Internal Audit Check list
VANDAGRAPH SENSOR TECHNOLOGIES LTD
POST MARKET SURVEILLANCE

Created:	17/May 1995	**Audit No 22**	
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Audit Date	23-5-25	Auditor *Helen Lamb*	

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 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.	Product reviews PMS Review External parties QA system
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).	Feedback management Review issues Doc index Route map QA Supplier review
VST Ltd ISO9001:2	**Customer communication** Communication with customers shall include:	

015 8.2.1	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.		Doc index Roles + titles Feedback
VST Ltd ISO9001:2 015 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 QA System Feed back
VST Ltd ISO9001:2 015 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.		Feed back Marketing Doc index Tech file Supplier Review Route Map
VST Ltd ISO9001:2 015 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.		QA Doc index Tech files Marketing Index PMS Supplier Review Feedback.
VST Ltd ISO9001:2 015 8.3.6	**Design and development changes** The organization shall identify, review and control changes made during, or subsequent to, the design and development of products and services, to		

		Doc index Tech files
	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 Tech files
VST Ltd ISO9001:2 015 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.	Route map Procedures QA Feedback Bercodes PMS
VST Ltd ISO9001:2 015 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.	PMS Feedback Issues.
VST Ltd ISO9001:2 015 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.	Management Review QA System Doc index Roles + task Supplier Review.

	QUESTION:	RESPONSE:	Y/N
1	Review Last years Audit. Update processes if required. Are all follow on Issue resolved satisfactory.	all issues completed nothing ongoing	Y

No Non conformances.

2	Verify that meetings are held every 6 Months. (Sales and Marketing Meeting / Management)			Y
3	Ascertain the chair of the meetings.			Y
4	Check that other relevant personnel are involved in the meeting.			Y
5	Check that the minutes are filed accordingly.			Y
6	Does the meeting produce a subsequent personnel action plan, issues.			Y
7	Are these actions and issues followed up in a timely manner.			Y

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

List Processes Per Title

Clone from Docid

Managing Director					
Process Scope	**Roll Task** **Roll Audit**	**Risk**	**Action**	*****	**Notes**
PROCESSID **5863** To review the current sales. Look at future sales including potential customer, tenders, markets, exhibitions, problems or barriers to sales.	Task: 267 362744 X Director 3 (Steve) Audit : Issue Sent 365215	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.	Task: 268 X 363727 Director 3 (Steve) X Audit : Issue Sent 365215	Freq 4 Risk 1 Overall 4	Task 3W		
PROCESSID **8014** Review VIAMED Product Feedback Positive	Task: 1189 365022 Managing Director Audit :	Freq 1 Risk 1 Overall 1	Task 1M		
PROCESSID **8015** Review VST Product Feedback Positive	Task: 1190 365023 Managing Director Audit :	Freq 1 Risk 1 Overall 1	Task 1M		
PROCESSID **8016**	Task: 1188 365021	Freq 1	Task		

Process Scope	Roll Task / Roll Audit	Risk	Action	*	Notes
Review Positive Customer Feedback	Managing Director Audit :	Risk 1 Overall 1	1M		
PROCESSID **8017** Review VST Customer Feedback Positive	Task: 1191 *365024* Managing Director Audit :	Freq 1 Risk 1 Overall 1	Task 1M		

Product Controller

Process Scope	Roll Task Roll Audit	Risk	Action	*	Notes
PROCESSID **7973** To produce Product performance report showing 2 years of returns. Which we can use to send to customers.	Task: 1095 *345629* Director 3 (Steve) *Issue Sent* Audit : *365215*	Freq 1 Risk 1 Overall 1	Task 12M		
PROCESSID **7974** To produce Product performance report for Suppliers PMS Files	Task: 1096 *345630* Director 3 (Steve) *x* Audit : *Issue Sent 365215*	Freq 1 Risk 1 Overall 1	Task 12M		

Marketing Controller

Process Scope	Roll Task Roll Audit	Risk	Action	*	Notes
PROCESSID **7809** Analyzing Existing product , sales trends, plan strategy.	Task: 671 *357126* Marketing Processes Audit :672 *358985* Director 3 (Steve)	Freq 2 Risk 2 Overall 4	Task 3M Audit 3M		
PROCESSID **7810** Investigating products and applications, existing and potential products.	Task: 675 *362649* Marketing Processes Audit :676 *360509* Director 3 (Steve) *x* *Issue Sent 365215*	Freq 3 Risk 1 Overall 3	Task 1M Audit 3M		
PROCESSID **8076** Review the results from the previous medica	Task: 1238 *336888* Marketing Processes Audit :	Freq 2 Risk 1 Overall 2	Task 12M		

Audits

Process Scope	Roll Task Roll Audit	Risk	Action	*	Notes
PROCESSID **7732** To carry out Audit 22 Post Market Surveillance Viamed	Task: *362859* Audit :14 *this Audit* Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M		
PROCESSID **7780**	Task:	Freq 1	Audit		

To carry out Audit 22 Post Market Surveillance VST	Audit :180 *362860 The Audit X* Company Secretary	Risk 2 Overall 2	12M			

Marketing Processes

Process Scope	Roll Task Roll Audit	Risk	Action	*	Notes	
PROCESSID **8070** Website Order VM-2160 VET Feedback	Task: 1230 Audit :	Freq 1 Risk 1 Overall 1				

Rolling Tasks Linked to Document :Task (14) Task (180) Task (267) Task (268) Task (671) Task (675) Task (1095) Task (1096) Task (1189) Task (1190) Task (1188) Task (1191) Task (1230) Task (1238)