

# Internal Audit Check list

## Software Validation

Created:	19 Oct 2017	Audit No 27	
Revised:	26 Oct 2017		Page 1 of 4
Audit Date		Auditor	

Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
Viamed Ltd ISO13485:2 016 4.1.6	<b>Quality management system</b> 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).	<i>In progress</i>

	<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.	<i>Nothing 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	368	417	Freq 4	Task 2W	
Keeps a month or so backup emails	Managing	Company	Risk 1	Audit 3M	
	Director	Secretary	Overall 4		
PROCESSID 7132	<i>NO Issues</i>	<i>NO Issues</i>	Freq		



# Internal Audit Check list

## Software Validation

Created:	19 Oct 2017	Audit No 27	
Revised:	26 Oct 2017		Page 2 of 3
Audit Date		Auditor	

### PROCESSID 7850

Test the Goods out process disabling picking of items not relating to an order

752

# 215245

753

Freq 3

Task 9M

Managing Risk 2

Audit

Director Overall 6

12M

### PROCESSID 7851

To test intrastats does not allow picking of unprocessed products to live customer orders

754

755

Freq 3

Task 6M

Managing Risk 4

Audit

Director Overall 12M

12

### PROCESSID 7852

To attempt to Scan a product that has gone past its expire date.

756

757

Freq 3

Task

Managing Risk 2

12M

Director Overall 6

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.

759

760

Freq 3

Task

Managing Risk 3

12M

Director Overall 9

Audit

12M

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

### PROCESSID 7854

Software Validation of the production lists.

761

762

Freq 2

Task 3M

Managing Risk 2

Audit 6M

Director Overall 4

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

Software Validation - Production Lists  
Review the current active production lists in intrastats to the actual in progress production lists

761

762

Freq 2

Task 3M

Managing Risk 2

Audit 6M

Director Overall 4

### PROCESSID 7856

To check order picking cannot pick against an unchecked order

764

765

Freq 2

Task

Office Managing Risk 2

12M

Processes Director Overall 4

Audit

12M

### PROCESSID 7857

To confirm Software Validation Stock Tracking Check, is functioning as expected

763

Freq 2

Task 6M

Goods In

Risk 1

Overall 2

### PROCESSID 7858

Test the QA System that Staff not trained for QA are unable to QA a Product.

766

Freq 3

Task 6M

Office

Risk 3

Overall 9

### PROCESSID 7861

Software Validating Of Training Documents via Forced Required Reading

768

Freq 1

Task

Managin

Risk 2

12M

Overall 2



# Internal Audit Check list

## Software Validation

Created:	19 Oct 2017	Audit No 27	
Revised:	26 Oct 2017		Page 3 of 3
Audit Date		Auditor	

PROCESSID 7865	Director	779	781	Freq 1	Task	
Software Validation of the system:	Managin		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.	g		Director	Overall 1	Audit	
	Director				12M	
	#199959	#200700				
PROCESSID 7870	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.	Managin			Risk 1	12M	
	g			Overall 1		
	Director					
	#201004					
PROCESSID 7875	802	803		Freq 1	Task	
To test document control is working as intended.	Managin	Company		Risk 1	12M	
	g	Secretary		Overall 1	Audit	
	Director	#203285			12M	
	#201294					
PROCESSID 7879	808	809		Freq 1	Task	
To check the Scheduled Tasks and Audits is working as Intended.	Managin	Company		Risk 4	12M	
To also Check the Out of Date documents is working as Intended.	g	Secretary		Overall 4	Audit 6M	
	Director					
	#211620	#201960				
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	Managin	Company		Risk 1	12M	
	g	Secretary		Overall 1	Audit 6M	
	#211620	Director #201960				
PROCESSID 7881	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		Managing		Risk 5	Audit 3M	
	#215738	Director		Overall 5		
		#209590				
<b>Audits</b>						
<b>Process Scope</b>	<b>Roll Task</b>	<b>Roll Audit</b>	<b>Risk</b>	<b>Action</b>	<b>Notes / Issues</b>	
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

