Internal Audit Check list			
Training			
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SCOPE

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 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; 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.
Viamed Ltd	**Human resources**

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;
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.

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

Viamed Ltd
ISO13485:2016 7.3.2

Design and development planning
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

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.

Review Last years Audit Are all follow on Issue resolved satisfactory?	No Issues Arising from Previous Audit	Y

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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 *TASK 314 ALL UPTODATE* ~~Remove~~ *issue #*
2. Each new employee must have the Induction recorded on there own training record. *need* *126629*
3. Training records are now held electronically — *All Training Signed off*
4. The competence level required is discussed regularly at management meetings *Task 589* *add notes* *Task 275* *on Training*
5. The identification of training is discussed at management meetings *# 126630*
6. Actions are taken at these meetings to ensure the company has correctly trained people.

follow on issues

Y

Question	Response/Answer	Y/N
Are arrangements for training personnel satisfactory Management Check courses over last year	*check Admin Employee intrastats July 2018*	*Y*
Check that personnel record any in-house training undertaken.		*Y*
Check that this training is entered onto training record.	*# 126631* *sent to New Stauff*	

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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	Roll Task	Roll Audit	Risk/Freq/Over all	Action	Notes / Issues
PROCESSID 7070 To discuss any problems, to assess work load and staffing. To review issues.	83 Managing Director	*needs meme ihf Held 2/8/18*	Risk 2 Freq: 1 Overall 2	Task 3M	
PROCESSID 7713 Ensure All tasks allocated to active Members of staff,	548 Managing Director	*# 124331 Auditing myself ?*	Risk 3 Freq: 2 Overall 6	Task 1M	

Accounts Processes

Process Scope	Roll Task	Roll Audit	Risk/Freq/Over all	Action	Notes / Issues
PROCESSID 5934 To check that any training that has been done is valid and then checked off the training record.	316 *signed off weekly* Company Secretary	560 *some 3 vate 2018* Managing Director	Risk 4 Freq: 1 Overall 4	Task 1W Audit 3M	✓

Audits

Process Scope	Roll Task	Roll Audit	Risk/Freq/Over all	Action	Notes / Issues
PROCESSID 7720 To carry out Audit 08 Training Viamed		10 Managing Director	Risk 1 Freq: 2 Overall 2	Audit 12M	
PROCESSID 7768 To carry out Audit 08 Training VST		184 Managing Director	Risk 1 Freq: 2 Overall 2	Audit 12M	

Human Resources

Process Scope	Roll Task	Roll Audit	Risk/Freq/Over all	Action	Notes / Issues
PROCESSID 5881 Keep Staff Training records upto date	314 *# 12108 29 may* Company Secretary	380 *me?* Managing Director	Risk 2 Freq: 1 Overall 2	Task 3M Audit 6M	
PROCESSID 5936	448 *each month # 126273*		Risk 3	Task 1M	

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To print the time sheets and add any extras, overtime, sick days, or commissions.

Company Secretary

Freq: 3
Overall 9

PROCESSID **6837**

 # Sign off training issue.

~~574~~ Company Secretary

Risk
Freq:
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 ✓ *me ?*
Managing Director

Risk 2
Freq: 2
Overall 4

Task 6M

PROCESSID **6877**
those that have keys and use the intruder alarm

771 ✓ *Reviewed 5/4/18* #177402
Company Secretary

Risk 2
Freq: 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 ✓ #112998
Company Secretary

Risk 1
Freq: 3
Overall 3

Task 12M