Internal Audit Check list			
Software Validation			
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Audit Date	9-3-23	Auditor Helen Combs	

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

	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

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 270649	753 ✓ 285505 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 280379 ✓	755 Managing Director 285253	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 274343 ✓	757 Managing Director 288429 ✓	Freq 1 Risk 1 Overall 1	Task 12M Audit 12M	
PROCESSID **7853** Warehouse shelfs 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 270652 ✓	760 Managing Director 279641 ✓	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 282041 ✓	762 Managing Director 276343 ✓	Freq 2 Risk 2 Overall 4	Task 3M Audit 6M	
PROCESSID **7855** Software Validation - Production Lists Review the current active production lists inintrastats to the actual in progress production lists	761 Goods In 282041 ✓	762 Managing Director 3 276343 ✓	Freq 2 Risk 2 Overall 4	Task 3M Audit 6M	
PROCESSID **7856** To check order picking cannot pick against an unchecked order 28204 x Sent Reminder	764 Office Processes	765 279644 Managing Director 288288	Freq 2 Risk 2 Overall 4	Task 12M Audit 12M	
PROCESSID **7857** To confirm Software Validation Stock Tracking Check, is functioning as expected 274108 ✓	763 Goods In	1155 ✓ Managing Director	Freq 2 Risk 1 Overall 2	Task 6M Audit 12M	
PROCESSID **7858** 279353 Test the QA System that Staff not trained for QA are unable to QA a Product.	766 Office Processes	1175 286059 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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Process Scope	Roll Task	Roll Audit	Risk	Action	Referenced in Document
PROCESSID **7865** Software Validiation 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 274110 ✓	781 Managing Director 274659 ✓	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 27477 o ✓		Freq 1 Risk 1 Overall 1	Task 12M	
PROCESSID **7875** To test document control is working as intended.	802 Managing Director 275153 ✓	803 Company Secretary 276346 ✓	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 284398 ✓	809 Company Secretary 275592 ✓	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 284398	809 Company Secretary 275592	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 ın ferms 288486 x	275592 ✓ 282057 ✓	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	276603 ✓	288128 x ın ferms			

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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This Audit

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