

# Internal Audit Check list

## Software Validation

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Audit Date	13-27-19	Auditor <i>Helen Lamb</i>	

Company  
/ ISO  
Section

Viamed  
Ltd  
ISO13485  
:2016  
4.1.6

Criteria of ISO Section

Auditor  
Comments /  
Issues

### 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).

*Rolling Issues  
+ task  
to validate  
Software  
Carried out through  
out company*

### 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	

#1357409  
✓ #135739  
✓

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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 3M
	#133390	✓	Overall Audit
	✓		6 6M
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 6M
	#137366	✓	Overall Audit
	✓		12 12M
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 6M
	#130155	#137367	Overall Audit
	✓	✓	6 6M
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
	#127215	#131323	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
	#135200		Overall Audit
	✓	#131324	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
Review the current active production lists inintrastats to the	#135200	#131324	Overall Audit
	✓	✓	4 6M

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actual in progress  
production lists

<b>PROCESSID 7856</b>	764	765	Freq 2	Task
To check order picking cannot pick against an unchecked order	Office Processes	Managing Director	Risk 2	3M
	#135201	#131325	Overall	Audit
			4	12M
<b>PROCESSID 7857</b>	763		Freq 2	Task
To confirm Software Validation Stock	Goods In		Risk 1	6M
Tracking Check, is functioning as expected	#129790		Overall	
			2	
<b>PROCESSID 7858</b>	766		Freq 3	Task
Test the QA System that Staff not trained for QA are unable to QA a Product.	Office Processes		Risk 3	6M
	#133394		Overall	
			9	
<b>PROCESSID 7861</b>	768		Freq 1	Task
Software Validating Of Training Documents via Forced Required Reading	Managing Director		Risk 2	12M
	#129550		Overall	
			2	
<b>PROCESSID 7865</b>	779	781	Freq 1	Task
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.	Managing Director	Managing Director	Risk 1	12M
	#129792	#130254	Overall	Audit
			1	12M
<b>PROCESSID 7870</b>	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.	Managing Director		Risk 1	12M
	#130316		Overall	
			1	
<b>PROCESSID 7875</b>	802	803	Freq 1	Task
To test document control is working as intended.	Managing Director	Company Secretary	Risk 1	3M
	#130316	#131327	Overall	Audit
			1	12M

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**PROCESSID 7879** 808 809 Freq 1 Task  
 To check the Managing Company Risk 4 3M  
 Scheduled Tasks and Director Secretary Overall Audit  
 Audits is working as 4 6M  
 Intended. *#137361 #130935*

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

**PROCESSID 7880** 808 809 Freq 1 Task  
 To confirm the out of Managing Company Risk 1 3M  
 documents computer Director Secretary Overall Audit  
 software functions as 1 6M  
 expected flagging out *#137361 #130935*  
 of date items on to the  
 list

**PROCESSID 7881** 810 Freq 1 Task  
 To compare Opera Managing Risk 3 12M  
 Live Orders to Director Overall  
 Intrastats Back order *#130703* 3  
 Active List

## Audits

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
<b>PROCESSID 7892</b> To confirm the Prime functions of the Software used is verified.		821	Freq 1	Audit	