

Internal Audit Check List

Software Validation

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Oct 2017

Audit No 27

Oct 2017

2-18

Auditor

Helen Lamb

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.

*Not needed
G16 needs
DC updating*

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.

*Audit
2-3-18*

Viamed
Ltd
ISO13485
:2016

Customer focus

Top management shall ensure that customer requirements and applicable regulatory requirements are determined and met.

Viamed
Ltd
ISO13485
:2016

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

Communication

The organization shall plan and document arrangements for communicating with customers in relation to:

7.2.3

a) product information;

b) enquiries, contracts or order handling, including amendments;

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- 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 Keeps a month or so backup emails	368 Managing Director	417 11890 Company Secretary	4	Freq 4 Risk 1 Overall Audit	Task 2W 3M
PROCESSID 7850 Test the Goods out process disabling picking of items not relating to an order	752 107512 Goods Out	753 113615 Goods In	6	Freq 3 Risk 2 Overall Audit	Task 1M 3M
PROCESSID 7851 To test intrastats does not allow picking of unprocessed products to live customer orders	754 104026 Goods Out	755 113591 Goods In	12	Freq 3 Risk 4 Overall Audit	Task 1M 3M
PROCESSID 7852 To attempt to Scan a product that has gone past its expire date.	756 101028 Goods Out	757 113592 Goods In		Freq 3 Risk 2 Overall Audit	Task 1M 3M
PROCESSID 7853 Warehouse shelves can be tagged as sellable	759 113594 Goods Out	760 113595 Goods In		Freq 3 Risk 3 Overall Audit	closed Task 1M 3M not done? chased- within limits in 20/218

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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

111246
 761 Goods In

762 Managing Director

Freq 2 Task
 Risk 2 3M
 Overall Audit
 4 6M

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

111247
 764 Office Processes

765 Managing Director

Freq 2 Task
 Risk 2 3M
 Overall Audit
 4 12M

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

104851
 763 Goods In

Freq 2 Task
 Risk 1 6M
 Overall
 2

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

109516
 766 Office Processes

Freq 3 Task
 Risk 3 1M
 Overall
 9

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PROCESSID 7861 Software Validating Of Training Documents via Forced Required Reading	768 Managing Director	106495 106853	Freq 1 Task Risk 2 12M Overall 2
PROCESSID 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.	779 Managing Director	781 Managing Director	105497 Freq 1 Task Risk 1 12M Overall Audit 1 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	105498 112844	Freq 1 Task Risk 1 12M Overall 1
PROCESSID 7875 To test document control is working as intended.	802 Managing Director	803 Company Secretary	107036 Freq 1 Task Risk 1 3M Overall Audit 1 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	809 Company Secretary	106456 112847 Freq 1 Task Risk 4 3M Overall Audit 4 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	809 Company Secretary	106456 112847 Freq 1 Task Risk 1 3M Overall Audit 1 6M
PROCESSID 7881 To compare Oprea Live Orders to Intrastats Backorder	810 Managing Director	106249 112847	Freq 1 Task Risk 3 12M Overall 3

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Active List,