

| VOP | | | |
|--|-----------------|---|----------------|
| Operating sub Process | | | |
| Software Validation | | | |
| Created: | 22/10/17 | VOP 27 | Issue 1 |
| Revised: | 28 October 2017 | Viamed Ltd ISO13485:2016: 4.1.6 , 7.5.6 , VST Ltd ISO9001:2015: 8.5.1 | Page 1 of 5 |
| Viamed Ltd ISO13485:2016: 4.1.6 | | | |

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 Task ining | Audit | Freq Risk Overall Action |
|----------------------|--------------------------|---|--------------|---------------------------------|
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|---|---|---------------|---------------|--------------|---|---|----|------------------|
| 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 | Software Validation In | User Training | 761 Goods In | 762 Managing | 2 | 2 | 4 | Task 3M |

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|--|--|---------------|----------------------|-----------------------|---|---|---|--|-------------------|
| Validation of the production lists. | Production List | | | Director | | | | | 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 | | | | | | | | | |
| 7855 Software Validation - Production Lists Review the current active production lists inintrastats 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 |

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|------|---|--|---------------|-------------------|-------------------|---|---|---|--------------------|
| 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 | | 3 | 3 | 9 | Task 1M |
| | | | | Office Processes | | | | | |
| 7861 | Software Validating Of Training Documents via Forced Reading Required Reading | Software Validation Of Training Documents Forced Reading | User Training | 768 | | 1 | 2 | 2 | Task 12M |
| | | | | Managing Director | | | | | |
| 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 | 781 | 1 | 1 | 1 | Task 12M Audit 12M |
| | | | | Managing Director | Managing Director | | | | |
| 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 | | 1 | 1 | 1 | Task 12M |
| | | | | Managing Director | | | | | |
| 7875 | To test document control is working as intended. | Software Validation Document Control | User Training | 802 | 803 | 1 | 1 | 1 | Task 3M Audit 12M |
| | | | | Managing Director | Company Secretary | | | | |
| 7880 | To confirm the | Software Validation | User Training | 808 | 809 | 1 | 1 | 1 | Task 3M |
| | | | | Managing Company | | | | | |

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|--|-----------------------------------|---------------|-----------------------|-----------|---|---|---|----------|
| out of documents computer software functions as expected flagging out of date items on to the list | Out Of Date Documents | | Director | Secretary | | | | 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 |