

Internal Audit Check list

Software Validation Viamed

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Audit Date	11/2/25	Auditor	Page 1 of 4

Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
Viamed Ltd ISO13485:2016 4.1.6	<p>Quality management system</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>Doc index</p> <p>Procedures</p> <p>Roles + titles</p>

	QUESTION:	RESPONSE:	Y/N
1	Review Last years Audit. Update processes if required. Are all follow on Issue resolved satisfactory.	Nothing outstanding	Y

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

IT Controller	Roll Task Roll Audit	Risk	Action	*	Notes
Process Scope PROCESSID 52 Keeps a month or so backup emails	Task: 368	Freq 2 Risk 1 Overall 2			

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	Audit :417			
PROCESSID 7850 Test the Goods out process disabling picking of items not relating to an order	Task: 752 Goods Out 348429 Audit :753 354355 ✓ Managing Director	Freq 1 Risk 1 Overall 1	Task 9M Audit 12M	
PROCESSID 7851 To test intrastats does not allow picking of unprocessed products to live customer orders	Task: 754 Goods Out 349461 ✓ Audit :755 354356 ✓ Managing Director	Freq 1 Risk 1 Overall 1	Task 6M Audit 12M	
PROCESSID 7852 To attempt to Scan a product that has gone past its expire date.	Task: 756 Goods Out 343778 ✓ Audit :757 322419 ✓ Managing Director	Freq 1 Risk 1 Overall 1	Task 12M Audit 12M	
PROCESSID 7853 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 Goods Out 339735 ✓ Audit :760 Managing Director 348619 ✓	Freq 1 Risk 3 Overall 3	Task 12M Audit 12M	
PROCESSID 7854 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 Goods In 350939 ✓ Audit :762 345610 ✓ Managing Director	Freq 2 Risk 2 Overall 4	Task 3M Audit 6M	
PROCESSID 7855 Software Validation - Production Lists Review the current active production lists in intrastats to the actual in progress production lists	Task: 761 Goods In 350939 ✓ Audit :762 345610 ✓ Managing Director	Freq 2 Risk 2 Overall 4	Task 3M Audit 6M	
PROCESSID 7856 To check order picking cannot pick against an unchecked order	Task: 764 350940 ✓ Office Processes Audit :765 348620 ✓ Managing Director	Freq 2 Risk 2 Overall 4	Task 12M Audit 12M	
PROCESSID 7857 To confirm Software Validation Stock	Task: 763 Goods In 343777 ✓	Freq 2 Risk 1	Task 6M Audit 12M	

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Tracking Check, is functioning as expected	Audit :1155 322436 ✓ Managing Director	Overall 2		
PROCESSID 7858 Test the QA System that Staff not trained for QA are unable to QA a Product.	Task: 766 348431 ✓ Office Processes Audit :1175 355071 ✓ 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 342883 ✓ 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 343228 ✓ Managing Director Audit :781 343780 ✓ 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 344073 ✓ Managing Director Audit :	Freq 1 Risk 1 Overall 1	Task 12M	
PROCESSID 7875 To test document control is working as intended.	Task: 802 344455 ✓ Managing Director Audit :803 345613 ✓ 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 353229 ✓ Managing Director Audit :809 344968 ✓ 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 353229 ✓ Managing Director Audit :809 344968 ✓ 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	Task: 810 ✓ Audit :	Freq 1 Risk 1 Overall 1		
NO LONGER REQUIRED Opera is now out of the system				
PROCESSID 7951	Task: 139	Freq 1	Task 1M	

354615 in terms.

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Check the Server space and Size of important files	Office Processes Audit :1033 Managing Director	350950 Risk 2 Overall 2	Audit 3M		
PROCESSID 8013 Ensure Email system working as intended	Task: 1179 Marketing Processes Audit :1180 Managing Director	345755 Risk 1 Overall 1	Freq 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 Managing Director Audit :1258 Company Secretary	1257 Risk 2 Overall 2	Freq 1 Task 12M Audit 12M		
Audits					
Process Scope	Roll Task Roll Audit	Risk	Action	*	Notes
PROCESSID 7892 To confirm the Prime functions of the Software used is verified.	Task: Audit :821 355055 This Audit Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M		

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)