

Internal Audit Check list			
Software Validation			
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Revised:	26 Oct 2017		Page 1 of 1
Audit Date	13-2-19	Auditor	Helen Lamb

Company
/ ISO
Section

Criteria of ISO Section

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).

Auditor
Comments /
Issues

*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	368	417	Freq 4	Task	
Keeps a month or so backup emails	Managing Director	Company Secretary	Risk 1	2W	
			Overall Audit	3M	

#137409
✓

#135739
✓

02/03/2018

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PROCESSID 7850 752 753 Freq 3 Task
 Test the Goods out Goods Out Goods In Risk 2 3M
 process disabling #137462 Overall Audit
 picking of items not #133390 6 6M
 relating to an order ✓

PROCESSID 7851 754 755 Freq 3 Task
 To test intrastats does Goods Out Goods In Risk 4 6M
 not allow picking of #137366 Overall Audit
 unprocessed products ✓ 12 12M
 to live customer #134106
 orders ✓

PROCESSID 7852 756 757 Freq 3 Task
 To attempt to Scan a Goods Out Goods In Risk 2 6M
 product that has gone #130155 Overall Audit
 past its expire date. #137367 6 6M
 ✓ ✓

PROCESSID 7853 759 760 Freq 3 Task
 Warehouse shelves can Goods Out Goods In Risk 3 1M
 be tagged as sellable #127215 Overall Audit
 stock / unsellable #131323 9 3M
 stock. Either for ✓ ✓
 quarantine purposes or
 holding items for
 other customer orders.

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

PROCESSID 7854 761 762 Freq 2 Task
 Software Validation Goods In Managing Risk 2 3M
 of the production lists. Director Overall Audit
 #135200 4 6M
 ✓ #131324
 ✓

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 - Goods In Managing Risk 2 3M
 Production Lists #135200 Director Overall Audit
 Review the current ✓ 4 6M
 active production lists #131324
 inintrastats to the ✓

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actual in progress
production lists

PROCESSID 7856 764 765 Freq 2 Task
To check order Office Managing Risk 2 3M
picking cannot pick Processes Director Overall Audit
against an unchecked order #135201 #131325 4 12M

PROCESSID 7857 763 Freq 2 Task
To confirm Software Goods In Risk 1 6M
Validation Stock #129790 Overall
Tracking Check, is functioning as 2
expected

PROCESSID 7858 766 Freq 3 Task
Test the QA System Office Risk 3 6M
that Staff not trained Processes Overall
for QA are unable to QA a Product. #133394 9

PROCESSID 7861 768 Freq 1 Task
Software Validating Managing Risk 2 12M
Of Training Director Overall
Documents via Forced #129550 2
Required Reading

PROCESSID 7865 779 781 Freq 1 Task
Software Validation Managing Managing Risk 1 12M
of the system: Director Director Overall Audit
To check all process(s) tasks and audits are not clashed with the same person doing the Task as the Audit. #129792 #130254 1 12M

PROCESSID 7870 789 Freq 1 Task
Scope to check the Managing Risk 1 12M
automatic system of Director Overall
tagging product non conformance and other issues to the post market surveillance review report. #130316 1

PROCESSID 7875 802 803 Freq 1 Task
To test document Managing Company Risk 1 3M
control is working as Director Secretary Overall Audit
intended. #130316 #131327 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
PROCESSID 7892		821	Freq 1	Audit	
To confirm the Prime		Company	Risk 2	12M	
functions of the		Secretary	Overall		
Software used is			2		
verified.		#137812			