Viamed

Internal Audit Check list			
Training			
Created:	17/May 1995	Audit No 08	VOP12
Revised:	20 September 2021		Page 4 of 7
Audit Date		Auditor DEREK 11/7/22	

ISO13485:2016 7.3.2	The organization shall plan and control the design and development of product. As appropriate, design and development planning documents shall be maintained and updated as the design and development progresses. During design and development planning, the organization shall document: a) the design and development stages; b) the review(s) needed at each design and development stage; c) the verification, validation, and design transfer activities that are appropriate at each design and development stage; d) the responsibilities and authorities for design and development; e) the methods to ensure traceability of design and development outputs to design and development inputs; f) the resources needed including necessary competence of personnel	Tech files marketing index Doc index
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.	Doc index Audit Calendar Route Map Roles and tasks.

	Question	Response/Answer	Y/N
1	Review Last years Audit Are all follow on Issue resolved satisfactory?	236944	Y
2	Each new employee must have the Induction recorded on there own training record. Check any staff that have been employed since the last Audit.	Jaine + Agis	Y

3	The requirement for every member of staff to re-evaluate there own training record is automatically generated as an Issue in Intrastats annually. Check Task ID 314.	See issue 262226	Y
4	Review the last Management meeting for review of capability/ competence of staff.	19.0	Y
5	Review the last Management meeting for the identification of training is discussed at management meetings.	19.0	Y
6	Check any actions or follow ups are completed in a timely manner.	No follow on Actions	Y
7	Training records are now held electronically. Task IDs 316 and 303. Check the tasks are carried out in a timely manner.	Both up to date	Y
8	Are arrangements for training personnel satisfactory. Check courses over last year.		Y
9	Check that personnel have updated their training records with any in-house training undertaken. Check recent training that has been carried out, is present on the training record.	Reviewed Aoife, SH, Phil	Y

Sub Processes Linked to Audit 08

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

List Processes Per Title

Managing Director					
Process Scope	**Roll Task**	**Roll Audit**	**Risk**	**Action**	Notes / Issues
PROCESSID **7070** To discuss any problems, to assess work load and staffing. To review issues.	83 Managing Director 258832✓		Freq 2 Risk 1 Overall 2	Task 3M	
PROCESSID **7713** Ensure All tasks allocated to active Members of staff.	548 Managing Director 263496✓		Freq 3 Risk 2 Overall 6	Task 1M	
Documentation And Records Controller					
Process Scope	**Roll Task**	**Roll Audit**	**Risk**	**Action**	Notes / Issues
PROCESSID **7907** To review which employees have Access to sensitive areas of Intrastats	887 Company Secretary 230431✓	888 Office Processes 232608✓	Freq 1 Risk 1 Overall 1	Task 12M Audit 12M	
IT Controller					
Process Scope	**Roll Task**	**Roll Audit**	**Risk**	**Action**	Notes / Issues
PROCESSID **7951** Check the Server space and Size of important files	139 Office Processes 265287✓ in terms	1033 Managing Director 264995✓	Freq 1 Risk 5 Overall 5	Task 1M Audit 3M	
Accounts Processes					
Process Scope	**Roll Task**	**Roll Audit**	**Risk**	**Action**	Notes / Issues
PROCESSID **5934** To check that any training that has been done is valid and then checked off the training record. Including enough detail to describe what has been coved in the training and any material used.	316 Company Secretary 265413✓	560 Office Processes 264855✓	Freq 4 Risk 1 Overall 4	Task 1W Audit 3M	
Audits					
Process Scope	**Roll Task**	**Roll Audit**	**Risk**	**Action**	Notes /

					Issues
PROCESSID **7720** To carry out Audit 08 Training Viamed		10 264799 + Managing Director	Freq 1 Risk 2 Overall 2	Audit 12M	This Audit
PROCESSID **7768** To carry out Audit 08 Training VST		184 Managing Director 264800	Freq 1 Risk 2 Overall 2	Audit 12M	VST Audit
Human Resources					
Process Scope	**Roll Task**	**Roll Audit**	**Risk**	**Action**	Notes / Issues
PROCESSID **5881** Keep Staff Training records upto date	314 261415 ✓ Company Secretary	380 Managing Director 253067 ✓	Freq 2 Risk 1 Overall 2	Task 3M Audit 6M	
PROCESSID **5936** To print the time sheets and add any extras. overtime. sick days. or commissions.	448 Company Secretary 263343 ✓		Freq 3 Risk 3 Overall 9	Task 1M	
PROCESSID **6837**	314 Company Secretary 261415 ✓		Freq Risk Overall	Task 3M	
PROCESSID **6851** To look through the accident book and make sure there were no breaches of Health and Safety that were not reported.	287 Managing Director 248136 ✓		Freq 2 Risk 2 Overall 4	Task 6M	
PROCESSID **6877** those that have keys and use the intruder alarm	771 Company Secretary 256262 ✓		Freq 2 Risk 3 Overall 6	Task 6M	
PROCESSID **7759** Information from the staff that would be used in case of emergency health issue. These are filled in by staff and filled securely.	606 Company Secretary 248840 ✓		Freq 1 Risk 3 Overall 3	Task 12M	
PROCESSID **7883** to review the staff. give feedback and discuss issues	813 Company Secretary ✓ 251762	814 Managing Director 262821	Freq 1 Risk 1 Overall 1	Task 12M Audit 24M	
PROCESSID **7884** Review the staff pay. ensure its above minimum living wage and at a level appropriate to the work	815 Company Secretary 262107 x in forms	816 Managing Director 193885 ✓	Freq 1 Risk 1 Overall 1	Task 12M Audit 24M	
PROCESSID **7908** remind staff about private information data and that it needs to be looked after and securely.	889 Company Secretary ✓ 230438	890 Office Processes ✓ 235501	Freq 1 Risk 1 Overall 1	Task 12M Audit 12M	
PROCESSID **7937** Diversity Impact Assessment	992 Managing Director ✓ 264607		Freq 1 Risk 1 Overall 1	Task 12M	

	the organization's objectives. NOTE 2 Organizational knowledge can be based on: a) internal sources (e.g. intellectual property; knowledge gained from experience; lessons learned from failures and successful projects; capturing and sharing undocumented knowledge and experience; the results of improvements in processes, products and services); b) external sources (e.g. standards; academia; conferences; gathering knowledge from customers or external providers)	
VST Ltd ISO9001:2015 7.2	**Competence** 7.2 Competence The organization shall: a) determine the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system; b) ensure that these persons are competent on the basis of appropriate education, training, or experience; c) where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken; d) retain appropriate documented information as evidence of competence. NOTE Applicable actions can include, for example, the provision of training to, the mentoring of, or the reassignment of currently employed persons; or the hiring or contracting of competent persons.	
VST Ltd ISO9001:2015 7.3	**Awareness** The organization shall ensure that persons doing work under the organization's control are aware of: a) the quality policy; b) relevant quality objectives; c) their contribution to the effectiveness of the quality management system, including the benefits of improved performance; d) the implications of not conforming with the quality management system requirements.	
VST Ltd ISO9001:2015 7.4	**Communication** 7.4 Communication The organization shall determine the internal and external communications relevant to the quality management system, including: a) on what it will communicate; b) when to communicate; c) with whom to communicate; d) how to communicate; e) who communicates.	
VST Ltd ISO9001:2015 8.5.1	**Control of production and service provision** The organization shall implement production and service provision under controlled conditions. Controlled conditions shall include, as applicable: a) the availability of documented information that defines: 1) the characteristics of the products to be produced, the services to be provided, or the activities to be performed; 2) the results to be achieved; b) the availability and use of suitable monitoring and measuring resources;	

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Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
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.	/
VST Ltd ISO9001:2015 7.1.2	**People** The organization shall determine and provide the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes.	/
VST Ltd ISO9001:2015 7.1.4	**Environment for the operation of processes** The organization shall determine, provide and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services. NOTE A suitable environment can be a combination of human and physical factors, such as: a) social (e.g. non-discriminatory, calm, non-confrontational); b) psychological (e.g. stress-reducing, burnout prevention, emotionally protective); c) physical (e.g. temperature, heat, humidity, light, airflow, hygiene, noise). These factors can differ substantially depending on the products and services provided.	/
VST Ltd ISO9001:2015 7.1.6	**Organizational knowledge** The organization shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services. This knowledge shall be maintained and be made available to the extent necessary. When addressing changing needs and trends, the organization shall consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates. NOTE 1 Organizational knowledge is knowledge specific to the organization; it is generally gained by experience. It is information that is used and shared to achieve	/

	c) the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met; d) the use of suitable infrastructure and environment for the operation of processes; e) the appointment of competent persons, including any required qualification; f) the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement; g) the implementation of actions to prevent human error; h) the implementation of release, delivery and post-delivery activities	
Viamed Ltd ISO13485:2016 5.5.1	**Responsibility and authority** Top management shall ensure that responsibilities and authorities are defined, documented and communicated within the organization. Top management shall document the interrelation of all personnel who manage, perform and verify work affecting quality and shall ensure the independence and authority necessary to perform these tasks.	Roles + tasks Doc index management Review
Viamed Ltd ISO13485:2016 6.2	**Human resources** Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience. The organization shall document the process(es) for establishing competence, providing needed training, and ensuring awareness of personnel. The organization shall: a) determine the necessary competence for personnel performing work affecting product quality; b) provide training or take other actions to achieve or maintain the necessary competence; c) evaluate the effectiveness of the actions taken; d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives; e) maintain appropriate records of education, training, skills and experience (see 4.2.5). NOTE The methodology used to check effectiveness is proportionate to the risk associated with the work for which the training or other action is being provided.	Doc index procedures Training Records management Renew
Viamed Ltd ISO13485:2016 6.4.1	**Work environment** The organization shall document the requirements for the work environment needed to achieve conformity to product requirements. If the conditions for the work environment can have an adverse effect on product quality, the organization shall document the requirements for the work environment and the procedures to monitor and control the work environment. The organization shall: a) document requirements for health, cleanliness and clothing of personnel if contact between such personnel and the product or work environment could affect medical device safety or performance; b) ensure that all personnel who are required to work temporarily under special environmental conditions within the work environment are competent or supervised by a competent person. NOTE Further information can be found in ISO 14644 and ISO 14698	Doc index CPM Hs Renew Training Records management Renew
Viamed Ltd	**Design and development planning**	