

Internal Audit Check list			
Software Validation			
Created:	19 Oct 2017	Audit No 27	
Revised:	26 Oct 2017	Viamed Ltd ISO13485:2016: 4.1.6	Page 1 of 1
Audit Date		Auditor	

	<u>QUESTION:</u>	<u>RESPONSE:</u>	<u>Y/ N</u>
1			
2			
3			
4			
5			
6			
7			

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	368	417	Freq 4	Task	

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Keeps a month or so backup emails	Managing Director	Company Secretary	Risk 1	2W
			Overall	Audit
			4	3M

PROCESSID 7850	752	753	Freq 3	Task
Test the Goods out process disabling picking of items not relating to an order	Goods Out	Goods In	Risk 2	1M
			Overall	Audit
			6	3M

PROCESSID 7851	754	755	Freq 3	Task
To test intrastats does not allow picking of unprocessed products to live customer orders	Goods Out	Goods In	Risk 4	1M
			Overall	Audit
			12	3M

PROCESSID 7852	756	757	Freq 3	Task
To attempt to Scan a product that has gone past its expire date.	Goods Out	Goods In	Risk 2	1M
			Overall	Audit
			6	3M

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	Goods In	Risk 3	1M
			Overall	Audit
			9	3M

Test that Order picking cannot pick unsellable stock locations to an Order

PROCESSID 7854	761	762	Freq 2	Task
Software Validation of the production lists.	Goods In	Managing Director	Risk 2	3M
			Overall	Audit
			4	6M

By confirming no extra production jobs are stuck in the system, and all listed production jobs are found. the production tracking is validated

PROCESSID 7855	761	762	Freq 2	Task
Software Validation - Production Lists	Goods In	Managing Director	Risk 2	3M
			Overall	Audit

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Review the current active production lists in intrastats to the actual in progress production lists			4	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 3M Audit 12M
PROCESSID 7857 To confirm Software Validation Stock Tracking Check, is functioning as expected	763 Goods In		Freq 2 Risk 1 Overall 2	Task 6M
PROCESSID 7858 Test the QA System that Staff not trained for QA are unable to QA a Product.	766 Office Processes		Freq 3 Risk 3 Overall 9	Task 1M
PROCESSID 7861 Software Validating Of Training Documents via Forced Required Reading	768 Managing Director		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.	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	802	803	Freq 1	Task

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To test document control is working as intended.	Managing Director	Company Secretary	Risk 1	3M
			Overall	Audit
			1	12M

PROCESSID 7879	808	809	Freq 1	Task
To check the Scheduled Tasks and Audits is working as Intended.	Managing Director	Company Secretary	Risk 4	3M
			Overall	Audit
			4	6M

To also Check the Out of Date documents is working as Intended.

PROCESSID 7880	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	Managing Director	Company Secretary	Risk 1	3M
			Overall	Audit
			1	6M

PROCESSID 7881	810		Freq 1	Task
To compare Oprea Live Orders to Intrastats Backorder Active List,	Managing Director		Risk 3	12M
			Overall	
			3	