Internal Audit Check list

Software Validation

Created:	19 Oct 2017	**Audit No 27**	
Revised:	26 Oct 2017		Page 1 of 1
Audit Date		Auditor	

Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
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;	

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 Company Secretary	Freq 4 Risk 1 Overall 4	Task 2W Audit 3M	
PROCESSID **7850** Test the Goods out process disabling picking of items not relating to an order	752 Goods Out	753 Goods In	Freq 3 Risk 2 Overall 6	Task 1M Audit 3M	
PROCESSID **7851** To test intrastats does not allow picking of unprocessed products to live customer orders	754 Goods Out	755 Goods In	Freq 3 Risk 4 Overall 12	Task 1M Audit 3M	
PROCESSID **7852** To attempt to Scan a product that has gone past its expire date.	756 Goods Out	757 Goods In	Freq 3 Risk 2 Overall 6	Task 1M Audit 3M	
PROCESSID **7853** Warehouse shelfs can be tagged as sellable	759 Goods Out	760 Goods In	Freq 3 Risk 3 Overall	Task 1M Audit	

stock / unsellable stock. Either for quarantine purposes or holding items for other customer orders.

9   3M

Test that Order picking cannot pick unsellable stock locations to an Order

Process	Dept	Role	Metrics	Task
PROCESSID **7854** Software Validation of the 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	761 Goods In	762 Managing Director	Freq 2 Risk 2 Overall 4	Task 3M Audit 6M
PROCESSID **7855** Software Validation - Production Lists Review the current active production lists inintrastats to the actual in progress production lists	761 Goods In	762 Managing Director	Freq 2 Risk 2 Overall 4	Task 3M Audit 6M
PROCESSID **7856** To check order picking cannot pick against an unchecked order	764 Office Processes	765 Managing Director	Freq 2 Risk 2 Overall 4	Task 3M Audit 12M
PROCESSID **7857** To confirm Software Validation Stock Tracking Check, is functioning as expected	763 Goods In		Freq 2 Risk 1 Overall 2	Task 6M
PROCESSID **7858** Test the QA System that Staff not trained for QA are unable to QA a Product.	766 Office Processes		Freq 3 Risk 3 Overall 9	Task 1M

PROCESSID **7861** Software Validating Of Training Documents via Forced Required Reading	768 Managing Director		Freq 1 Risk 2 Overall 2	Task 12M
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	Freq 1 Risk 1 Overall 1	Task 12M Audit 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		Freq 1 Risk 1 Overall 1	Task 12M
PROCESSID **7875** To test document control is working as intended.	802 Managing Director	803 Company Secretary	Freq 1 Risk 1 Overall 1	Task 3M Audit 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	Freq 1 Risk 4 Overall 4	Task 3M Audit 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	Freq 1 Risk 1 Overall 1	Task 3M Audit 6M
PROCESSID **7881** To compare Oprea Live Orders to Intrastats Backorder	810 Managing Director		Freq 1 Risk 3 Overall 3	Task 12M

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Active List,