Vlamed VST

Internal Audit Check list			
MANAGEMENT REVIEW			
Created:	17/May 1995	**Audit No 18**	
Revised:	25 October 2021	Last printed 25/10/2021 10:10:31 AM	Page 1 of 11
Audit Date	26/10/21	Auditor Helen Camb	

SCOPE

Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
VST Ltd ISO9001:2015 10.3	**Continual improvement** The organization shall continually improve the suitability, adequacy and effectiveness of the quality management system. The organization shall consider the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities that shall be addressed as part of continual improvement.	Renews Intrastats
VST Ltd ISO9001:2015 4.1	**Understanding the organization and its context** The organization shall determine external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system. The organization shall monitor and review information about these external and internal issues. NOTE 1 Issues can include positive and negative factors or conditions for consideration. NOTE 2 Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, market, cultural, social and economic environments, whether international, national, regional or local. NOTE 3 Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge and performance of the organization.	Issues feedback. Doc index
VST Ltd ISO9001:2015 4.2	**Understanding the needs and expectations of interested parties** Due to their effect or potential effect on the organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, the organization shall determine: a) the interested parties that are relevant to the quality management system; b) the requirements of these interested parties that are relevant to the quality management system. The organization shall monitor and review information about these interested parties and their relevant requirements.	Reviews Quality system
VST Ltd ISO9001:2015 4.3	**Determining the scope of the quality management system** The organization shall determine the boundaries and applicability of the quality management system to establish its scope. When determining this scope, the organization shall consider: a) the external and internal issues referred to in 4.1; b) the requirements of relevant interested parties referred to in 4.2; c) the products and services of the organization. The organization shall apply all the requirements of this International Standard if they are applicable within the determined scope of its	Management Review Intrastats

	quality management system. The scope of the organization's quality management system shall be available and be maintained as documented information. The scope shall state the types of products and services covered, and provide justification for any requirement of this International Standard that the organization determines is not applicable to the scope of its quality management system. Conformity to this International Standard may only be claimed if the requirements determined as not being applicable do not affect the organization's ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction.	
VST Ltd ISO9001:2015 5.1.1	**General** Top management shall demonstrate leadership and commitment with respect to the quality management system by: a) taking accountability for the effectiveness of the quality management system; b) ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of the organization; c) ensuring the integration of the quality management system requirements into the organization's business processes; d) promoting the use of the process approach and risk-based thinking; e) ensuring that the resources needed for the quality management system are available; f) communicating the importance of effective quality management and of conforming to the quality management system requirements; g) ensuring that the quality management system achieves its intended results; h) engaging, directing and supporting persons to contribute to the effectiveness of the quality management system; i) promoting improvement; j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility. NOTE Reference to "business" in this International Standard can be interpreted broadly to mean those activities that are core to the purposes of the organization's existence, whether the organization is public, private, for profit or not for profit.	management review Intrastats Doc index Issues Rdes + tasks
VST Ltd ISO9001:2015 6.1	When planning for the quality management system, the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to: a) give assurance that the quality management system can achieve its intended result(s); b) enhance desirable effects; c) prevent, or reduce, undesired effects; d) achieve improvement.	Reviews issues
VST Ltd ISO9001:2015		

6.1.2	The organization shall plan: a) actions to address these risks and opportunities; b) how to: 1) integrate and implement the actions into its quality management system processes (see 4.4); 2) evaluate the effectiveness of these actions. Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services. NOTE 1 Options to address risks can include avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision. NOTE 2 Opportunities can lead to the adoption of new practices, launching new products, opening new markets, addressing new customers, building partnerships, using new technology and other desirable and viable possibilities to address the organization's or its customers' needs.	Issues Intrastats Reviews
VST Ltd ISO9001:2015 7.1.1 General	**General** The organization shall determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system. The organization shall consider: a) the capabilities of, and constraints on, existing internal resources; b) what needs to be obtained from external providers.	Issues reviews
VST Ltd ISO9001:2015 9.2.2	The organization shall: a) plan, establish, implement and maintain an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits; b) define the audit criteria and scope for each audit; c) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process; d) ensure that the results of the audits are reported to relevant management; e) take appropriate correction and corrective actions without undue delay; f) retain documented information as evidence of the implementation of the audit programme and the audit results. NOTE See ISO 19011 for guidance.	Audit Calendar Tasks + mini Audits
VST Ltd ISO9001:2015 9.3.2	**Management review inputs** 9.3.2 Management review inputs The management review shall be planned and carried out taking into consideration: a) the status of actions from previous management reviews; b) changes in external and internal issues that are relevant to the quality management system; c) information on the performance and effectiveness of the quality management system, including trends in:	Management review Intrastats

Internal Audit Check list

MANAGEMENT REVIEW

Created:	17/May 1995	**Audit No 18**	
Revised:	25 October 2021	Last printed 25/10/2021 10:10:31 AM	Page 4 of 11
Audit Date		Auditor	

	1) customer satisfaction and feedback from relevant interested parties; 2) the extent to which quality objectives have been met; 3) process performance and conformity of products and services; 4) nonconformities and corrective actions; 5) monitoring and measurement results; 6) audit results; 7) the performance of external providers; d) the adequacy of resources; e) the effectiveness of actions taken to address risks and opportunities (see 6.1); f) opportunities for improvement.	
VST Ltd ISO9001:2015 9.3.3	**Management review outputs** The outputs of the management review shall include decisions and actions related to: a) opportunities for improvement; b) any need for changes to the quality management system; c) resource needs. The organization shall retain documented information as evidence of the results of management reviews.	Issues Reports
Viamed Ltd ISO13485:2016 4.1.1	**Quality management system** The organization shall document a quality management system and maintain its effectiveness in accordance with the requirements of this International Standard and applicable regulatory requirements. The organization shall establish, implement and maintain any requirement, procedure, activity or arrangement required to be documented by this International Standard or applicable regulatory requirements. The organization shall document the role(s) undertaken by the organization under the applicable regulatory requirements. NOTE Roles undertaken by the organization can include manufacturer, authorized representative, importer or distributor.	Roles + Responsibilities Reviews
Viamed Ltd ISO13485:2016 4.1.3	**Quality management system** For each quality management system process, the organization shall: a) determine criteria and methods needed to ensure that both the operation and control of these processes are effective; b) ensure the availability of resources and information necessary to support the operation and monitoring of these processes; c) implement actions necessary to achieve planned results and maintain the effectiveness of these processes; d) monitor, measure as appropriate, and analyse these processes; e) establish and maintain records needed to demonstrate conformance to this International Standard and compliance with applicable regulatory requirements (see 4.2.5).	Reviews Issues Intrastats.
Viamed Ltd ISO13485:2016 4.1.4	**Quality management system** For each quality management system process, the organization shall: The organization shall manage these quality management system processes in accordance with the requirements of this International Standard and applicable regulatory requirements. Changes to be made to these processes shall be:	Route map Intrastats Doc index

	a) evaluated for their impact on the quality management system; b) evaluated for their impact on the medical devices produced under this quality management system. c) controlled in accordance with the requirements of this International Standard and applicable regulatory requirements.	
Viamed Ltd ISO13485:2016 5.1	**Management commitment** Top management shall provide evidence of its commitment to the development and implementation of the quality management system and maintenance of its effectiveness by: a) communicating to the organization the importance of meeting customer as well as applicable regulatory requirements; b) establishing the quality policy; c) ensuring that quality objectives are established; d) conducting management reviews; e) ensuring the availability of resources.	Issues Doc index Reviews
Viamed Ltd ISO13485:2016 5.3	**Quality policy** Top management shall ensure that the quality policy: a) is applicable to the purpose of the organization; b) includes a commitment to comply with requirements and to maintain the effectiveness of the quality management system; c) provides a framework for establishing and reviewing quality objectives; d) is communicated and understood within the organization; e) is reviewed for continuing suitability.	issues Doc index Intrastats
Viamed Ltd ISO13485:2016 5.6.1	**General** The organization shall document procedures for management review. Top management shall review the organization's quality management system at documented planned intervals to ensure its continuing suitability, adequacy, and effectiveness. The review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives. Records from management reviews shall be maintained.	Management Review Intrastats
Viamed Ltd ISO13485:2016 5.6.2 Review input	**General** The input to management review shall include, but is not limited to, information arising from: a) feedback; b) complaint handling; c) reporting to regulatory authorities; d) audits; e) monitoring and measurement of processes; f) monitoring and measurement of product; g) corrective action; h) preventive action; i) follow-up actions from previous management reviews; j) changes that could affect the quality management system; k) recommendations for improvement; l) applicable new or revised regulatory requirements.	Intrastats Management Review agenda
Viamed Ltd	**Review output**	

ISO13485:2016 5.6.3	The output from management review shall be recorded (see 4.2.5) and include the input reviewed and any decisions and actions related to: a) improvement needed to maintain the suitability, adequacy, and effectiveness of the quality management system and its processes; b) improvement of product related to customer requirements; c) changes needed to respond to applicable new or revised regulatory requirements; d) resource needs.	
Viamed Ltd ISO13485:2016 8.2.4	**Internal audit** The organization shall conduct internal audits at planned intervals to determine whether the quality management system: a) conforms to planned and documented arrangements, requirements of this International Standard, quality management system requirements esablished by the organization, and applicable regulatory requirements; b) is effectively implemented and maintained. The organization shall document a procedure to describe the responsibilities and requirements for planning and conducting audits and recording and reporting audit results. An audit program shall be planned, taking into consideration the status and importance of the processes and area to be audited, as well as the results of previous audits. The audit criteria, scope, interval and methods shall be defined and recorded (see 4.2.5). The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work. Records of the audits and their results, including identification of the processes and areas audited and the conclusions, shall be maintained (see 4.2.5). The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected nonconformities and their causes. Follow-up activities shall include the verification of the actions taken and the reporting of verification results. NOTE Further information can be found in ISO 19011.	Doc index Intrastats tasks + mini Audits.
Viamed Ltd ISO13485:2016 8.5.1	**General** The organization shall identify and implement any changes necessary to ensure and maintain the continued suitability, adequacy and effectiveness of the quality management system as well as medical device safety and performance through the use of the quality policy, quality objectives, audit results, postmarket surveillance, analysis of data, corrective actions, preventive actions and management review.	Issues + Reviews

Internal Audit Check list

MANAGEMENT REVIEW

Created:	17/May 1995	**Audit No 18**	
Revised:	25 October 2021	Last printed 25/10/2021 10:10:31 AM	Page 7 of 11
Audit Date		Auditor	

	Question	Response	Y/N
1	Review Last years Audit. Update processes if required. Are all follow on Issue resolved satisfactory.	All complete Nothing outstanding	Y
2	Check the Review is carried out in a timely manner. Task 746 Meeting Minutes should be attached to latest Issue. *New task 1094*	#234280 ✱¹ both companies	Y
3	Verify that all relevant persons were present. See minutes at the bottom.	all present	Y
4	Check that the review was carried out to the preset agenda. As per VOP 13.	yes checked all covered	Y
5	Is this agenda adequate? Look at any other business, do any other sections need to be added? List and issue any needed.	all agreed agenda is good.	Y
6	Check that an action plan is generated from the review. Check Section – Recommendations or improvement, and if there any further linked issues to the primary issue.	These are Issues sent from Review ✱	Y
7	Check that actions are completed in a timely manner.	Carried out today, last years yes	Y
8	Are minutes retained from the review? Are the minutes attached to the issue		Y
9	Can these minutes be accessed readily?		Y

2✱ should we have issue to link Reports two specifically per meeting # 240067

✱1 this should be split in to Vlamed + VST seperately. # 240068

Internal Audit Check list

MANAGEMENT REVIEW

Created:	17/May 1995	**Audit No 18**	
Revised:	25 October 2021	Last printed 25/10/2021 10:10:31 AM	Page 8 of 11
Audit Date		Auditor	

Sub Processes Linked to Audit 18

Review the below processes tasks and audits and ensure they are completed in a timely manner.

List Processes Per Title

Share Holder

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID **7834** The review the Financial requirements	733 Managing Director *23 B06*	769 Company Secretary *257661*	Freq 1 Risk 1 Overall	Task 1M Audit 3M	

Managing Director

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID **22** Ensure the company policys are still current and upto date	300 Managing Director *233452*	1063	Freq 1 Risk 1 Overall 1	Task 12M	
PROCESSID **23** Ensure the company Objects are still current and upto date	300 Managing Director *233452*		Freq 1 Risk 1 Overall 1	Task 12M	
PROCESSID **26** Overview of the Company using various data Reporting Screens	114 Managing Director *23782*		Freq 3 Risk 1 Overall 3	Task 1M	
PROCESSID **27** To review and close all automatic rolling Issues. Including all rolling tasks and audits	290 Managing Director *235429*	775 Company Secretary *2390024*	Freq 4 Risk 1 Overall	Task 1W Audit 6M	
PROCESSID **32** Complete the CMDCAS Paperwork once per year to Keep the Licence to sell in canada NO LONGER KEEP THIS CERTIFICATE	49 Managing Director *235613*		Freq 1 Risk 0 Overall	Task 12M	
PROCESSID **55** Business Continuity Plan	266 Managing Director *215840*		Freq 1 Risk 1 Overall 1	Task 12M	
PROCESSID **6861** Non Minuted Management discussions on issues	456 Managing Director *235696* *in terms*		Freq 4 Risk 1 Overall	Task 1W	

Internal Audit Check list

MANAGEMENT REVIEW

Created:	17/May 1995	**Audit No 18**	
Revised:	25 October 2021	Last printed 25/10/2021 10:10:31 AM	Page 9 of 11
Audit Date		Auditor	

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
			4		
PROCESSID 7070 To discuss any problems, to assess work load and staffing. To review issues.	83 Managing Director _230778_ ✓		Freq 2 Risk 1 Overall 2	Task 3M	
PROCESSID 7874 To Ensure we have the latest version of Med Dev 2.12. and update management if its been updated	128 Managing _238295_ ✓ Director		Freq 1 Risk 1 Overall 1	Task 12M	
PROCESSID 7876 To review Route map VIAMED 13485:2016 and VST 9001:2015 See if a new Summary sheet needs producing, print new PDF, and upload on top of the old summary	804 Managing Director _239753_ ×	805 Company Secretary _239010_ ✓ _w terms_	Freq 2 Risk 1 Overall 2	Task 1W Audit 1M	
PROCESSID 7877 To Plan for disaster	806 Managing Director _239460_ ✓		Freq 1 Risk 4 Overall 4	Task 12M	
PROCESSID 7878 Review possible legal / regulator changes that might affect Viamed / VST	807 Managing Director _239599_ ✓		Freq 3 Risk 3 Overall 9	Task 3M	
PROCESSID 7890 To get the next years UPS zone and areas and Pricing Import into intrastats, No formal procedure as UPS keep changing style and layout, can be done manually	42 Managing Director _208545_ ✓	1070 Company Secretary _212348_ ✓	Freq 2 Risk 1 Overall	Task 12M Audit 12M	
PROCESSID 7895 To coninue our FDA registration (for the Apgar timer)	825 Managing Director _203288_ ✓		Freq 1 Risk 1 Overall 1	Task 12M	

IT Controller

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID 6813 Ensure the turnover report is accurate	459 Managing Director _238565_ ✓	460 Company Secretary _224688_ ✓	Freq 3 Risk 1 Overall 12M	Task 1M Audit 12M	
PROCESSID 7918 To backup Jeans files	923 Company Secretary _238164_ ✓		Freq 1 Risk 1 Overall 1	Task 1M	

Internal Audit Check list	
MANAGEMENT REVIEW	

Created:	17/May 1995	**Audit No 18**	
Revised:	25 October 2021	Last printed 25/10/2021 10:10:31 AM	Page 10 of 11
Audit Date		Auditor	

ISO Controller

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID 29 Annual license check, ensure no changes to Products licenced through CMDCAS, and Issue CMDCAS a statement that No changes have occured. 235613 ✓ Certificate will go out of date 1st November, Check Canadian Gazette for Latest Version of the MDR	49 Managing Director		Freq 1 Risk 3 Overall 3	Task 12M	
PROCESSID 5889 To Review the Rolling Tasks and Mini Audits, Look for High number outstanding tasks and audits. Locate the reason for High number outstanding tasks and audits. Decide on course of action to reduce / redistribute the tasks and audits	290 Managing Director 239429 ✓		Freq 4 Risk 1 Overall 4	Task 1W	
PROCESSID 6871 Not yet Applied Rolling Issue to see if we should apply this standard in the future	748 Managing Director 236903 ✓		Freq 1 Risk 1 Overall 1	Task 12M	
PROCESSID 7744 FDA registration and the CMDCAS products In order to sell in the USA / Canada Markets products need to be registered with the FDA.	565 Managing Director 237054 ✓		Freq 1 Risk 1 Overall 1	Task 12M	
PROCESSID 7833 To Remind Staff of the Importance of the ISO systems and they should be following the procedures	732 Managing Director 237419 ✓		Freq 2 Risk 1 Overall 2	Task 6M	
PROCESSID 7888 Ensure All Sub Processes are linked to a VOP and an Audit.	818 Managing Director 239699 ✓	819 Company Secretary 206912 ✓	Freq 3 Risk 1 Overall 3	Task 1M Audit 12M	
PROCESSID 7895 To conitune our FDA registration (for the Apgar timer)	825 Managing Director 203288 ✓		Freq 1 Risk 1 Overall 1	Task 12M	

Warehouse Team Leader

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID 7753 To discuss any problems, to assess work load and staffing. To review issues with regard the Warehouse.	589 Managing Director 235578 ✓ Over-due #235791	590 Company Secretary 230682 ✓	Freq 3 Risk 1 Overall	Task 1M Audit 3M	

Internal Audit Check list

MANAGEMENT REVIEW

Created:	17/May 1995	**Audit No 18**	
Revised:	25 October 2021	Last printed 25/10/2021 10:10:31 AM	Page 11 of 11
Audit Date		Auditor	

3

Audits

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID **7886** To carry out Audit 18 Management Review Viamed		21 Company Secretary	Freq 1 Risk 2 Overall	Audit 12M	
		238938 X2 in terms this Audit			
PROCESSID **7887** To carry out Audit 18 Management Review VST		188 Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M	
		238807X This Audit			

Data Protection Officer

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID **7912** Review The Personel Information We Collect Or Store, is the personal information that we collect and store - relevant, accurate and not excessive.	912 Company Secretary *238219 ✓*		Freq 1 Risk 3 Overall 3	Task 12M	
PROCESSID **7913** To Review the personnel files to check we remove old data to stay within the GDPR	913 Company Secretary *238861*		Freq 1 Risk 1 Overall 1	Task 3M	

Office Processes

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID **7750** Meeting between management and office team leader to discuss improvement of systems and address any issues	275 Managing Director	*238298 X in terms*	Freq 3 Risk 1 Overall 3	Task 1M	
PROCESSID **7793** Duplicate Issue needs process removing see processid 7750	639		Freq 3 Risk 1 Overall 3		

Human Resources

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID **7964** To check the Roles and tasks tables for any gaps /red crosses Fill in the missing information where needed.	1065 Company Secretary	1066 Managing Director	Freq 1 Risk 2 Overall 2	Task 3M Audit 12M	
	230669 / 227551 ✓				