VOP
Operating Sub Process
Personnel, Responsibility, Roles and Tasks

Created:	27/03/06	VOP 02	**Issue 1**
Revised:	04 September 2018	Viamed Ltd ISO13485:2016: 5.1 , 5.5.1 ,5.5 ,5.5.2 ,6.2 ,6.1 VST Ltd ISO9001:2015: 5.3 ,5.1.1 , 7.2 ,7.3 ,8.5.1	Page 1 of 6

SCOPE

This procedure is established to describe the system used within the company for the Personnel, Responsibility, HR Staff and Staffing Issue, Training, Roles and Tasks. It is used in conjunction with the individual sub procedures, which show the relevant information necessary.

RESPONSIBILITIES

It is the responsibility of the Managing Director, to ensure that the contents of this procedure, and related procedures, are adhered to. He has the ultimate responsibility for directing and co-ordinating all company policies and therefore for ensuring that appropriate systems and procedures are in operation for the success of the Quality Assurance Programme. He is the Management Representative, as required by ISO 9001:2015 and ISO 13485:2016, and is responsible for ensuring that everyone in the organisation accepts and meets their responsibilities for satisfactory quality attainment. He is responsible for communicating the importance of an effective quality management.

To Review the Scope of the ISO 9001 / ISO 13485 Standards, accountable for the effectiveness of the QMS, reviews the Quality Policies for Viamed and VST, management commitment to ISO Responsibility, ISO System Management Review and review of latest version Med Dev 2.12. To review the risks and opportunities of external interested parties and how they effect the procedures and the scope of the company.

He allocates staff in the roles and responsibilities, tasks and processes. Allocating area controllers responsible for reporting to top management on the effectiveness of the system and its underlying processes. Responsible for the documentation control as per VOP 01, MDALL Listings, that the Insurance is up to date, the Audits up to date and Confirm next years Audit schedule.

Also the Business Continuity Plan, Disaster Planning. Review Company Data Responsibility, Customer Complaints, Complaints and Vigilance Notifications, Corrective Actions Responsibility, Calibration Index and Non Conformance Issues Any New QC21.

He is responsible for ensuring that there are adequate resources and capable personnel to effectively carry out all necessary verification activities. For the control and maintenance of the Quality and Procedures Manual. For Management Reviews and has responsible for Audits and maintains the Approved Supplier List.

He is responsible with the Financial Controller for purchasing. They is responsible for insuring that there are adequate resources and capable personnel to effectively carry out all necessary process activities.
He is also responsible for CMDCAS updates, licences including MDALL product listings http://www.hc-sc.gc.ca/dhp-mps/md-im/licen/mdlic-eng.php and submitting Certificate updates within 30 day.
He is responsible for notifications to notified body's of system changes and is responsible for MHRA, notifications should they be required.

ROLES AND RESPONSIBILITIES
ISO Controller
The ISO Controller is responsible for compliance to ISO Standards, Supplier Review, Non Conformance Issues and Non Conformance Effectiveness.

Accounts Controller
The Accounts Controller is responsible to the Managing Director for all financial matters and also has the following quality duties, Overall responsibility for processing customer quotations, purchasing functions, Carrying out quality audits (with the Managing Director), controlling supplier documentation.
For all the financial matters affecting the company. Including debtors, creditors, wages, banking and VAT.

Directors
The Directors are responsible for directing and co-coordinating the day-to-day operations of the business, and therefore ensuring that all personnel abide by the dictates of the company Health and Safety policy. They are also responsible for the sales and purchasing functions and will also, with the Managing Director, ensure that there are adequate resources available for the company to perform to its best capability.

IT Controller
The IT Controller is responsible for the company's software and hardware requirements and is also responsible for the purchasing functions, for ensuring that adequate resources are available and ergonomic practices are followed. Website technical maintenance, internal telephone and internet provision, off site backup of company data and software validation of internal QMS processes.

Health And Safety Controller
The Health And Safety Controller is responsible for the fire alarm, fire alarm maintenance, emergency lights, fire extinguisher, evacuation drill, first aider, first aid boxes, accident book, review of the accident book and Risk Assessment HSE.

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Maintenance Controller
The Maintenance Controller is responsible for the general maintenance of the buildings and infrastructure.

HR Controller
Is responsible for the employment of staff, processing CVs, interviewing, upholding employment law, maintaining staff, contracts, paperwork, discipline and grievances. The general health and well being of all staff, support to them when needed. Training internal and external, arranging training when needed, maintaining of the training manager. For training see VM3COP12. Keeping the staff training records up to date.

Looking after sick, holidays, parental leave, appraisals, working hours, working conditions, conflict management,
Contacting the accountants regarding pays and managing the pensions.
Alarm Key Holders, Working Environment and 7.1.4 Environment Of Operations.

Office Controller
The Office Controller is responsible for the day-to-day sales processing, Sales Order , office tasks and dealing with suppliers. For the processes carried out by the office. Assisting customers with enquiries, taking customer orders, entering orders on to the accounts package and Intrastats, checking orders, quote and proformas, filing of documentation. The customer database updates, purchase back orders review.

Warehouse Controller
The Warehouse Controller responsible for control of all dispatch processes affecting products and / or service. All incoming stock and day-today running of the warehouse. The writing of instrument check procedures and checklists. Maintaining up-to-date manufacturers or suppliers.
Purchase order requirements, supplier review – outstanding orders, quarantine production responsibility, quarantine repairs, returns stock report, current stock levels, current repairs, production requirements, control of nonconforming product, goods in processes, goods out processes, the clear identification and despatch of orders.

Technical Support Controller
The Technical Controller is responsible for Quality Assurance, repairs, maintaining up-to-date manufacturers or suppliers catalogues/technical data sheets. Investigating customer complaints/warranty claims and the recall of suspect product procedure and Calibration of test equipment.

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Controlling the work of the Technicians. Who quality assurance of incoming products requiring 'low level' testing, quarantining and labelling non conforming products, packaging, labelling, testing and placing products in the appropriate stock location.

Also responsible for the production and repair of products passing through the workshop, the control of all personnel under his control and the control of the working environment and resources.

Engineers are responsible to the Technical Manager the repair and maintenance activity, technical investigation of non conforming products, customer complaints/warranty claims, quality assurance of incoming product and after repair. Servicing of demonstration instruments.

QA Controller
The QA Controller is responsible for the QA functions with regard to the inspection of incoming products for stock and the function and safety testing of repaired items, minor repairs of instruments, the movement of stock that has been through QA to the correct location, storage and identification of products and the quarantining of non conforming products.

Product Controller
Product Controller is responsible for price checking, product details and information, projects, product Document requirements, manufacturing Processes, yearly Pricing Review and on site environment review (product based).

Marketing Controller
The Marketing Controller is responsible for mail shots, mailing lists, mailshot calendar,.

Sales Controller
The Sales Personnel are responsible to the Managing Director for visits to customers / potential customers as necessary to assist and advise the customer on the use of products, following up customer enquiries and quotations, customer complaints and minor repairs and maintaining regular contact with key customers. Service existing responsibility, sales responsibility, customer pricing agreements and distributor agreements.

All personnel not listed above are responsible for performing the tasks allocated to them, and for complying with the specific procedures for their job functions. They are also responsible for the general upkeep and tidiness of their tools and working areas.

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All of the Controllers are responsible to the Managing Director

Training
Refer to VM3COP12.

HUMAN RESOURCES AND STAFFING
Job descriptions and roles will be written by the Managing Director for all staff whose activities could affect quality.

Newcomers will be given Induction training, product training and training in procedures. All service engineers will be suitably qualified and trained to meet standards of workmanship set out in manufacturer's installation instructions, Viamed procedures and codes of practice.

Technicians are assigned to elementary stages of their job function until they are competent. Training will also be carried out at manufacturers premises on product specifications and servicing. Alternatively, manufacturers will be invited to carry out training at Viamed when appropriate eg. new product line or periodically with users representatives.

Where there is any shortfall on skills/experience, a training programme will be drawn up for that individual ,by the Managing Director. This programme will identify basic skills required, equipment familiarisation needed and procedures required to be learnt, including test procedures and use of test and calibration equipment.

A Training Record (Form QC16) will be used to record all training carried out either at Viamed, equipment manufacturers or outside agencies. The Intrastats staff admin form will be signed off after training and reviewed monthly. Training requirements will be examined at the management review. Then updated and assessed by the Managing Director at least once per year the managing director will assess the effectiveness of training and amend the training programmes as necessary.

For Responsibilities to End Level Employees Use Intrastats, Employee Menu.
For Complete List See:
Employee Roles and Titles → Roles Titles Processes and Procedures ADMIN   - click Overview for complete break down.

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For Individual Employee
Admin Employee → Admin Employee → Select Employee and Click the Roles Link