

# Internal Audit Check list

Software Validation Viamed

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Audit Date	23-2-26	Auditor	Helen Lamb

Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
Viamed Ltd ISO13485:2016 4.1.6	<p><b>Quality management system</b></p> <p>For each quality management system process, the organization shall:</p> <p>The organization shall document procedures for the validation of the application of computer software used in the quality management system. Such software applications shall be validated prior to initial use and, as appropriate, after changes to such software or its application.</p> <p>The specific approach and activities associated with software validation and revalidation shall be proportionate to the risk associated with the use of the software.</p> <p>Records of such activities shall be maintained (see 4.2.5).</p>	<p><i>Doc index rules + titles</i></p>

	<u>QUESTION:</u>	<u>RESPONSE:</u>	Y/ N
1	Review Last years Audit. Update processes if required. Are all follow on Issue resolved satisfactory.	<p><i>All completed</i></p> <p><i>Nothing ongoing</i></p> <p><i>or outstanding</i></p> <p><i>No Non conformance</i></p>	<p><i>Y</i></p>

**Sub Processes Linked to Audit**

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

**List Processes Per Title**

Clone from Docid

<b>IT Controller</b>			
<b>Process Scope</b>	<b>Roll Task Roll Audit</b>	<b>Risk</b>	<b>Action</b>

Notes

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<b>PROCESSID 52</b> Keeps a month or so backup emails	Task: <del>368</del> Audit: <del>417</del>	Freq 2 Risk 1 Overall 2	
<b>PROCESSID 7850</b> Test the Goods out process disabling picking of items not relating to an order	Task: 752 <i>374024</i> Goods Out Audit :753 <i>387474</i> Managing Director	Freq 1 Risk 1 Overall 1	Task 9M Audit 12M
<b>PROCESSID 7851</b> To test intrastats does not allow picking of unprocessed products to live customer orders	Task: 754 <i>383300</i> ✓ Goods Out Audit :755 <i>387475</i> ✓ Managing Director	Freq 1 Risk 1 Overall 1	Task 6M Audit 12M
<b>PROCESSID 7852</b> To attempt to Scan a product that has gone past its expire date.	Task: 756 <i>377841</i> ✓ Goods Out Audit :757 <i>357131</i> ✓ Managing Director	Freq 1 Risk 1 Overall 1	Task 12M Audit 12M
<b>PROCESSID 7853</b> Warehouse shelves can be tagged as sellable stock / unsellable stock. Either for quarantine purposes or holding items for other customer orders.  Test that Order picking cannot pick unsellable stock locations to an Order	Task: 759 <i>374026</i> ✓ Goods Out Audit :760 <i>382674</i> ✓ Managing Director	Freq 1 Risk 3 Overall 3	Task 12M Audit 12M
<b>PROCESSID 7854</b> Software Validation of the production lists.  By confirming no extra production jobs are stuck in the system, and all listed production jobs are found. the production tracking is validated	Task: 761 <i>384686</i> ✓ Goods In Audit :762 <i>379682</i> ✓ Managing Director	Freq 2 Risk 2 Overall 4	Task 3M Audit 6M
<b>PROCESSID 7855</b> Software Validation - Production Lists Review the current active production lists in intrastats to the actual in progress production lists	Task: 761 <i>384686</i> ✓ Goods In Audit :762 <i>379682</i> ✓ Managing Director	Freq 2 Risk 2 Overall 4	Task 3M Audit 6M
<b>PROCESSID 7856</b> To check order picking cannot pick against an unchecked order	Task: 764 <i>384687</i> ✓ Office Processes Audit :765 <i>382675</i> ✓ Managing Director	Freq 2 Risk 2 Overall 4	Task 12M Audit 12M
<b>PROCESSID 7857</b> To confirm Software Validation Stock Tracking	Task: 763 <i>377454</i> ✓ Goods In	Freq 2 Risk 1	Task 6M Audit

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Check, is functioning as expected	Audit :1155 357163 ✓ Managing Director	Overall 2	12M
PROCESSID 7858 Test the QA System that Staff not trained for QA are unable to QA a Product.	Task: 766 382177 ✓ Office Processes  Audit :1175 388338 ✓ Managing Director	Freq 1 Risk 3 Overall 3	Task 6M Audit 12M
PROCESSID 7861 Software Validating Of Training Documents via Forced Required Reading	Task: 768 377169 ✓ Managing Director  Audit :	Freq 1 Risk 2 Overall 2	Task 12M
PROCESSID 7865 Software Validation of the system: To check all process(s) tasks and audits are not clashed with the same person doing the Task as the Audit.	Task: 779 377455 ✓ Managing Director  Audit :781 378013 ✓ Managing Director	Freq 1 Risk 1 Overall 1	Task 12M Audit 12M
PROCESSID 7870 Scope to check the automatic system of tagging product non conformance and other issues to the post market surveillance review report.	Task: 789 378259 ✓ Managing Director  Audit :	Freq 1 Risk 1 Overall 1	Task 12M
PROCESSID 7875 To test document control is working as intended.	Task: 802 378525 ✓ Managing Director  Audit :803 379686 ✓ Company Secretary	Freq 1 Risk 1 Overall 1	Task 12M Audit 12M
PROCESSID 7879 To check the Scheduled Tasks and Audits is working as Intended. To also Check the Out of Date documents is working as Intended.	Task: 808 386560 ✓ Managing Director  Audit :809 379075 ✓ Company Secretary	Freq 1 Risk 1 Overall 1	Task 12M Audit 6M
PROCESSID 7880 To confirm the out of documents computer software functions as expected flagging out of date items on to the list	Task: 808 386560 ✓ Managing Director  Audit :809 379075 ✓ Company Secretary	Freq 1 Risk 1 Overall 1	Task 12M Audit 6M
PROCESSID 7881 To compare Opera Live Orders to Intrastats Back order Active List  NO LONGER REQUIRED Opera is now out of the system	Task: 810  Audit :	Freq 1 Risk 1 Overall 1	
PROCESSID 7951 Check the Server space and Size of important files	Task: 139 387854 ✓ Office Processes	Freq 1 Risk 2	Task 1M Audit 3M

in terms.

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	Audit :1033 <i>384697</i> Managing Director ✓	Overall 2	
PROCESSID 8013 Ensure Email system working as intended	Task: 1179 <i>379716</i> Marketing Processes ✓  Audit :1180 <i>357165</i> Managing Director ✓	Freq 1 Risk 1 Overall 1	Task 6M Audit 12M
PROCESSID 8083 Issue to verify process works as intended - Create a New SRS, Add in a test item stock reference, generate the SRS, Go in via engineer mode, Flag the SRS as a non conformance or customer complaint, check the non conformance page for it appearing in the list, clear form the list, complete the SRS	Task: 1257 <i>379729</i> Managing Director ✓  Audit :1258 <i>380527</i> Company Secretary ✓	Freq 1 Risk 2 Overall 2	Task 12M Audit 12M
<b>Audits</b>			
<b>Process Scope</b>	<b>Roll Task Roll Audit</b>	<b>Risk</b>	<b>Action</b>
PROCESSID 7892 To confirm the Prime functions of the Software used is verified.  Any follow on issues must be identified with Observation Issue or a Non Conformance Issue.  If the issue is a Non Conformance a QC21 form must be filled in, as per the QC21 form procedure, and investigated as such.	Task:  Audit :821 <i>388321</i> Company Secretary <i>audit</i>	Freq 1 Risk 2 Overall 2	Audit 12M

Notes

Rolling Tasks Linked to Document :Task (368) Task (752) Task (754) Task (756)  
Task (759) Task (761) Task (764) Task (763) Task (766) Task (768) Task (779) Task  
(789) Task (802) Task (808) Task (810) Task (821) Task (139) Task (1179) Task  
(1257)