Internal Audit Check list

Software Validation

Created	19 Oct 2017	**Audit No 27**	
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Audit Date	8-2-24	Auditor _Helen lamb_	

Viamed and VST

Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
Viamed Ltd ISO13485:2016 4.1.6	**Quality management system** For each quality management system process, the organization shall: The organization shall document procedures for the validation of the application of computer software used in the quality management system. Such software applications shall be validated prior to initial use and, as appropriate, after changes to such software or its application. The specific approach and activities associated with software validation and revalidation shall be proportionate to the risk associated with the use of the software. Records of such activities shall be maintained (see 4.2.5).	

	QUESTION:	**RESPONSE:**	**Y/N**
1	Review Last years Audit. Update processes if required. Are all follow on Issue resolved satisfactory.	Nothing outstanding	Y

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	Referenced in Document
PROCESSID 52 Keeps a month or so backup emails	368	417	Freq 2 Risk 1 Overall 2		
PROCESSID 7850	752	753	Freq 1	Task 9M	

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Test the Goods out process disabling picking of items not relating to an order	Goods Out	Managing Director	Risk 1 Overall 1	Audit 12M
PROCESSID 7851 To test intrastats does not allow picking of unprocessed products to live customer orders	754 Goods Out 314863 ✓	755 Managing Director 319323 ✓	Freq 1 Risk 1 Overall 1	Task 6M Audit 12M
PROCESSID 7852 To attempt to Scan a product that has gone past its expire date.	756 Goods Out 309206 ✓	757 Managing Director 20 258420 ✓	Freq 1 Risk 1 Overall 1	Task 12M Audit 12M
PROCESSID 7853 Warehouse shelfs 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	759 Goods Out 305449 ✓	760 Managing Director 314082 ✓	Freq 1 Risk 3 Overall 3	Task 12M Audit 12M
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 316374 ✓	762 Managing Director 311158 ✓	Freq 2 Risk 2 Overall 4	Task 3M Audit 6M
PROCESSID 7855 Software Validation - Production Lists Review the current active production lists in intrastats to the actual in progress production lists	761 Goods In 316374 ✓	762 Managing Director 311158 ✓	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 316375 in terms	765 Managing Director 314083 ✓	Freq 2 Risk 2 Overall 4	Task 12M Audit 12M
PROCESSID 7857 To confirm Software Validation Stock Tracking Check, is functioning as expected	763 Goods In 308784 ✓	1155 Managing Director 288288 ✓	Freq 2 Risk 1 Overall 2	Task 6M Audit 12M
PROCESSID 7858 Test the QA System that Staff not	766 Office Processes 313935 ✓	1175 Managing 286154 ✓	Freq 1 Risk 3	Task 6M Audit

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trained for QA are unable to QA a Product.		Director	Overall 3	12M
PROCESSID **7861** Software Validating Of Training Documents via Forced Required Reading	768 Managing Director *308423* ✓		Freq 1 Risk 2 Overall 2	Task 12M
PROCESSID **7865** Software Validiation 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 *308786* ✓	781 Managing Director *309454*	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 ✓ *309455*		Freq 1 Risk 1 Overall 1	Task 12M
PROCESSID **7875** To test document control is working as intended.	802 Managing Director *310085* ✓	803 Company Secretary ✓ *311161*	Freq 1 Risk 1 Overall 1	Task 12M 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 *318298* ✓	809 Company Secretary *310518* ✓	Freq 1 Risk 1 Overall 1	Task 12M 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 *318298* ✓	809 Company Secretary *3105* ✓	Freq 1 Risk 1 Overall 1	Task 12M Audit 6M
PROCESSID **7881** To compare Opera Live Orders to Intrastats Back order Active List NO LONGER REQUIRED Opera is now out of the system	810	*316386* ✓	Freq 1 Risk 1 Overall 1	
PROCESSID **7951** Check the Server space and Size of important files	139 *in terms* Office Processes *319648*	1033 Managing Director	Freq 1 Risk 2 Overall 2	Task 1M Audit 3M
PROCESSID **8013** Ensure Email system working as intended	1179 Marketing Processes *311375* ✓	1180 Managing Director *288128* ✓	Freq 1 Risk 1 Overall 1	Task 6M Audit 12M

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Audits

Process Scope	Roll Task	Roll Audit	Risk	Action	Referenced in Document
PROCESSID **7892** To confirm the Prime functions of the Software used is verified.		821 Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M	

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This Audit
Viewed + VST