Internal Audit Check list

Software Validation

Created:	19 Oct 2017	**Audit No 27**	
Revised:	26 Oct 2017		Page 1 of 4
Audit Date	I S Sept 24	Auditor Helen Lamb	

Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
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).	Intrastats Tasks + Issues Rolling

	QUESTION:	**RESPONSE:**	**Y/N**
1	Review Last years Audit. Update processes if required. Are all follow on Issue resolved satisfactory.	Nothing outstanding	Y

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

196784 ✓   # 189940 ✓

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 Director	Company Secretary	Risk 1 Overall 4	Audit 3M	
PROCESSID **7132**			Freq		

Internal Audit Check list
Software Validation

Created:	19 Oct 2017	Audit No 27	
Revised:	26 Oct 2017		Page 2 of 4
Audit Date		Auditor	

Ensure the Smooth running of the contact management databses — Risk Overall

PROCESSID **7668**
To improve Intrastats and its functionality — Freq 2 / Risk 2 / Overall 4

PROCESSID **7850**	752	753	Freq 3	Task 3M
Test the Goods out process disabling picking of items not relating to an order	Goods Out #19544 ✓	Managing Director #164016 ✓	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 #186913	Managing Director #164017	Risk 4 Overall 12	Audit 12M

PROCESSID **7852**	756	757	Freq 3	Task 12M
To attempt to Scan a product that has gone past its expire date.	Goods Out # 156616	Managing Director #167405	Risk 2 Overall 6	Audit 12M

PROCESSID **7853**	759	760	Freq 3	Task 12M
Warehouse shelfs can be tagged as sellable stock / unsellable stock. Either for quarantine purposes or holding items for other customer orders.	Goods Out # 195645	Managing Director #159799	Risk 3 Overall 9	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 #189070	Managing Director #175534	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

PROCESSID **7855**	761	762	Freq 2	Task 3M
Software Validation - Production Lists	Goods In #189070	Managing Director #175534	Risk 2 Overall 4	Audit 6M
Review the current active production lists inintrastats to the actual in progress production lists				

PROCESSID **7856**	764	765	Freq 2	Task 12M
To check order picking cannot pick against an unchecked order	Office Processes #161540	Managing Director #159800	Risk 2 Overall 4	Audit

Internal Audit Check list

Software Validation

Created:	19 Oct 2017	**Audit No 27**	
Revised:	26 Oct 2017		Page 3 of 4
Audit Date		Auditor	

12M

PROCESSID 7857
To confirm Software Validation
Stock Tracking Check, is
functioning as expected

763
Goods In

172862 ✓

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

185657 ✓

Freq 3
Risk 3
Overall 9

Task 6M

PROCESSID 7861
Software Validating Of Training
Documents via Forced Required
Reading

768
Managing
Director

155911 ✓

Freq 1
Risk 2
Overall 2

Task
12M

PROCESSID 7865
Software Validiation 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

156187 ✓

781
Managing
Director

156618 ✓

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

156791 ✓

Freq 1
Risk 1
Overall 1

Task
12M

PROCESSID 7875
To test document control is working
as intended.

802
Managing
Director

157063

803
Company
Secretary

157854 ✓

Freq 1
Risk 1
Overall 1

Task
12M
Audit
12M

PROCESSID 7879
To check the Scheduled Tasks and
Audits is working as Intended.
To also Check the Out of Date
documents is working as Intended.

808
Managing
Director

162935

809
Company
Secretary

175036 ✓

Freq 1
Risk 4
Overall 4

Task
12M
Audit 6M

PROCESSID 7880
To confirm the out of documents
computer software functions as
expected flagging out of date items
on to the list

808
Managing
Director

162935 ✓

809
Company
Secretary

175036 ✓

Freq 1
Risk 1
Overall 1

Task
12M
Audit 6M

PROCESSID 7881
To compare Opera Live Orders to
Intrastats Back order Active List

810
Managing
Director # 157161 ✓

Freq 1
Risk 3
Overall 3

Task
12M

PROCESSID 7951
Check the Server space and Size of
important files

139

195288 ✓

1033
Managing
Director

189080 ✓

Freq 1
Risk 5
Overall 5

Task 1M
Audit 3M

Audits

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID **7892** To confirm the Prime functions of the Software used is verified.		821 Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M	

#
1 64800