

VOP			
Operating sub Process			
<u>Software Validation</u>			
Created:	22/10/17	VOP 27	Issue 1
Revised:	04 September 2018	Viamed Ltd ISO13485:2016: 4.1.6 , 7.5.6 , VST Ltd ISO9001:2015: 8.5.1	Page 1 of 5
<u>Viamed Ltd ISO13485:2016: 4.1.6</u>			

SCOPE

This procedure is established to describe the system used within the company for the control of Software Validation. It is used in conjunction with the individual sub procedures, which show the relevant information necessary.

RESPONSIBILITIES

It is the responsibility of the Managing Director, to ensure that the contents of this procedure, and related procedures, are adhered to.

PROCEDURE

Third party software used to maintain the QMS system shall be validated against its required outputs before it is used unless it has been certified for use with ISO 9001 ISO 13485 QMS systems.

All new Intrastats processes shall be validated against required inputs and outputs as of 04/09/2018.

Existing processes have been in use before the introduction of 9001:2015. and have been classed as validated through use.

Accounts package is externally Audited via Accountants to produce year end accounts.

Accounts are cross matched to Banks, and Vat returns Etc..

Backup Software

Rolling task : 454, to Compare Turnover screen of the Live Server and VMserver8, indicates the backup system has updated correctly.

Intrastats – Accounts package Imports,

Where data is imported a Rolling Task 459, Compares turnover from Opera report screen to intrastats report screen. As Intrastats works out the turnover via each individual credit / Invoice, and is compared to the Overall figure within Opera. The data import routines are regularly Validated.

Intrastats, general.

Depending on the severity of the operation several rolling tasks have been identified to validate functions of the intrastats system.

IT Controller

Process Scope	Brief Description	Responsibility/ Procedure/Tra ining	Task	Audit	Freq	Risk	Overall	Action
7850 Test the Goods out process disabling picking of items not relating to an order	Software Validation Scan In Correct Product	User Training	752 Goods Out	753 Goods In	3	2	6	Task 1M Audit 3M
7851 To test intrastats does not allow picking of unprocessed products to live customer orders	Software Validation Scan Un-QA Product To Order	User Training	754 Goods Out	755 Goods In	3	4	12	Task 1M Audit 3M
7852 To attempt to Scan a product that has gone past its expire date.	Software Validation Expired Stock	User Training	756 Goods Out	757 Goods In	3	2	6	Task 1M Audit 3M
7853 Warehouse shelves can be tagged as sellable stock / unsellable stock. Either for quarantine purposes or holding items for other customer orders.	Software Validation Non Sell Able Shelf	User Training	759 Goods Out	760 Goods In	3	3	9	Task 1M Audit 3M
Test that								

Order
picking
cannot pick
unsellable
stock
locations to
an Order

7854	Software	User Training	761	762	2	2	4	Task
Software	Validation In		Goods In	Managing				3M
Validation of	Production			Director				Audit
the	List							6M
production								
lists.								

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

7855	Software	User Training	761	762	2	2	4	Task
Software	Validation -		Goods In	Managing				3M
Validation -	Production			Director				Audit
Production	Lists							6M
Lists								

Review the
current active
production
lists
in intrastats to
the actual in
progress
production
lists

7856 To	Software	User Training	764	765	2	2	4	Task
check order	Validation		Office	Managing				3M
picking	Unchecked		Processes	Director				Audit
cannot pick	Orders							12M
against an								
unchecked								
order								

7857 To confirm Software Validation Stock Tracking Check, is functioning as expected	Software Validation Stock Tracking Check	User Training	763 Goods In		2	1	2	Task 6M
7858 Test the QA System that Staff not trained for QA are unable to QA a Product.	Software Validation Attempt To QA Some Stock	User Training	766 Office Processes		3	3	9	Task 1M
7861 Software Validating Of Training Documents via Forced Required Reading	Software Validation Of Training Documents Forced Reading	User Training	768 Managing Director		1	2	2	Task 12M
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.	Software Validation Conflicting Audits	User Training	779 Managing Director	781 Managing Director	1	1	1	Task 12M Audit 12M
7870 Scope to check the automatic system of tagging product non conformance and other issues to the post market surveillance	Software Validation Non Conformance Product Risk Feedback Loop	User Training	789 Managing Director		1	1	1	Task 12M

review
report.

7875 To test document control is working as intended.	Software Validation Document Control	User Training	802 Managing Director	803 Company Secretary	1	1	1	Task 3M Audit 12M
7880 To confirm the out of documents computer software functions as expected flagging out of date items on to the list	Software Validation Out Of Date Documents	User Training	808 Managing Director	809 Company Secretary	1	1	1	Task 3M Audit 6M
7881 To compare Oprea Live Orders to Intrastats Backorder Active List,	Software Validation - Live Orders	User Training	810 Managing Director		1	3	3	Task 12M