

Internal Audit Check list			
Training			
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Audit Date	9/9/19	Auditor <i>D LAMBS</i>	

SCOPE

Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
VST Ltd ISO9001:2015 5.1.1	<p>General</p> <p>Top management shall demonstrate leadership and commitment with respect to the quality management system by:</p> <ul style="list-style-type: none"> a) taking accountability for the effectiveness of the quality management system; <i>management meeting</i> 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; <i>Reviewed Board meeting</i> 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; <i>External Risk & Process</i> e) ensuring that the resources needed for the quality management system are available; <i>Business & meeting</i> f) communicating the importance of effective quality management and of conforming to the quality management system requirements; <i>Business</i> g) ensuring that the quality management system achieves its intended results; <i>Business & meeting</i> h) engaging, directing and supporting persons to contribute to the effectiveness of the quality management system; <i>Business & meeting</i> i) promoting improvement; <i>Business / Audit</i> j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility. <i>Business / Audit</i> <p>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.</p>	
VST Ltd ISO9001:2015 7.1.2	<p>People</p> <p>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. <i>Human Resource</i></p>	
VST Ltd ISO9001:2015 7.1.4	<p>Environment for the operation of processes</p> <p>The organization shall determine, provide and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services. <i>HSE Review</i></p> <p>NOTE A suitable environment can be a combination of human and physical factors, such as:</p>	

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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.

Issue Rolling

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 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)

Meeting/Issues/SOS Log/Workshops

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.

Training Review/ Appraisal

Tasks & Audit Rolling

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 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;

Issue Rolling Issue

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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.

involvement

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.

*involvement
control*

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;
 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

Training records

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.

Role & responsibility

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.

Viamed Ltd

Human resources

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ISO13485:2016 6.2 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; *Records + Information*

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.

Work environment

ISO13485:2016 6.4.1 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

Design and development planning

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

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ISO13485:2016 7.3.2

14698 Revision

DGJW
D. J. W.

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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

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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.

*AV.1.4
cal
povel
infrastructrue*

Review Last years Audit Are all follow on Issue resolved satisfactory?	<i>#126631 Some no other follow on issues</i>	<i>Y</i>
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Internal audits has been moved totally to the “Intrastat” system.

1. The requirement for every member of staff to re-evaluate there own training record is automatically generated as an “Issue” in Intrastats annually ✓ *HD discussed with HL, the solution is verbal.*
2. Each new employee must have the Induction recorded on there own training record ✓
3. Training records are now held electronically ✓
4. The competence level required is discussed regularly at management meetings ✓
5. The identification of training is discussed at management meetings ✓
6. Actions are taken at these meetings to ensure the company has correctly trained people. ✓

Question		Response/Answer	Y/N
Are arrangements for training personnel satisfactory			?
Management Check courses over last year			?
Check that personnel record any in-house training undertaken.	✓		Y
Check that this training is entered onto training record.	✓		Y

* came up last year Audit no new staff since plan.

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Sub Processes Linked to Audit 08

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

Managing Director

Process Scope	Brief Description	Responsibility/Procedure/Training	Measurable Objective	Task	Audit	Freq	Risk	Overall	Action
7070 - History/Details To discuss any problems, to assess work load and staffing. To review issues.	Management Review	27178 VOP 13 Process Monitoring, System Reviews, Audits, Management Review, Analysis Data 24125 VOP 19 FeedBack Customer Complaints Vigilance and Notifications Viamed Ltd 24129 VOP 19 FeedBack Customer Complaints Vigilance and Notifications VST Ltd	none - this is a subjective review by the Management of the current state of staffing / workload etc.	83 Managing Director	✓ 1/8/19 3/5/19	2	1	2	Task 3M
7713 - History/Details Ensure All tasks allocated to active Members of staff,	Review Roles And Responsibilities	27244 VOP 02 Personnel and Responsibility, Staff and Staffing Issues, Training, Roles and Tasks	No Job Clashes in the list (Aside from Software Validation Conflicting Audits) No Yellow Employees in	548 Managing Director	# 151952 up to date	3	2	6	Task 1M

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	the list (aside from Auditor) No Areas with High outstanding Issues
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Director 3 (Steve)

Process Scope	Brief Description	Responsibility/Procedure/Training	Measurable Objective	Task	Audit	Freq	Risk	Overall Action
6841 Define whom is responsible for researching and obtaining Grants	Grants	27244 VOP 02 Personnel and Responsibility , Staff and Staffing Issues, Training, Roles and Tasks		W ^o Task Responsibility only		1	1	1

Documentation And Records Controller

Process Scope	Brief Description	Responsibility/Procedure/Training	Measurable Objective	Task	Audit	Freq	Risk	Overall Action
7907 - History/Details To review which employees have Access to sensitive areas of Management Intrastats	Annual Review Doc	27244 VOP 02 Personnel and Responsibility , Staff and Staffing Issues, Training, Roles and Tasks	Last review date, See previous Issue History	887 Company Secretary	888 Managing Director	1	1	1 Task 12M Audit 12M #150456✓ 29/1/19

Accounts Processes

Process Scope	Brief Description	Responsibility/Procedure/Training	Measurable Objective	Task	Audit	Freq	Risk	Overall Action
5934 To check that any training that has been done is valid and then checked off the training record.	Staff Training	27438 VOP 01 Documentation / Records - Control, Creation, Storage, Retrieval and	dynamic process no measurable	316 Company Secretary	560 Managing Director	4	1	4 Task 1W Audit 3M #153429✓ checked training Records

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	Revision control 27244 VOP 02 Personnel and Responsibility , Staff and Staffing Issues, Training, Roles and Tasks
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Audits

Process Scope	Brief Description	Responsibility/Procedure/Training	Measurable Objective	Task	Audit	Freq	Risk	Overall	Action
7720 - History/Details To carry out Audit 08 Training Viamed	Audit 08 Training Viamed	27178 VOP 13 Process Monitoring, System Reviews, Audits, Management Review, Analysis Data			10 Managing Director	1	2	2	Audit 12M
7768 - History/Details To carry out Audit 08 Training VST	Audit 08 Training VST	27178 VOP 13 Process Monitoring, System Reviews, Audits, Management Review, Analysis Data			184 Managing Director	1	2	2	Audit 12M

Human Resources

Process Scope	Brief Description	Responsibility/Procedure/Training	Measurable Objective	Task	Audit	Freq	Risk	Overall	Action
5881 - History/Details Keep Staff Training records upto date	Training Records Review	27244 VOP 02 Personnel and Responsibility , Staff and Staffing Issues, Training, Roles and Tasks		314 Company Secretary	380 Managing Director	2	1	2	Task 3M Audit 6M
5904	Taking On New Staff	27244 VOP 02 Personnel and				#152254			

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			Responsibility , Staff and Staffing Issues, Training, Roles and Tasks	23381 VOP 04 Accounts, Bank, Loans, Debtors, Creditors, Accountant Processes	448 Company Secretary	3 3 9	Task 1M	#151756 Tasks up to date
5936 - History/Details	Wages Calculations		27244 VOP 02 Personnel and Responsibility , Staff and Staffing Issues, Training, Roles and Tasks	314 Company Secretary		Task 3M	# Needs Risk analysis filling in Task up to date	
6837 - History/Details	Personnel Requirements and Training		14718 CPM 04 Personnel Holidays and Time Adjustments	8926 CPMF 06 Holiday Request Form, 27244 VOP 02 Personnel and Responsibility , Staff and Staffing Issues, Training, Roles and Tasks	1 1 1		No Rolling Saves Reactive Responsibility .	
6851 - History/Details	Review Accident Book		23316 VOP 16 Health and Safety, Company Personnel Manual	287 Managing Director	2 2 4	Task 6M	Revised 16/7/19	
6877	Alarm Key Holders		27244 VOP 02 Personnel and Responsibility , Staff and Staffing Issues, Training, Roles and Tasks	771 Company Secretary	2 3 6	Task 6M	Review all #141932	
6906	Time Working Away		27244 VOP 02 Personnel and					

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6928	Staff	Responsibility , Staff and Staffing Issues, Training, Roles and Tasks	See 6877 records Duplicate					
		27244 VOP 02 Personnel and Responsibility , Staff and Staffing Issues, Training, Roles and Tasks	2	Empty possible was Duplicate and removed	see 6877 records			
7759 - History/Details	Health Declaration Sheet	23316 VOP 16 Health and Safety, Company Personnel Manual	606 Company Secretary	1 #136846 Action Issue 137262 Sent to all	3 3	Task 12M		
7883 - History/Details	Appraisal	23527 VOP 12 Training	813 Company Secretary	814 Managing Director	1 #132661	1	Task 12M Audit 24M	
7884 - History/Details	Pay Review	23381 VOP 04 Accounts, Bank, Loans, Debtors, Creditors, Accountant Processes	815 Company Secretary	816 Managing Director	1 #146712 6/6/19	1	Task 12M Audit 24M	
7908 - History/Details	Private Information Data	27244 VOP 02 Personnel and Responsibility , Staff and Staffing Issues, Training, Roles and Tasks	889 Company Secretary	890 Managing Director	1 #150457 Follow on 3566 #153817	1	Task 12M Audit 12M	