

Internal Audit Check list			
Contract Review and Sales Order Processing			
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Audit Date	18-9-18	Auditor <i>Helen Lamb</i>	

*Vlamed +*

SCOPE

*VST*

Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
VST Ltd ISO9001:2015 5.1.2	<b>Customer focus</b> 5.1.2 Customer focus Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that: a) customer and applicable statutory and regulatory requirements are determined, understood and consistently met; b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed; c) the focus on enhancing customer satisfaction is maintained.	
VST Ltd ISO9001:2015 8.2.1	<b>Customer communication</b> Communication with customers shall include: a) providing information relating to products and services; b) handling enquiries, contracts or orders, including changes; c) obtaining customer feedback relating to products and services, including customer complaints; d) handling or controlling customer property; e) establishing specific requirements for contingency actions, when relevant.	
VST Ltd ISO9001:2015 8.2.2	<b>Determining the requirements for products and services</b> When determining the requirements for the products and services to be offered to customers, the organization shall ensure that: a) the requirements for the products and services are defined, including: 1) any applicable statutory and regulatory requirements; 2) those considered necessary by the organization; b) the organization can meet the claims for the products and services it offers.	
VST Ltd ISO9001:2015 8.2.3.1	The organization shall ensure that it has the ability to meet the requirements for products and services to be offered to customers. The organization shall conduct a review before committing to supply	

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	<p>products and services to a customer, to include:</p> <ul style="list-style-type: none"> <li>a) requirements specified by the customer, including the requirements for delivery and postdelivery activities;</li> <li>b) requirements not stated by the customer, but necessary for the specified or intended use, when known;</li> <li>c) requirements specified by the organization;</li> <li>d) statutory and regulatory requirements applicable to the products and services;</li> <li>e) contract or order requirements differing from those previously expressed.</li> </ul> <p>The organization shall ensure that contract or order requirements differing from those previously defined are resolved.</p> <p>The customers requirements shall be confirmed by the organization before acceptance, when the customer does not provide a documented statement of their requirements.</p> <p>NOTE In some situations, such as internet sales, a formal review is impractical for each order. Instead, the review can cover relevant product information, such as catalogues.</p>
VST Ltd ISO9001:2015 8.2.3.2	<p>The organization shall retain documented information, as applicable:</p> <ul style="list-style-type: none"> <li>a) on the results of the review;</li> <li>b) on any new requirements for the products and services.</li> </ul>
VST Ltd ISO9001:2015 8.2.4	<p>Changes to requirements for products and services</p> <p>The organization shall ensure that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed.</p>
Viamed Ltd ISO13485:2016 5.2	<p><b>Customer focus</b></p> <p>Top management shall ensure that customer requirements and applicable regulatory requirements are determined and met.</p>
Viamed Ltd ISO13485:2016 7.2.1	<p><b>Determination of requirements related to product</b></p> <p>The organization shall determine:</p> <ul style="list-style-type: none"> <li>a) requirements specified by the customer, including the requirements for delivery and postdelivery activities;</li> <li>b) requirements not stated by the customer but necessary for specified or intended use, as known;</li> <li>c) applicable regulatory requirements related to the</li> </ul>

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			<p>product;</p> <p>d) any user training needed to ensure specified performance and safe use of the medical device;</p> <p>e) any additional requirements determined by the organization</p>
Viamed Ltd ISO13485:2016 7.2.2	<p><b>Review of requirements related to product</b></p> <p>The organization shall review the requirements related to product. This review shall be conducted prior to the organization's commitment to supply product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that:</p> <p>a) product requirements are defined and documented;</p> <p>b) contract or order requirements differing from those previously expressed are resolved;</p> <p>c) applicable regulatory requirements are met;</p> <p>d) any user training identified in accordance with 7.2.1 is available or planned to be available;</p> <p>e) the organization has the ability to meet the defined requirements.</p> <p>Records of the results of the review and actions arising from the review shall be maintained (see 4.2.5).</p> <p>When the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance.</p> <p>When product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.</p>		
Viamed Ltd ISO13485:2016 7.2.3	<p><b>Communication</b></p> <p>The organization shall plan and document arrangements for communicating with customers in relation to:</p> <p>a) product information;</p> <p>b) enquiries, contracts or order handling, including amendments;</p> <p>c) customer feedback, including complaints;</p> <p>d) advisory notices.</p> <p>The organization shall communicate with regulatory authorities in accordance with applicable regulatory requirements.</p>		
Viamed Ltd ISO13485:2016 8.2.4	<p><b>Internal audit</b></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,</p>		

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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.
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INTERNAL AUDIT CHECKLIST / QUESTIONNAIRE			
<u>DATE:</u>	<u>AUDITOR:</u> Audit No 02 Contract Review and Sales Order Processing	<u>AUDIT PROCEDURE</u> COP's 03, 20.5	
<u>QUESTION:</u>	<u>RESPONSE:</u>	<u>Y/N</u>	
Review Last years Audit Are all follow on Issue resolved satisfactory?	#103237 from 2017 Audits Done	Y	
Are Telephone orders being logged in the call log correctly	6164 ✓ 6158 ✓ 6081 ✓ #128252 -	Y	
Are Contact Details being updated in the system correctly Check 5 of this weeks Invoices: Check the Invoice, ORD customer paperwork and CRM are correct. Stamped, initialled and dated correctly	ORD94120 ✓ ORD94101 ✓ ORD94032 ✓ VSORD1001 ✓		Reminder sent more details #128418
1. VN158768 - 2191 - Princess Royal 2. VN158751 - 2609 - Lincoln 3. VN158728 - 14072 - SHA 4. VST1NO1095 - VST0111 Marked 5. VST1NO1096 - VST0004 Envitec	VSORD1002 ✗ NO CRM Details		
ORD File(s) are in ORD number order and archived correctly		Y	
Quotes and proformas file used correctly check 3 of each, Box size where relevant, checked as per order, stamped emailed and dated. - check any over the limit set in vm3COP03 have been signed by a director.			Y
Quotes			
1. QVO05474 ✓✓ No box size	No Quotes for VST		
2. QVO05447 ✓✓			
3. QVO05432 ✓✓			
Proformas			
1. PRO05210 ✓✓ ✓ VS PRO000011	✓✓	✓✓	
2. PRO05206 ✓✓ ✓			
3. PRO05197 ✓✓ No box size			

Sub Processes Linked to Audit 02  
Review the below processes tasks and audits and ensure they are completed in a timely manner.

## Product Controller

Process Scope	Roll Task	Roll Audit	Risk/Freq/Ove	Action	Notes / Issues
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PROCESSID 5905	418	71	not done within terms	Roll	Risk 3	Task 1M
Check we have constant pricing across the different databases	Director 3 (Steve)	Managing Director	12126	Roll	Freq: 1	Audit 3M
PROCESSID 7697	501	502		Roll	Overall 3	
To review the current pricing and impact of increases	Director 3 (Steve)	Managing Director	119381	Roll	Risk 1	Task 12M
			121153	Roll	Freq: 2	Audit 12M
				Roll	Overall 2	

## Sales Controller

Process Scope	Roll Task	Roll Audit	Risk/Freq/Ove	Action	Notes / Issues
PROCESSID 7801	653	654	Roll	Risk 1	Task 12M
To review the current pricing and impact of increases	Office Processes	Director 3 (Steve)	Roll	Freq: 2	Audit 12M
			Roll	Overall 2	

## Humanmed Controller

Process Scope	Roll Task	Roll Audit	Risk/Freq/Ove	Action	Notes / Issues
PROCESSID 7670	611	121681	Roll	Risk 3	Task 1M
Review of Humanmed sales and orders and clear any duplicates or problems.	Office Processes		Roll	Freq: 1	
PROCESSID 7782	770	123328	Roll	Overall 3	
Remove Started But Not Used Order Numbers from intrastats.	Managing Director		Roll	Risk 2	Task 3M
			Roll	Freq: 1	
			Roll	Overall 2	

## UK Sales Force

Process Scope	Roll Task	Roll Audit	Risk/Freq/Ove	Action	Notes / Issues
PROCESSID 5871	292	121123	Roll	Risk 3	Task 1M
Review the Sale or Return list in intrastats. Ensure it is up to date.	UK Sales Controller	Managing Director	Roll	Freq: 2	Audit 3M
PROCESSID 5876	361		Roll	Overall 6	
To Collect E.Commerce Cardea And Multiquote Orders			Roll	Risk 5	
	X	No process	Roll	Freq: 1	
			Roll	Overall 5	

## EX Sales Force

Process Scope	Roll Task	Roll Audit	Risk/Freq/Ove	Action	Notes / Issues
PROCESSID 5872	291	121123	Roll	Risk 3	Task 1M
Review the Sale or Return list in intrastats. Ensure it is up to date.	EX Sales Controller	Managing Director	Roll	Freq: 2	Audit 3M
			Roll	Overall 6	

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## OEM Sales Controller

Process Scope	Roll Task	Roll Audit	Risk/Freq/Ove rall	Action	Notes / Issues
PROCESSID 7808 To find and Tag any sales that are removed from commissions, as they are break even products for relationships purposes	127131 ✓ 670 Managing Director	123629 ✓ 704 Director 3 (Steve)	Risk 3 Freq: 1 Overall 3	Task 1M Audit 3M	

## Audits

Process Scope	Roll Task	Roll Audit	Risk/Freq/Ove rall	Action	Notes / Issues
PROCESSID 7715 To carry out Audit 02 Contract Review Viamed		36 <i>This Audit</i>	Risk 1 Freq: 2 Overall 2	Audit 12M	
PROCESSID 7763 To carry out Audit 02 Contract Review VST		187 <i>This Audit</i>	Risk 1 Freq: 2 Overall 2	Audit 12M	

## Vandagraph

Process Scope	Roll Task	Roll Audit	Risk/Freq/Ove rall	Action	Notes / Issues
PROCESSID 7791 Changing of the prices lists without informing the sales team. Issue to check these are current	127499 ✓ 636 EX Sales Controller		Risk 3 Freq: 2 Overall 6	Task 1M	

\*Vandagraph is not an ISO company

## Office Processes

Process Scope	Roll Task	Roll Audit	Risk/Freq/Ove rall	Action	Notes / Issues
PROCESSID 2 Office Answering taking calls and either dealing with the enquiry or passing the call onto someone who can, or making a call log for someone to return a call		127196 ✓ 668 Managing Director	Risk 2 Freq: 1 Overall 2	Audit 3M	
PROCESSID 14 Ensuring that fax reports have been generated for both sent and received faxes and ensuring there is paper in the	367 Office Processes	411 Office Processes	Risk 4 Freq: 1 Overall 4	Task 1W Audit 1M	

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fax machine

128163 ✓ 127965 ✓

PROCESSID 36

Invoices are emailed to customers

430 Office Processes

362 Company Secretary

Risk 4 Freq: 1 Overall 4

Task 1W Audit 1W

PROCESSID 37

Viamed has a consignment stock with West Yorkshire Ambulance,

117306 348 ✓

Office Processes

349 126335 UK Sales Controller

Risk 4 Freq: 1 Overall 4

Task 1W Audit 1M

We scan stock to a shelf, then send them the consignment stock

As and when they use stock each week we do a rational and invoice them for the used stock and replenish the consignment stock.

WYA Stock check via the website.

We can now check their stock agrees with ours.

127871 ✓

128083

239 Office Processes

401 ✓ Managing Director

Risk 4 Freq: 1 Overall 4

Task 1W Audit 1M

PROCESSID 5875

Checking the PayPal website for payments from customers that may have been missed or not emailed to the main inbox

127966 ✓

382 ✓ Office Processes

128158 ✓

383 ✓ Office Processes

Risk 4 Freq: 1 Overall 4

Task 1W Audit 4W

PROCESSID 5882

Humanedmed post is received, it needs to be forwarded to Humanmed UK Sales Manager

128160 ✓

397 ✓ Office Processes

536 No process

Risk 3 Freq: 1 Overall 3

Audit 2M

PROCESSID 5891

To process the Repair Quotes And Orders as they come in.

395 No process

Office Processes

396 128081 ✓

Company ✓ Secretary

Risk 5 Freq: 1 Overall 5

Task 1D Audit 1M

PROCESSID 5892

Checking the eBay and Amazon accounts for orders that have not been emailed to the main inbox and checking to see if there are messages or questions.

397 ✓

Office Processes

398 ✓

Office Processes

Risk 5 Freq: 1

Overall 5

Task 1D Audit 1M

PROCESSID 5893

Answering any questions that are asked via the website from within Instrastats

395 No process

Office Processes

396 128081 ✓

Company ✓ Secretary

Risk 5 Freq: 1 Overall 5

Task 1D Audit 1M

PROCESSID 5895

PROCESSID 5897  
Task to Frank outgoing Mail

128133 ✓

Office Processes

777 126394 ✓

Managing ✓ Director

Risk Freq: 1 Overall

Task 1W Audit 1M

127822 ✓

564 Within terms Goods Out

568 127631 ✓

Office Processes

Risk 5 Freq: 1 Overall 5

Task 1D Audit 1D

PROCESSID 5899

409 127801 ✓

410 128089 ✓

Risk 5

Task 1D

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Chase outstanding Quotes and Proformas	Office Processes	Managing Director	Freq: 1 Overall 5	Audit 1M
<b>PROCESSID 5913</b> Checking the mailbox from within the main inbox for outstanding Humanmed orders.	128165 465 ✓ Office Processes	466 127163 Office Processes	Risk 4 Freq: 1 Overall 4	Task 1W Audit 1M
<b>PROCESSID 5943</b> Checking the Cardea and Multiquote websites for outstanding orders or requests	128116 530 ✓ Office Processes	127464 279 ✓ Office Processes	Risk 4 Freq: 1 Overall 4	Task 1W Audit 1M
<b>PROCESSID 5948</b> Adding customer accounts to account management software	128176 504 ✓ Office Processes	121476 669 ✓ Company Secretary	Risk 1 Freq: 1 Overall 1	Audit 12M
<b>PROCESSID 7676</b> Process of PDF ing Invoices into the system for easy of use in the future and the Emailing of Invoices to customers	128100 478 ✓ Office Processes	126314 531 ✓ Office Processes	Risk 4 Freq: 1 Overall 4	Task 1W Audit 1M
<b>PROCESSID 7678</b> Checking the Catalog 360 Circle website for outstanding orders or requests	128166 487 ✓ Office Processes	127880 569 ✓ Company Secretary	Risk 5 Freq: 1 Overall 5	Task 1D Audit 1M
<b>PROCESSID 7686</b> Check that outstanding orders with unresolved issues are being followed up and addressed	128174 496 ✓ Office Processes	128118 537 ✓ Office Processes	Risk 5 Freq: 1 Overall 5	Task 1D Audit 1W
<b>PROCESSID 7696</b> Emailing Notifications of shipments	128167 523 ✓ Office Processes	127668 524 ✓ Managing Director	Risk 5 Freq: 1 Overall 5	Task 1D Audit 1M
<b>PROCESSID 7709</b> Ensure invoices are generated for shipped orders	128180 528 <sup>within 10 days</sup> Office Processes	127906 529 ✓ Office Processes	Risk 5 Freq: 1 Overall 5	Task 1D Audit 1W
<b>PROCESSID 7712</b> Review the payments received to ensure proformas can be shipped	127998 549 ✓ Office Processes	127189 550 ✓ Office Processes	Risk 4 Freq: 1 Overall 4	Task 1W Audit 1M
<b>PROCESSID 7735</b> Ensure samples and Sale or Return items are followed up after 4 weeks for feedback and the item(s) is returned as appropriate	127823 603 ✓ Office Processes	126336 604 ✓ Office Processes	Risk 4 Freq: 1 Overall 4	Task 1W Audit 1M
<b>PROCESSID 7758</b> Check the emails for orders from GHX	128186 620 ✓ Office Processes	128005 621 ✓ Office Processes	Risk 5 Freq: 1 Overall 5	Task 1D Audit 1W
<b>PROCESSID 7761</b> Emailing Notifications of shipments	128074 612 ✓ Office Processes	127911 613 ✓ Office Processes	Risk 4 Freq: 1	Task 1W Audit 1M
<b>PROCESSID 7783</b> Process of PDF ing Invoices into the				

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system for easy of use in the future and the Emailing of Invoices to customers

**PROCESSID 7795**

Answering any questions that are asked via the website from within Intrastats

**PROCESSID 7822**

To check we have the stock available to supply our customer Oxylink.

12873  
643 ✓ Risk 5 Task 1D  
Office Processes  
127208 127206  
708 ✓ 709 ✓ Risk 3 Task 1M  
Office Processes Goods In Freq: 1 Audit 1M  
Overall 5 Overall 3