

Internal Audit Check list			
Software Validation Viamed			
Created:	19 Oct 2017	Audit No 27	
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Audit Date	11/2/25	Auditor	

Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
Viamed Ltd ISO13485:2016 4.1.6	Quality management system For each quality management system process, the organization shall: 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. The specific approach and activities associated with software validation and revalidation shall be proportionate to the risk associated with the use of the software. Records of such activities shall be maintained (see 4.2.5).	Doc index Procedures Roles + titles.

	<u>QUESTION:</u>	<u>RESPONSE:</u>	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						
Process Scope	Roll Task Roll Audit	Risk	Action	*	Notes	
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 348429 Goods Out 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 349461 ✓ Goods Out 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 343778 ✓ Goods Out 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 339735 ✓ Goods Out Audit :760 348619 ✓ Managing Director	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 350939 ✓ Goods In 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 350939 ✓ Goods In 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 343227 ✓ Goods In	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 NO LONGER REQUIRED Opera is now out of the system	Task: 810 Audit :	Freq 1 Risk 1 Overall 1			
PROCESSID 7951	Task: 139	Freq 1	Task 1M		

35465 in terms.

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Check the Server space and Size of important files	Office Processes 350950 Audit :1033 Managing Director	Risk 2 Overall 2	Audit 3M			
PROCESSID 8013 Ensure Email system working as intended	Task: 1179 345755 Marketing Processes Audit :1180 322256 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 Managing Director Audit :1258 Company Secretary	Freq 1 Risk 2 Overall 2	Task 12M Audit 12M			
Audits						
Process Scope	Roll Task Roll Audit	Risk	Action	*	Not es	
PROCESSID 7892 To confirm the Prime functions of the Software used is verified.	Task: 355055 Audit :821 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)