

| Internal Audit Check list |                           |             |
|---------------------------|---------------------------|-------------|
| Software Validation       |                           | Page 1 of 1 |
| Oct 2017                  | Audit No 27               |             |
| Oct 2017                  | Auditor <i>Helen Lamb</i> |             |
| <i>2-18</i>               |                           |             |

Auditor  
Comments /  
Issues

Company / ISO Section      Criteria of ISO Section

- VST Ltd ISO9001:2015 5.1.2 **Customer focus**  
 5.1.2 Customer focus  
 Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that:  
 a) customer and applicable statutory and regulatory requirements are determined, understood and consistently met;  
 b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;  
 c) the focus on enhancing customer satisfaction is maintained.
- VST Ltd ISO9001:2015 8.2.2 **Determining the requirements for products and services**  
 When determining the requirements for the products and services to be offered to customers, the organization shall ensure that:  
 a) the requirements for the products and services are defined, including:  
 1) any applicable statutory and regulatory requirements;  
 2) those considered necessary by the organization;  
 b) the organization can meet the claims for the products and services it offers.
- Viamed Ltd ISO13485:2016 5.2 **Customer focus**  
 Top management shall ensure that customer requirements and applicable regulatory requirements are determined and met.
- Viamed Ltd ISO13485:2016 7.2.1 **Determination of requirements related to product**  
 The organization shall determine:  
 a) requirements specified by the customer, including the requirements for delivery and postdelivery activities;  
 b) requirements not stated by the customer but necessary for specified or intended use, as known;  
 c) applicable regulatory requirements related to the product;  
 d) any user training needed to ensure specified performance and safe use of the medical device;  
 e) any additional requirements determined by the organization
- Viamed Ltd ISO13485:2016 7.2.3 **Communication**  
 The organization shall plan and document arrangements for communicating with customers in relation to:  
 a) product information;  
 b) enquiries, contracts or order handling, including amendments;

*Not needed*  
*416 needs*  
*adela's*  
*DL updating*  
*audit*  
*2-3-18*



| Internal Audit Check list |             |             |             |
|---------------------------|-------------|-------------|-------------|
| Software Validation       |             |             |             |
| Created:                  | 19 Oct 2017 | Audit No 27 | Page 1 of 1 |
| Revised:                  | 26 Oct 2017 |             |             |
| Audit Date                |             | Auditor     |             |

- c) customer feedback, including complaints;  
d) advisory notices.  
The organization shall communicate with regulatory authorities in accordance with applicable regulatory requirements.

### 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<br>Keeps a month or so backup emails   | 368<br>Managing Director | 417<br>Company Secretary | Freq 4<br>Risk 1<br>Overall      | Task<br>2W<br>Audit       |                |
| PROCESSID 7850<br>Test the Goods out process disabling picking of items not relating to an order            | 752<br>Goods Out         | 753<br>Goods In          | 4<br>Freq 3<br>Risk 2<br>Overall | 3M<br>Task<br>1M<br>Audit |                |
| PROCESSID 7851<br>To test intrastats does not allow picking of unprocessed products to live customer orders | 754<br>Goods Out         | 755<br>Goods In          | 6<br>Freq 3<br>Risk 4<br>Overall | 3M<br>Task<br>1M<br>Audit |                |
| PROCESSID 7852<br>To attempt to Scan a product that has gone past its expire date.                          | 756<br>Goods Out         | 757<br>Goods In          | 3<br>Freq 3<br>Risk 2<br>Overall | Task<br>1M<br>Audit       |                |
| PROCESSID 7853<br>Warehouse shelves can be tagged as sellable   | 759<br>Goods Out         | 760<br>Goods In          | 3<br>Freq 3<br>Risk 3<br>Overall | Task<br>1M<br>Audit       |                |

not done?  
Chased.  
within limits  
in 20/2/18



| Internal Audit Check list |             |             |             |
|---------------------------|-------------|-------------|-------------|
| Software Validation       |             |             |             |
| Created:                  | 19 Oct 2017 | Audit No 27 | Page 1 of 1 |
| Revised:                  | 26 Oct 2017 |             |             |
| Audit Date                |             | Auditor     |             |

9 3M

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  
PROCESSID 7854  
Software Validation of the production lists.

111246 761 Goods In 762 Managing Director Freq 2 Task Risk 2 3M Overall Audit 4 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  
Software Validation - Production Lists

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

PROCESSID 7856  
To check order picking cannot pick against an unchecked order

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

PROCESSID 7858  
Test the QA System that Staff not trained for QA are unable to QA a Product.

111246 761 Goods In 762 Managing Director Freq 2 Task Risk 2 3M Overall Audit 4 6M

111247 764 Office Processes 765 Managing Director Freq 2 Task Risk 2 3M Overall Audit 4 12M

104851 763 Goods In Freq 2 Task Risk 1 6M Overall 2

109516 766 Office Processes Freq 3 Task Risk 3 1M Overall 9



| Internal Audit Check list |             |             |             |
|---------------------------|-------------|-------------|-------------|
| Software Validation       |             |             |             |
| Created:                  | 19 Oct 2017 | Audit No 27 | Page 1 of 1 |
| Revised:                  | 26 Oct 2017 |             |             |
| Audit Date                |             | Auditor     |             |

|                          |          |        |           |        |               |
|--------------------------|----------|--------|-----------|--------|---------------|
| PROCESSID 7861           | 768      | 106495 |           |        | Freq 1 Task   |
| Software Validating      | Managing |        |           |        | Risk 2 12M    |
| Of Training              | Director |        |           |        | Overall       |
| Documents via Forced     |          |        |           |        | 2             |
| Required Reading         |          |        |           |        |               |
| PROCESSID 7865           | 779      | 104853 | 781       | 105497 | Freq 1 Task   |
| Software Validation      | Managing |        | Managing  |        | Risk 1 12M    |
| of the system:           | Director |        | Director  |        | Overall Audit |
| To check all             |          |        |           |        | 1 12M         |
| process(s) tasks and     |          |        |           |        |               |
| audits are not clashed   |          |        |           |        |               |
| with the same person     |          |        |           |        |               |
| doing the Task as the    |          |        |           |        |               |
| Audit.                   |          |        |           |        |               |
| PROCESSID 7870           | 789      | 105498 |           |        | Freq 1 Task   |
| Scope to check the       | Managing |        |           |        | Risk 1 12M    |
| automatic system of      | Director |        |           |        | Overall       |
| tagging product non      |          |        |           |        | 1             |
| conformance and          |          |        |           |        |               |
| other issues to the post |          |        |           |        |               |
| market surveillance      |          |        |           |        |               |
| review report.           |          |        |           |        |               |
| PROCESSID 7875           | 802      | 112844 | 803       | 107036 | Freq 1 Task   |
| To test document         | Managing |        | Company   |        | Risk 1 3M     |
| control is working as    | Director |        | Secretary |        | Overall Audit |
| intended.                |          |        |           |        | 1 12M         |
| PROCESSID 7879           | 808      | 112847 | 809       | 106456 | 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.                |          |        |           |        |               |
| To also Check the Out    |          |        |           |        |               |
| of Date documents is     |          |        |           |        |               |
| working as Intended.     |          |        |           |        |               |
| PROCESSID 7880           | 808      | 112847 | 809       | 106456 | 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    |          |        |           |        |               |
| of date items on to the  |          |        |           |        |               |
| list                     |          |        |           |        |               |
| PROCESSID 7881           | 810      | 106249 |           |        | Freq 1 Task   |
| To compare Oprea         | Managing |        |           |        | Risk 3 12M    |
| Live Orders to           | Director |        |           |        | Overall       |
| Intrastats Backorder     |          |        |           |        | 3             |



| Internal Audit Check list |             |             |             |
|---------------------------|-------------|-------------|-------------|
| Software Validation       |             |             |             |
| Created:                  | 19 Oct 2017 | Audit No 27 |             |
| Revised:                  | 26 Oct 2017 |             | Page 1 of 1 |
| Audit Date                |             | Auditor     |             |

Active List,