

Internal Audit Check list			
Software Validation			
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Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
Viamed Ltd ISO13485:2 016 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).	

	<u>QUESTION:</u>	<u>RESPONSE:</u>	<u>Y/ N</u>
1	Review Last years Audit. Update processes if required. Are all follow on Issue resolved satisfactory.		

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

IT Controller					
Process Scope	Roll Task	Roll Audit	Risk	Action	Referenced in Document
PROCESSID 52 Keeps a month or so backup emails	368	417	Freq 2 Risk 1 Overall 2		

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PROCESSID 7850 Test the Goods out process disabling picking of items not relating to an order	752 Goods Out	753 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	754 Goods Out	755 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.	756 Goods Out	757 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	759 Goods Out	760 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	761 Goods In	762 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	761 Goods In	762 Managing Director	Freq 2 Risk 2 Overall 4	Task 3M Audit 6M	
PROCESSID 7856 To check order picking cannot pick against an unchecked order	764 Office Processes	765 Managing Director	Freq 2 Risk 2 Overall 4	Task 12M Audit 12M	
PROCESSID 7857 To confirm Software Validation Stock Tracking Check, is functioning as expected	763 Goods In	1155 Managing Director	Freq 2 Risk 1 Overall 2	Task 6M Audit 12M	
PROCESSID 7858 Test the QA System that Staff not trained for QA are unable to QA a Product.	766 Office Processes	1175 Managing Director	Freq 1 Risk 3 Overall 3	Task 6M Audit 12M	
PROCESSID 7861 Software Validating Of Training Documents via Forced Required Reading	768 Managing Director		Freq 1 Risk 2 Overall 2	Task 12M	

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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.	779 Managing Director	781 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.	789 Managing Director		Freq 1 Risk 1 Overall 1	Task 12M	
PROCESSID 7875 To test document control is working as intended.	802 Managing Director	803 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.	808 Managing Director	809 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	808 Managing Director	809 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	810		Freq 1 Risk 1 Overall 1		
PROCESSID 7951 Check the Server space and Size of important files	139 Office Processes	1033 Managing Director	Freq 1 Risk 2 Overall 2	Task 1M Audit 3M	
PROCESSID 8013 Ensure Email system working as intended	1179 Marketing Processes	1180 Managing Director	Freq 1 Risk 1 Overall 1	Task 6M Audit 12M	
Audits					
Process Scope	Roll Task	Roll Audit	Risk	Action	Referenced in Document
PROCESSID 7892 To confirm the Prime functions of the Software used is verified.		821 Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M	

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