

VOP			
Operating sub Process			
<u>Software Validation</u>			
Created:	22/10/17	VOP 27	Issue 1
Revised:	25 October 2017	Viamed Ltd ISO13485:2016: 4.1.6	Page 1 of 5
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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

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 corectly.

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 Software		User Training	752	753	3	2	6	Task

Goods out process disabling picking of items not relating to an order	Validation Scan In Correct Product		Goods Out	Goods In				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. Test that Order picking cannot pick unsellable stock locations to an Order	Software Validation Non Sell Able Shelf	User Training	759 Goods Out	760 Goods In	3	3	9	Task 1M Audit 3M
7854 Software Validation of	Software Validation In Production	User Training	761 Goods In	762 Managing Director	2	2	4	Task 3M Audit

the production lists.	List							6M
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 Validation - Production Lists Review the current active production lists in intrastats to the actual in progress production lists	Software Validation - Production Lists	User Training	761 Goods In	762 Managing Director	2	2	4	Task 3M Audit 6M
7856 To check order picking cannot pick against an unchecked order	Software Validation Unchecked Orders	User Training	764 Office Processes	765 Managing Director	2	2	4	Task 3M Audit 12M
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 Software	Software	User Training	766		3	3	9	Task

QA System that Staff not trained for QA are unable to QA a Product.	Validation Attempt To QA Some Stock		Office Processes					1M
7861 Software Validating Of Training Documents via Forced Reading 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 review report.	Software Validation Non Conformance Product Risk Feedback Loop	User Training	789 Managing Director		1	1	1	Task 12M
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	Software Validation Out Of Date	User Training	808 Managing Director	809 Company Secretary	1	1	1	Task 3M Audit

documents computer software functions as expected flagging out of date items on to the list	Documents						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