Internal Audit Check list
POST MARKETING

Created:	17/May 1995	Audit No 22	
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Audit Date	22·6-21	Auditor *Helen Combs*	

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.	*management Review*
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.	*Rcute map Intrastats*
VST Ltd ISO9001:2015 8.1	**Operational planning and control** The organization shall plan, implement and control the processes (see 4.4) needed to meet the requirements for the provision of products and services, and to implement the actions determined in Clause 6, by: a) determining the requirements for the products and services; b) establishing criteria for: 1) the processes; 2) the acceptance of products and services; c) determining the resources needed to achieve conformity to the product and service requirements; d) implementing control of the processes in accordance with the criteria; e) determining, maintaining and retaining documented information to the extent necessary: 1) to have confidence that the processes have been carried out as planned; 2) to demonstrate the conformity of products and services to their requirements. The output of this planning shall be suitable for the organizations operations. The organization shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary. The organization shall ensure that outsourced processes are controlled (see 8.4).	*Intrastats vaps Doc index Rolling Tasks + Audits*

VST Ltd ISO9001:2015 8.2.1	**Customer communication** Communication with customers shall include: a) providing information relating to products and services; b) handling enquiries, contracts or orders, including changes; c) obtaining customer feedback relating to products and services, including customer complaints; d) handling or controlling customer property; e) establishing specific requirements for contingency actions, when relevant.	VOPS + procedures Doc index
VST Ltd ISO9001:2015 8.2.3.2	The organization shall retain documented information, as applicable: a) on the results of the review; b) on any new requirements for the products and services.	Doc index
VST Ltd ISO9001:2015 8.3.3	**Design and development inputs** The organization shall determine the requirements essential for the specific types of products and services to be designed and developed. The organization shall consider: a) functional and performance requirements; b) information derived from previous similar design and development activities; c) statutory and regulatory requirements; d) standards or codes of practice that the organization has committed to implement; e) potential consequences of failure due to the nature of the products and services. Inputs shall be adequate for design and development purposes, complete and unambiguous. Conflicting design and development inputs shall be resolved. The organization shall retain documented information on design and development inputs.	Infrastructs Tasks + Audits
VST Ltd ISO9001:2015 8.3.4	**Design and development controls** The organization shall apply controls to the design and development process to ensure that: a) the results to be achieved are defined; b) reviews are conducted to evaluate the ability of the results of design and development to meet requirements; c) verification activities are conducted to ensure that the design and development outputs meet the input requirements; d) validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use; e) any necessary actions are taken on problems determined during the reviews, or verification and validation activities; f) documented information of these activities is retained. NOTE Design and development reviews, verification and validation have distinct purposes. They can be conducted separately or in any combination, as is suitable for the products and services of the organization.	Design index
VST Ltd	**Design and development changes**	

ISO9001:2015 8.3.6	The organization shall identify, review and control changes made during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements. The organization shall retain documented information on: a) design and development changes; b) the results of reviews; c) the authorization of the changes; d) the actions taken to prevent adverse impacts.	*Doc index, tec files*
VST Ltd ISO9001:2015 8.5.5	**Post-delivery activities** The organization shall meet requirements for post-delivery activities associated with the products and services. In determining the extent of post-delivery activities that are required, the organization shall consider: a) statutory and regulatory requirements; b) the potential undesired consequences associated with its products and services; c) the nature, use and intended lifetime of its products and services; d) customer requirements; e) customer feedback. NOTE Post-delivery activities can include actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.	*Intraslets*
VST Ltd ISO9001:2015 9.1.2	**Customer satisfaction** The organization shall monitor customers' perceptions of the degree to which their needs and expectations have been fulfilled. The organization shall determine the methods for obtaining, monitoring and reviewing this information. NOTE Examples of monitoring customer perceptions can include customer surveys, customer feedback on delivered products and services, meetings with customers, market-share analysis, compliments, warranty claims and dealer reports.	*Reviews*
VST Ltd ISO9001:2015 9.1.3	**Analysis and evaluation** The organization shall analyse and evaluate appropriate data and information arising from monitoring and measurement. The results of analysis shall be used to evaluate: a) conformity of products and services; b) the degree of customer satisfaction; c) the performance and effectiveness of the quality management system; d) if planning has been implemented effectively; e) the effectiveness of actions taken to address risks and opportunities; f) the performance of external providers; g) the need for improvements to the quality management system. NOTE Methods to analyse data can include statistical techniques.	*Intraslets* *Supplier review*
Viamed Ltd ISO13485:2016 5.6.2 Review	**General** The input to management review shall include, but is not limited to, information arising from: a) feedback; b) complaint handling;	*Intraslets*

input	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.	*Mangement Review*
Viamed Ltd ISO13485: 2016 7.1	**Planning of product realization** The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system. The organization shall document one or more processes for risk management in product realization. Records of risk management activities shall be maintained (see 4.2.5). In planning product realization, the organization shall determine the following, as appropriate: a) quality objectives and requirements for the product; b) the need to establish processes and documents (see 4.2.4) and to provide resources specific to the product, including infrastructure and work environment; c) required verification, validation, monitoring, measurement, inspection and test, handling, storage, distribution and traceability activities specific to the product together with the criteria for product acceptance; d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.5). The output of this planning shall be documented in a form suitable for the organization's method of operations. NOTE Further information can be found in ISO 14971.	*Design udev* *Tech files*
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	*Procedures vaps intrastats*
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	*Intrastats CRM*

	accordance with applicable regulatory requirements.	
Viamed Ltd ISO13485: 2016 8.1	**General** The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed to: a) demonstrate conformity of product; b) ensure conformity of the quality management system; c) maintain the effectiveness of the quality management system. This shall include determination of appropriate methods, including statistical techniques, and the extent of their use.	*Intrastats QA Routemap*
Viamed Ltd ISO13485: 2016 8.2.1	**Feedback** As one of the measurements of the effectiveness of the quality management system, the organization shall gather and monitor information relating to whether the organization has met customer requirements. The methods for obtaining and using this information shall be documented. The organization shall document procedures for the feedback process. This feedback process shall include provisions to gather data from production as well as post-production activities. The information gathered in the feedback process shall serve as potential input into risk management for monitoring and maintaining the product requirements as well as the product realization or improvement processes. If applicable regulatory requirements require the organization to gain specific experience from post production activities, the review of this experience shall form part of the feedback process.	*Intrastats*
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 established 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.	*Issues Tasks + Audit System Doc index*

Viamed Ltd ISO13485: 2016 8.4	**Analysis of data** The organization shall document procedures to determine, collect and analyse appropriate data to demonstrate the suitability, adequacy and effectiveness of the quality management system. The procedures shall include determination of appropriate methods, including statistical techniques and the extent of their use. The analysis of data shall include data generated as a result of monitoring and measurement and from other relevant sources and include, at a minimum, input from: a) feedback; b) conformity to product requirements; c) characteristics and trends of processes and product including opportunities for improvement; d) suppliers; e) audits; f) service reports, as appropriate. If the analysis of data shows that the quality management system is not suitable, adequate or effective, the organization shall use this analysis as input for improvement as required in 8.5. Records of the results of analyses shall be maintained (see 4.2.5).	*Indrastats management Review*
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.	*Management Review*

	QUESTION:	RESPONSE:	Y/N
1	Review Last years Audit. Update processes if required. Are all follow on Issue resolved satisfactory.	#175333 Done #175331 System problem	
2	Verify that meetings are held every 6 Months. (Sales and Marketing Meeting / Management) *VST*	April 21 Carried out also weekly zoom - covid	Y 19
3	Ascertain the chair of the meetings.	Intrastats	Y
4	Check that other relevant personnel are involved in the meeting. *Covid 19 meeting*	Held by zoom	Y
5	Check that the minutes are filed accordingly.	attached to meetings issues	Y
6	Does the meeting produce a subsequent personnel action plan, issues.	Issues where relevant	Y

| 7 | Are these actions and issues followed up in a timely manner. | | | | |

Issue system ✓
all outstanding reviewed

List Processes Per Title

Managing Director

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID 5863 To review the current sales. Look at future sales including potential customer, tenders, markets, exhibitions, problems or barriers to sales.	267 Director 3 (Steve) *227212 in terms*		Freq 4 Risk 1 Overall 4	Task 4W	
PROCESSID 5864 To review the current sales. Look at future sales including potential customer, tenders, markets, exhibitions, problems or barriers to sales.	268 Director 3 (Steve) *227213 in terms*		Freq 4 Risk 1 Overall 4	Task 3W	

Marketing Controller

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID 7809 Analyzing Existing product , sales trends, plan strategy.	671 *22420* Marketing Processes	672 Director 3 (Steve) *226373*	Freq 2 Risk 2 Overall 4	Task 3M Audit 3M	
PROCESSID 7810 Investigating products and applications, existing and potential products.	675 Marketing Processes *227096*	676 Director 3 (Steve) *218602*	Freq 3 Risk 1 Overall 3	Task 1M Audit 3M	

Audits

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID 7732 To carry out Audit 22 Post Market Survellance Viamed		14 Company Secretary *221043*	Freq 1 Risk 2 Overall 2	Audit 12M	*This Audit*
PROCESSID 7780 To carry out Audit 22 Post Market Surveillance VST		180 Company Secretary *221046*	Freq 1 Risk 2 Overall 2	Audit 12M	*This Audit*