

Internal Audit Check List

Software Validation		
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Audit Date		Auditor

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>	<i>Invarstant</i>

	<u>QUESTION:</u>	<u>RESPONSE:</u>	Y/ N
1	Review Last years Audit. Update processes if required. Are all follow on Issue resolved satisfactory.	<i>No findings outstanding</i>	

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	Notes / Issues
PROCESSID 52 Keeps a month or so backup emails	368 Managing Director	417 Company Secretary	Freq 4 Risk 1 Overall 4	Task 2W Audit 3M	
PROCESSID 7132	<i>No Issues</i>	<i>No Issues</i>	<i>Freq</i>		



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PROCESSID 7850	752	753	Freq 3	Task 9M
Test the Goods out process disabling picking of items not relating to an order	Goods Out	Managing Director	Risk 2 Overall 6	Audit 12M
PROCESSID 7851	754	755	Freq 3	Task 6M
To test intrastats does not allow picking of unprocessed products to live customer orders	Goods Out	Managing Director	Risk 4 Overall 12	Audit 12M
PROCESSID 7852	756	757	Freq 3	Task
To attempt to Scan a product that has gone past its expire date.	Goods Out	Managing Director	Risk 2 Overall 6	12M Audit
PROCESSID 7853	759	760	Freq 3	Task
Warehouse shelves can be tagged as sellable stock / unsellable stock. Either for quarantine purposes or holding items for other customer orders.	Goods Out	Managing Director	Risk 3 Overall 9	12M Audit 12M
Test that Order picking cannot pick unsellable stock locations to an Order				
PROCESSID 7854	761	762	Freq 2	Task 3M
Software Validation of the production lists.	Goods In	Managing Director	Risk 2 Overall 4	Audit 6M
By confirming no extra production jobs are stuck in the system, and all listed production jobs are found. the production tracking is validated	#209510	#2095282		
PROCESSID 7855	761	762	Freq 2	Task 3M
Software Validation - Production Lists	Goods In	Managing Director	Risk 2 Overall 4	Audit 6M
Review the current active production lists in intrastats to the actual in progress production lists	#209510	#2095282		
PROCESSID 7856	764	765	Freq 2	Task
To check order picking cannot pick against an unchecked order	Office Processes	Managing Director	Risk 2 Overall 4	12M Audit
PROCESSID 7857	763		Freq 2	Task 6M
To confirm Software Validation Stock Tracking Check, is functioning as expected	Goods In		Risk 1	
PROCESSID 7858	766		Freq 3	Task 6M
Test the QA System that Staff not trained for QA are unable to QA a Product.	Office Processes	Managing Director	Risk 3 Overall 9	
PROCESSID 7861	768		Freq 1	Task
Software Validating Of Training Documents via Forced Required Reading	Managin g		Risk 2 Overall 2	12M

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PROCESSID 7865	Director	779	781	Freq 1	Task
Software Validation of the system:	Manager	Managing	Managing	Risk 1	12M
To check all process(s) tasks and audits are not clashed with the same person doing the Task as the Audit.	Director	g	Director	Overall 1	Audit
		#199959	#200700		12M
PROCESSID 7870	Director	789		Freq 1	Task
Scope to check the automatic system of tagging product non conformance and other issues to the post market surveillance review report.	Manager	g		Risk 1	12M
	Director			Overall 1	
		#201004			
PROCESSID 7875	Director	802	803	Freq 1	Task
To test document control is working as intended.	Manager	g	Company	Risk 1	12M
	Secretary		Secretary	Overall 1	Audit
	Director		#203285		12M
PROCESSID 7879	Director	808	809	Freq 1	Task
To check the Scheduled Tasks and Audits is working as Intended.	Manager	g	Company	Risk 4	12M
	Secretary		Secretary	Overall 4	Audit 6M
To also Check the Out of Date documents is working as Intended.	Director	#211620	#201960		
PROCESSID 7880	Director	808	809	Freq 1	Task
To confirm the out of documents computer software functions as expected flagging out of date items on to the list	Manager	g	Company	Risk 1	12M
	Secretary		Secretary	Overall 1	Audit 6M
	#211620	#201960			
PROCESSID 7881	Director	810		Freq 1	
To compare Opera Live Orders to Intrastats Back order Active List				Risk 3	
				Overall 3	
NO LONGER REQUIRED					
Opera is now out of the system					
PROCESSID 7951	139	1033	Freq 1	Task 1M	
Check the Server space and Size of important files	#215738	Managing	Risk 5	Audit 3M	
		Director	Overall 5		
		#209590			
Audits					
Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID 7892		821	Freq 1	Audit	
To confirm the Prime functions of the Software used is verified.		Company	Risk 2	12M	
		Secretary	Overall 2		
		#213154			
		This Audit			

