Internal Audit Check list			
Design			
Created:	17/May 1995	**Audit No 03**	VOP 17
Revised:	23 February 2018		Page 1 of 10
Audit Date	23-2-18	Auditor Helen Lamb	

Sub Processes Linked to Audit 03

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

Company / ISO Section	Criteria of ISO Section	Auditor Comments / Issues
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).	N/A
VST Ltd ISO9001:2015 8.3.1 General	The organization shall establish, implement and maintain a design and development process that is appropriate to ensure the subsequent provision of products and services.	N/A
VST Ltd ISO9001:2015 8.3.2	**Design and development planning** In determining the stages and controls for design and development, the organization shall consider: a) the nature, duration and complexity of the design and development activities; b) the required process stages, including applicable design and	N/A

	development reviews; c) the required design and development verification and validation activities; d) the responsibilities and authorities involved in the design and development process; e) the internal and external resource needs for the design and development of products and services; f) the need to control interfaces between persons involved in the design and development process; g) the need for involvement of customers and users in the design and development process; h) the requirements for subsequent provision of products and services; i) the level of control expected for the design and development process by customers and other relevant interested parties; j) the documented information needed to demonstrate that design and development requirements have been met.	
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.	N/A
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	N/A

	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.	
VST Ltd ISO9001:2015 8.3.5	**Design and development outputs** The organization shall ensure that design and development outputs: a) meet the input requirements; b) are adequate for the subsequent processes for the provision of products and services; c) include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria; d) specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision. The organization shall retain documented information on design and development outputs.	N/A
VST Ltd ISO9001:2015 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 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.	N/A
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	N/A

	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	
VST Ltd ISO9001:2015 8.6	**Release of products and services** The organization shall implement planned arrangements, at appropriate stages, to verify that the product and service requirements have been met. The release of products and services to the customer shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and, as applicable, by the customer. The organization shall retain documented information on the release of products and services. The documented information shall include: a) evidence of conformity with the acceptance criteria; b) traceability to the person(s) authorizing the release	
Viamed Ltd ISO13485:2016 4.2.3 Medical device file	**Documentation requirements** IT480 Technical files index For each medical device type or medical device family, the organization shall establish and maintain one or more files either containing or referencing documents generated to demonstrate conformity with the requirement of this International Standard and compliance with applicable regulatory requirements. The content of the file(s) shall include, but is not limited to: a) general description of the medical device, intended use/purpose, and labelling, including any instructions for use; F1- ID140046, F7, FS-ID15571 b) specifications for product; M3- ID23855, ID15373 c) specifications or procedures for manufacturing, packaging, storage, handling and distribution; VOP7. F7 on label d) procedures for measuring and monitoring; - QA ID25360 e) as appropriate, requirements for installation; — N/A - not installed f) as appropriate, procedures for servicing. — ID22120	
Viamed Ltd ISO13485:2016	**Planning of product realization** The organization shall plan and develop the processes needed for	

7.1	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.	Issue #1150 88 QC 22 Reword Initial Risk QA Forms Vops per product VOP 18 QA, Barcodes KM3, QA Forms per product ID2465 ID2446 validation Replaced QC 30. Different level process. old project
Viamed Ltd ISO13485:2016 7.3.1	**General** The organization shall document procedures for design and development	
Viamed Ltd ISO13485:2016 7.3.10	**Design and development files** The organization shall maintain a design and development file for each medical device type or medical device family. This file shall include or reference records generated to demonstrate conformity to the requirements for design and development and records for design and development changes.	Tech files Y, Z yes
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	Y, Z adding stages VOP 17 Issue #115092 VOP 17*QC30 Y1 Y7 Y16 QC24

*1 Project product development Check list admin

	appropriate at each design and development stage; QC30 Stages d) the responsibilities and authorities for design and development; Doc Id 7742 e) the methods to ensure traceability of design and development outputs to design and development inputs; project manager QC30 f) the resources needed including necessary competence of personnel VOP02	
Viamed Ltd ISO13485:2016 7.3.3	**Design and development inputs** Inputs relating to product requirements shall be determined and records maintained (see 4.2.5). These inputs shall include: a) functional, performance, usability and safety requirements, according to the intended use; QC30 #11509Z Issue b) applicable regulatory requirements and standards; 4D c) applicable output(s) of risk management; QC30 d) as appropriate, information derived from previous similar designs; 12R e) other requirements essential for design and development of the product and processes. QC30 These inputs shall be reviewed for adequacy and approved. Requirements shall be complete, unambiguous, able to be verified or validated, and not in conflict with each other. NOTE Further information can be found in IEC 62366–1.	QC30
Viamed Ltd ISO13485:2016 7.3.4	**Design and development outputs** Design and development outputs shall: a) meet the input requirements for design and development; QC30, QC22 b) provide appropriate information for purchasing, production and service provision; purchasing technical files T1, U1, R1, M5, M4 c) contain or reference product acceptance criteria; QC30B - verification + validation Doc Id 2399Z d) specify the characteristics of the product that are essential for its safe and proper use. QC22 The outputs of design and development shall be in a form suitable for verification against the design and development inputs and shall be approved prior to release. QA System QC30 validation Records of the design and development outputs shall be maintained (see 4.2.5). VOP17	
Viamed Ltd ISO13485:2016 7.3.5	**Design and development review** At suitable stages, systematic reviews of design and development shall be performed in accordance with planned and documented arrangements to: a) evaluate the ability of the results of design and development to meet requirements; QC30 b) identify and propose necessary actions. issues Participants in such reviews shall include representatives of functions concerned with the design and development stage being reviewed, as well as other specialist personnel.	QC28B QC28 Y14 email, intrastate Reviews undertaken where needed

	Records of the results of the reviews and any necessary actions shall be maintained and include the identification of the design under review, the participants involved and the date of the review (see 4.2.5).	Intrastats
Viamed Ltd ISO13485:2016 7.3.7	**Design and development validation** Issue #82097 Clinical Review Carried out VOP17 Design and development validation shall be performed in accordance with planned and documented arrangements to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use. The organization shall document validation plans that include methods, acceptance criteria, and, as appropriate, statistical techniques with rationale for sample size. Design validation shall be conducted on representative product. Representative product includes initial production units, batches or their equivalents. The rationale for the choice of product used for validation shall be recorded (see 4.2.5). As part of design and development validation, the organization shall perform clinical evaluations or performance evaluations of the medical device in accordance with applicable regulatory requirements. A medical device used for clinical evaluation or performance evaluation is not considered to be released for use to the customer. If the intended use requires that the medical device be connected to, or have an interface with, other medical device(s), validation shall include confirmation that the requirements for the specified application or intended use have been met when so connected or interfaced. Validation shall be completed prior to release for use of the product to the customer. Records of the results and conclusion of validation and necessary actions shall be maintained (see 4.2.4 and 4.2.5).	Y15, Y19, Y16 H3.27 H4.1 Section 7.3.6 needs adding QC30 Doch added ✓
Viamed Ltd ISO13485:2016 7.3.8	**Design and development transfer** Document to be added JSL. The organization shall document procedures for transfer of design and development outputs to manufacturing. These procedures shall ensure that design and development outputs are verified as suitable for manufacturing before becoming final production specifications and that production capability can meet product requirements. Results and conclusions of the transfer shall be recorded (see 4.2.5).	J11, J5, Y11, Y11.1, F3 F4, F6, F7, G1, S6, J52, J7, M3, M4
Viamed Ltd ISO13485:2016 7.3.9	**Control of design and development changes** The organization shall document procedures to control design and development changes. The organization shall determine the significance of the change to function, performance, usability, safety and applicable regulatory requirements for the medical device and its intended use. Design and development changes shall be identified. Before	QC28B Issue #115187

	implementation, the changes shall be: a) reviewed; b) verified; c) validated, as appropriate; d) approved. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product in process or already delivered, inputs or outputs of risk management and product realization processes. Records of changes, their review and any necessary actions shall be maintained (see 4.2.5).	
Viamed Ltd ISO13485:2016 7.5.6	**Validation of processes for production and service provision** The organization shall validate any processes for production and service provision where the resulting output cannot be or is not verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered. Validation shall demonstrate the ability of these processes to achieve planned results consistently. The organization shall document procedures for validation of processes including: a) defined criteria for review and approval of the processes; b) equipment qualification and qualification of personnel; c) use of specific methods, procedures and acceptance criteria; d) as appropriate, statistical techniques with rationale for sample sizes e) requirements for records (see 4.2.5); f) revalidation, including criteria for revalidation; g) approval of changes to the processes. The organization shall document procedures for the validation of the application of computer software used in production and service provision. Such software applications shall be validated prior to initial use and, as appropriate, after changes to such software or its application. The specific approach and activities associated with software validation and revalidation shall be proportionate to the risk associated with the use of the software including the effect on the ability of the product to conform to specifications. Records of the results and conclusion of validation and necessary actions from the validation shall be maintained (see 4.2.4 and 4.2.5).	We QA everything QC30 VOP 17 issue #115092

Question	Response	Y/N
Check that the final design responsibility is a Sole Authority. Top management	VOP 17	Y
Check that all products are C.E. marked and Viamed products have a C.E. file. Intrastats	Tom Thumb Microstim	Y Y
Pick 5 Products from the Files product list	Only two ClassIIa	Y
Declaration on Conformance Certificates present	Tom Thumb Doc ID 19534 Microstim Doc ID 15383	Y Y
Verify that EMC testing has been identified where required.	Tom Thumb DocId 2176 Microstim Docid 22327, 1017, 1634, 1635, 3280, 15602, 3445	Y
Are the latest BS ISO MDD, CMDCAS requirements are available List DOCIDS	BS EN ISO 13485-2016 Document ID / Version Control #19400 BS EN ISO 9001:2015 Document ID / Version Control #16229 Council Directive 2007 47 EC European Parliament MDD Document ID / Version Control #6108 No longer used - CMDCAS Canadian Medical Devices Regulations Document ID / Version Control #1693	Y
Check that product classification is done to MDD, CMDCAS principles.	D1 D2 in the technical	Y
Verify that each design was initiated from a job description & specification		Y
Has each design has received a job number and a job progress form	QC25, Y8	Y
Verify the existence of a design documentation check list.	QC22	Y
Check that estimated times have been noted. Electronic timing being introduced	Y5	Y
Have final testing requirements, and test criteria, been identified	Y18, Z1	Y
Have concession notes have been raised on non-approved suppliers	N/A	
Check that current status is identified on a regular basis.	NO DESIGN IN PROGRESS	
Verify that design reviews are undertaken and that records are retained	Y16	Y
Check that any amendments to design are logged	Y16	Y
Check that design output records are verified against design input	QC 30 Design inputs Outputs Validations	Y
Does design verification comply with COP 16 - 7.7.1 - .4	Q 30	Y
Check that clinical trials have been carried out and relevant records retained	H3	Y
Verify that design validation has been carried out as required by form QC30	Y15, QC30, QC30b	
Check that any design changes have been identified, recorded and approved	Y14	Y
Have risk analysis has been carried out and recorded at all relevant stages	E3, E4, E5, E11	Y

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Check that CE files are complete, correct and maintained		Y
Are design components kept separate from stock and adequately stored	R&D boxes	Y
Are design component stocks labelled		Y
Check the existence of design compliance forms	Docid 2997 Y6	Y
Check that these files are maintained		Y
Auditor Helen lamb	Date 26th February 2018	
General Comments : Currently only two Class IIa products covered by ISO13485 Tom Thumb and Microstim		

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Design			
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ISO Controller

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID **5887** To Keep Products and Services up-to date with current regulations and standards	235 Managing Director		Freq 2 Risk 2 Overall 4	Task 3M	~~#103637~~ not completed later issue #110916 done rest done

Product Controller

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID **7045**	50 Managing Director		Freq Risk Overall	Task 2M	done #112354 ✓

Audits

Process Scope	Roll Task	Roll Audit	Risk	Action	Notes / Issues
PROCESSID **7716** To carry out Audit 03 Design Control Viamed		22 Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M	#111148 re this Audit
PROCESSID **7764** To carry out Audit 03 Design Control VST		193 Company Secretary	Freq 1 Risk 2 Overall 2	Audit 12M	#111166 re this Audit ✓ VST No Design. Remove