 Managing Director	Freq 3 Risk 1 Overall 3	Task 1M Audit 3M	
PROCESSID **5868** To get Returns numbers from suppliers with return shipments pending.	66 Goods In	69 Managing Director	Freq 4 Risk 1 Overall 4	Task 1W Audit 2M	
PROCESSID **6829** Orders that have not been supplied in the time scale provided.	616 Goods In		Freq 4 Risk 1 Overall 4	Task 2W	
PROCESSID **6832** Orders that will be placed in the future.	483 Goods In		Freq 3 Risk 1 Overall 3	Task 1M	
PROCESSID **7679** To check that we have stock in for customer proformas and orders. Or review if any stock needs to be ordered.	479 Goods In		Freq 4 Risk 1 Overall 4	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.	480 Goods In		Freq 4 Risk 1 Overall 4	Task 2W	
PROCESSID **7681** To check that we have stock in for customer proformas and orders. Or review if any stock needs to be ordered.	481 Goods In		Freq 4 Risk 1 Overall 4	Task 2W	
PROCESSID **7682** To check that we have stock in for customer proformas and orders. Or review if any stock needs to be	482 Goods In		Freq 4 Risk 1 Overall 4	Task 2W	

ordered.

PROCESSID **7683** To check that we have stock in for customer proformas. Or review if any stock needs to be ordered.	484 Goods In		Freq 4 Risk 1 Overall 4	Task 1W	
PROCESSID **7784** Supplier returns to Envitec, return any products waiting to be returned	622 Goods In	625 Managing Director	Freq 4 Risk 1 Overall 4	Task 1W Audit 1M	
PROCESSID **7785** Supplier returns to Teledyne, return any products waiting to be returned	624 Goods In	625 Managing Director	Freq 4 Risk 1 Overall 4	Task 2W Audit 1M	
PROCESSID **7786** Supplier returns to Maxtec, return any products waiting to be returned	623 Goods In	625 Managing Director	Freq 4 Risk 1 Overall 4	Task 2W Audit 1M	
PROCESSID **7787** Review the returns that are present in the duckets, for each supplier as per the issues.	626 Goods In	625 Managing Director	Freq 3 Risk 1 Overall 3	Task 1M Audit 1M	

Accounts Processes

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID **7745** 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.	572 Company Secretary		Freq 3 Risk 2 Overall 6	Task 1M	
PROCESSID **7746** 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.	573 Company Secretary		Freq 3 Risk 2 Overall 6	Task 1M	
PROCESSID **7747** 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.	571 Company Secretary		Freq 3 Risk 2 Overall 6	Task 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.	635 Company Secretary	688 Managing Director	Freq 3 Risk 1 Overall 3	Task 1M Audit 12M	
PROCESSID **7794** To review the payments of commisions for the v1000 Product	641 Director 3 (Steve)		Freq 2 Risk 1 Overall 2	Task 3M	

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Audits

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID **7717** To carry out Audit 05 Purchasing Suppliers Viamed		37 Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M	
PROCESSID **7765** To carry out Audit 05 Purchasing Suppliers VST		190 Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M	

Office Processes

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID **5850** Check the PO log is up to date with confirmations and expected shipping dates	262 Office Processes	263 Office Processes	Freq 4 Risk 1 Overall 4	Task 1W Audit 2W	
PROCESSID **6972** Update the UPS rates to ensure we charge the correct amount of carriage	64 Office Processes	467 Managing Director	Freq 3 Risk 1 Overall 3	Task 1M Audit 3M	
PROCESSID **7707** Emailing purchase orders to suppliers	520 Office Processes	521 Goods In	Freq 5 Risk 1 Overall 5	Task 1D Audit 1W	
PROCESSID **7751** Check the VST PO log is up to date with confirmations and expected shipping dates	584 Office Processes	585 Office Processes	Freq 4 Risk 1 Overall 4	Task 1W Audit 1W	