Internal Audit Check list

MANAGEMENT REVIEW

Created:	17/May 1995	**Audit No 18**	
Revised:	06 November 2023	Last printed 06/11/2023 03:19:24 PM	Page 1 of 13
Audit Date	3-11-23	Auditor Helen Lamb	

VST

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.	Doc index intrastats issues
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.	Roles + titles Processes 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.	interested parties in Roles + titles Management Renew QMS
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 quality	management Renew Feedback Issues Procedures

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	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.	Doc index Training Supplier Review Marketing index Route map
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.	Feedback Roles + titles management Review Procedures H + S questionaire Review meetings
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.	Roles + titles Risk assessment Review of Risk

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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.	Review meeting management Review
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.	management Review Feedback Supplier Review procedures
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.	Doc index Audit Calendar Risk map Management Review Issues
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;	management Review Relevant titles

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	c) information on the performance and effectiveness of the quality management system, including trends in: 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.	Feedback PMS QC21 forms QA + barcode tracking Audit calendar
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.	management Review. Issues Route map
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.	
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).	
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: 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.	
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.	
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.	
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.	
Viamed Ltd ISO13485:2016 5.6.3	**Review output** 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.	
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.	

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	Question	Response	Y/N
1	Review Last years Audit. Update processes if required. Are all follow on Issue resolved satisfactory.	Nothing outstanding	Y
2	Check the Review is carried out in a timely manner. Task 746 and Task 1094. due 26 Oct 23 Meeting Minutes should be attached to latest Issue. Still in terms Vicmell 302478		Y
3	Verify that all relevant persons were present. See minutes at the bottom.		Y
4	Check that the review was carried out to the preset agenda. As per VOP 13.		Y
5	Is this agenda adequate? Look at any other business, do any other sections need to be added? List and issue any needed.		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.	Issues	Y
7	Check that actions are completed in a timely manner.		Y
8	Are minutes retained from the review? Are the minutes attached to the issue		Y
9	Can these minutes be accessed readily?		Y

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List Processes Per Title

Share Holder

Process Scope	Roll Task	Roll Audit	Risk	Action	Referenced in Document
PROCESSID **7834** The review the Financial requirements	733 Managing Director 310082 ✓	769 Company Secretary 305266 ✓	Freq 1 Risk 1 Overall 1	Task 1M Audit 3M	

Managing Director

Process Scope	Roll Task	Roll Audit	Risk	Action	Referenced in Document
PROCESSID **22** Ensure the company policys are still current and upto date	300 Managing Director 304697 ✓	1063	Freq 1 Risk 1 Overall 1	Task 12M	
PROCESSID **23** Ensure the company Objects are still current and upto date	300 Managing Director 304697 ✓		Freq 1 Risk 1 Overall 1	Task 12M	
PROCESSID **26** Overview of the Company using various data Reporting Screens	114 Managing Director 311527 ✓		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 311238 ✓	775 Company ✓ Secretary 305594	Freq 3 Risk 1 Overall 3	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 306748 ✓		Freq 1 Risk 1 Overall 1	Task 12M	
PROCESSID **55** Business Continuity Plan	266 Managing Director ✓ 286576		Freq 1 Risk 1 Overall 1	Task 12M	
PROCESSID **6861** Non Minuted Management discussions on issues	456 311525 ✓ Managing Director		Freq 2 Risk 1 Overall 2	Task 1W	
PROCESSID **7070** To discuss any problems, to assess work load and staffing.	83 Managing Director 311097 ✓		Freq 2 Risk 1 Overall	Task 3M	

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To review issues.

2

PROCESSID **7874**
To Ensure we have the latest version of Med Dev 2.12.
and update management if its been updated

128
Managing Director
309061 ✓

Freq 1 Task
Risk 1 12M
Overall 1

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
311592 ✓

805
Company Secretary
304710 ✓

Freq 2 Task 1W
Risk 1 Audit 1M
Overall 2

PROCESSID **7877**
To Plan for disaster

806
Managing Director
310211 x in terms

Freq 1 Task
Risk 3 12M
Overall 3

PROCESSID **7878**
Review possible legal / regulator changes that might affect Viamed / VST

807
Managing Director
310212 ✓

Freq 1 Task 3M
Risk 3
Overall 3

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
281142 ✓

1070
Company Secretary
284946

Freq 2 Task
Risk 1 12M
Overall Audit
2 12M

PROCESSID **7895**
To conitune our FDA registration
(for the Apgar timer)

825
Managing Director
311162 ✓

Freq 1 Task
Risk 1 12M
Overall 1

PROCESSID **7972**
To Comply with Top Level
Re-authorise the Current Audits for next 12 Months
Cover the Agenda as Per VOP13
Director 1 (Derek)

1094
Managing Director
310635 ✓ 5 terms

Freq 1 Task
Risk 1 12M
Overall 1

Process Scope	**Roll Task**	**Roll Audit**	**Risk**	**Action**	Referenced in Document
PROCESSID **8018** Rolling Issue for Notes During the Weekly Meeting To discuss any problems, to assess work load	1193 Managing Director 311166 ✓		Freq 1 Risk 1 Overall 1	Meeting 1W	

and staffing.
To review issues.

ISO Controller

Process Scope	Roll Task	Roll Audit	Risk	Action	Referenced in Document
PROCESSID **29** Annual license check, ensure no changes to Products licenced through CMDCAS, and Issue CMDCAS a statement that No changes have occured. NO LONGER KEEP THIS CERTIFICATE Certificate will go out of date 1st November, Check Canadian Gazette for Latest Version of the MDR	49 Managing Director 306638 ✓		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 311238 ✓		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 307633 ✓		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 307889 ✓		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 308127 ✓		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 310336 ✓	819 Company Secretary	Freq 3 Risk 1 Overall 3	Task 1M Audit 12M	
PROCESSID **7895**	825 311162 ✓		Freq 1	Task	

To conitune our FDA registration (for the Apgar timer)	Managing Director		Risk 1 Overall 1	12M
PROCESSID **7977** To review the Agenda of the Management review. Make sure no headers are missed that should be being discussed. Make sure Objectives are appropriate and effective.	1100 Company Secretary 303017 ✓	1101 Managing Director 307898 ✓	Freq 1 Risk 2 Overall 2	Task 12M Audit 12M
PROCESSID **7978** To Regulatory Requirements and a Review of QC21 form template. To ensure they are up to date to the current standards review Qc 21 Form to ensure it is still appropriate and valid	48 Managing Director 310719 ✓		Freq 1 Risk 3 Overall 3	Task 12M
PROCESSID **7979** To review the QC 21 form to make sure it is fit for purpose and covers all the areas we need to assess when filling in this form	1102 Managing Director 302055 ✓		Freq 1 Risk 2 Overall 2	Task 12M
PROCESSID **7980** Review the Government Website For Applicable Required Standards ISO 9001 Check if any other standards have been introduced that may have an affect on the company www.gov.uk European Commission harmonised standards to check documentation upto date http://ec.europa.eu/enterprise/policies/european-standards/documents/harmonised-standards-legislation/list-references/medical-devices/index_en.htm	1103 Managing Director 277948 ✓		Freq 1 Risk 2 Overall 2	Task 12M
PROCESSID **7981** To review monthly any changes, to any processes, for risks to ISO systems. **IT Controller**	1104 Managing Director 310220 ✓	1105 Company Secretary 311174 ✓	Freq 1 Risk 1 Overall 1	Task 1M Audit 12M

Process Scope	**Roll Task**	**Roll Audit**	**Risk**	**Action**	Referenced in Document
PROCESSID **6813** Ensure the turnover report is accurate	459 Managing Director 304300 ✓	460 Company Secretary 216185 ✓	Freq 3 Risk 1 Overall 3	Task 1M Audit 12M	
PROCESSID **7918**	923		Freq 1		

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To backup Jeans files
NO LONGER REQUIRED JEAN DOES NOT HAVE FOLDER ANYMORE

Risk 1
Overall 1

Warehouse Team Leader

Process Scope	Roll Task	Roll Audit	Risk	Action	Referenced in Document
PROCESSID **7753** To discuss any problems, to assess work load and staffing. To review issues with regard the Warehouse.	589 Managing Director 3 29761	590 Company Secretary 310841	Freq 3 Risk 1 Overall 3	Task 1M Audit 3M	

UK Sales Controller

Process Scope	Roll Task	Roll Audit	Risk	Action	Referenced in Document
PROCESSID **8026** To review competitor automotive prices	1210 Marketing Processes 303211 Aug X		Freq 1 Risk 1 Overall 1	Task 1M	

Human Resources

Process Scope	Roll Task	Roll Audit	Risk	Action	Referenced in Document
PROCESSID **7964** To check the Roles and tasks tables for any gaps /red crosses Fill in the missing information where needed.	1065 Company Secretary 310809	1066 Managing Director 299494	Freq 1 Risk 2 Overall 2	Task 3M Audit 12M	
PROCESSID **8025** Review the below statement and make sure it is still valid and correct. 'Viamed Group of companies does not involve the large-scale use of special category or criminal offence data. We also only occasionally process low risk data of individuals in the EU. We do not need to appoint a EU European representatives.' With this in mind we have reasoned we are not required to appoint any EU European representatives in EU member states.	1208 Company Secretary 310843	1209 Managing Director 303375	Freq 1 Risk 3 Overall 3	Task 12M Audit 12M	

Data Protection Officer

Process Scope	Roll Task	Roll Audit	Risk	Action	Referenced in Document
PROCESSID **7912**	912 308704		Freq 1	Task	

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Review The Personel Information We Collect Or Store, is the personal information that we collect and store - relevant, accurate and not excessive.	Company Secretary	Risk 3 Overall 3	12M
PROCESSID **7913** To Review the personnel files to check we remove old data to stay within the GDPR	913 Company Secretary 309624 ✓	Freq 1 Risk 1 Overall 1	Task 3M

Audits

Process Scope	Roll Task	Roll Audit	Risk	Action	Referenced in Document
PROCESSID **7886** To carry out Audit 18 Management Review Viamed	Viamed Audit in terms ✓	21 309391 Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M	
PROCESSID **7887** To carry out Audit 18 Management Review VST	VST Audit in terms ✓	188 309399 Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M	

Office Processes

Process Scope	Roll Task	Roll Audit	Risk	Action	Referenced in Document
PROCESSID **7750** Meeting between management and office team leader to discuss improvement of systems and address any issues	275 Managing Director 308755 ✓		Freq 3 Risk 1 Overall 3	Task 1M	
PROCESSID **7793** Duplicate Issue needs process removing see processid 7750	639		Freq 1 Risk 1 Overall 1		