

<p style="text-align: center;">VOP</p> <p style="text-align: center;">Operating Sub Process</p> <p style="text-align: center;"><u>Personnel and Responsibilities, Staff and Staffing Issues, Training, Roles and Tasks</u></p>			
Created:	27/03/06	VOP 02	Issue 1
		See the Route Map for related ISO Standards.	Page 1 of 7

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.

The Managing Director 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 effective quality management, to review the scope of the ISO 9001 and ISO 13485 Standards. Be accountable for the effectiveness of the QMS system, reviews the Quality Policies for Viamed and Vandagraph Sensor Technologies (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.

To assess the Risks throughout the companies and their processes. To make sure all risks are assessed and are as low as they possibly can be.

The Managing Director 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, its underlying processes and any risks.

The Managing Director is responsible for the documentation control as per VOP 01. That the Product Liability and Company Insurance is up to date, the Audits are up to date and has confirmed with the Board of Directors that next years Audit schedule is agreed to and signed off.

He is responsible for the Business Continuity Plan, Disaster Planning, Review of Company Data Responsibility, Customer Complaints, Complaints and Vigilance Notifications, Corrective Actions Responsibility, Calibration Index and Non Conformance Issues and any new QC21.

<p style="text-align: center;">VOP</p> <p style="text-align: center;">Operating Sub Process</p> <p style="text-align: center;"><u>Personnel and Responsibilities, Staff and Staffing Issues, Training, Roles and Tasks</u></p>			
Created:	27/03/06	VOP 02	Issue 1
		See the Route Map for related ISO Standards.	Page 2 of 7

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 responsibility for the Audits and maintaining the Approved Supplier List.

He is responsible with the Financial Controller for purchasing. They are responsible for insuring that there are adequate Resources and capable personnel to effectively carry out all necessary process activities.

He is also responsible for, where needed 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 Significant System Changes and is responsible for MHRA, notifications should they be required.

OBJECTIVES

It is the Objective of this VOP to demonstrate the processes involved, in the companies, in relation to the roles of staff and their responsibilities.

How we assess them for effectiveness Risk and who has responsibility for what roles and who is ultimately responsible.

ROLES AND RESPONSIBILITIES

ISO Controller

The ISO Controller is responsible to the Managing Director and responsible for compliance to ISO Standards, Supplier Review, Non Conformance Issues and Non Conformance Effectiveness, Feedback, Risk Assessment, review of Resources Required and specifying Objectives. Ensuring the quality audits are carried appropriately out by a qualified / experienced suitable impartial member of staff. Has overall responsibility for customer complaints, feedback and QA monitoring.

Accounts Controller

The Accounts Controller is responsible to the Managing Director for all financial matters and also has the following quality duties. For all the financial matters affecting the company. Including debtors, creditors, wages, banking and VAT. Customs Activities. Overall responsibility for processing customer sales and quotations. Reporting any changes to risks or effectiveness to the Managing Director in relation to the above.

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, and company procedures. They are also responsible for the sales and purchasing functions and will also, with

<p style="text-align: center;">VOP</p> <p style="text-align: center;">Operating Sub Process</p> <p style="text-align: center;"><u>Personnel and Responsibilities, Staff and Staffing Issues, Training, Roles and Tasks</u></p>			
Created:	27/03/06	VOP 02	Issue 1
		See the Route Map for related ISO Standards.	Page 3 of 7

the Managing Director, ensure that there are adequate resources available for the company to perform to its best capability. They are also responsible for reporting any changes to risks or effectiveness to the Managing Director in relation to the above, or in any other areas they feel need to be reviewed.

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, software validation of internal QMS processes and Cyber Security. The IT Controller is also responsible for reporting any changes to risks or effectiveness to the Managing Director in relation to any of the above responsibilities.

Health And Safety Controller

The Health And Safety Controller is responsible for the fire alarm and fire alarm maintenance, emergency lights and emergency lights maintenance, fire extinguisher and fire extinguisher maintenance, evacuation drill, first aider and monitoring First aider training, first aid boxes and them being kept up to date, accident book, review of the accident book and Risk Assessment HSE. The Health And Safety Controller is also responsible for reporting any changes to risks or effectiveness in relation to any of the above responsibilities, to the Managing Director.

Maintenance Controller

The Maintenance Controller is responsible for the general maintenance of the buildings and infrastructure. With the approval of the board, initiating works were needed and monitoring said works. The Maintenance Controller is also responsible for reporting any changes to risks or effectiveness to the Managing Director in relation to any of the above responsibilities.

Human Resources 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 VOP 12. Keeping the staff training records up to date.

Ensuring GDPR rules are followed.

Looking after sick, holidays, maternity and parental leave, appraisals, working hours, working conditions, conflict management.

Contacting the accountants regarding pays and managing the pensions.

<p style="text-align: center;">VOP</p> <p style="text-align: center;">Operating Sub Process</p> <p style="text-align: center;"><u>Personnel and Responsibilities, Staff and Staffing Issues, Training, Roles and Tasks</u></p>			
Created:	27/03/06	VOP 02	Issue 1
		See the Route Map for related ISO Standards.	Page 4 of 7

Monitoring Alarm Key Holders, Working Environment and 7.1.4 Environment Of Operations.

The Human Resources Controller is also responsible for reporting any changes to risks or effectiveness, to the Managing Director, in relation to any of the above responsibilities.

Office Team Leader

The Office Team Leader 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 in to Intrastats, checking orders, quote and proformas, filing of documentation. The customer database updates, purchase back orders review.

The Office Team Leader is also responsible for reporting any changes to risks or effectiveness to the Managing Director in relation to any of the above responsibilities.

Warehouse Team Leader

The Warehouse Team Leader 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.

The Warehouse Team Leader also responsible for reporting any changes to risks or effectiveness to the Managing Director in relation to any of the above responsibilities.

QA Controller and Technical Support Controller

The QA Controller and Technical Support 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. Maintains the Calibration Index of test equipment.

Controlling the work of the Technicians.

Packaging, labelling, testing and placing products in the appropriate stock location. The quality assurance of incoming products, QA monitoring, quarantining and labelling non conforming products.

<p style="text-align: center;">VOP</p> <p style="text-align: center;">Operating Sub Process</p> <p style="text-align: center;"><u>Personnel and Responsibilities, Staff and Staffing Issues, Training, Roles and Tasks</u></p>			
Created:	27/03/06	VOP 02	Issue 1
		See the Route Map for related ISO Standards.	Page 5 of 7

Also responsible for the repair and production 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.

The QA Controller and Technical Support Controller is responsible for the QA functions with regards 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.

The QA Controller and Technical Support Controller is also responsible for reporting any changes to risks or effectiveness, to the Managing Director, in relation to any of the above responsibilities.

Product Controller

The Product Controller is responsible for price checking, product details and information, projects, product documentation requirements, manufacturing processes, yearly pricing review and on site environment review (product based). Purchasing functions and controlling supplier documentation.

The Product Controller is also responsible for reporting any changes to risks or effectiveness to the Managing Director in relation to any of the above responsibilities.

Marketing Controller

The Marketing Controller is responsible for mail shots, mailing lists, mailshot calendar, online web shop and web site.

The Marketing Controller is also responsible for reporting any changes to risks or effectiveness to the Managing Director in relation to any of the above responsibilities.

Sales Controller

The Sales Controller is 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.

The Sales Controller is also responsible for reporting any changes to risks or effectiveness to the Managing Director in relation to any of the above responsibilities.

<p style="text-align: center;">VOP</p> <p style="text-align: center;">Operating Sub Process</p> <p style="text-align: center;"><u>Personnel and Responsibilities, Staff and Staffing Issues, Training, Roles and Tasks</u></p>			
Created:	27/03/06	VOP 02	Issue 1
		See the Route Map for related ISO Standards.	Page 6 of 7

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.

All of the Controllers are responsible to the Managing Director. For their areas, for assessing the risk in their areas and the effectiveness of their staff and associated risk in their areas, processes and roles in their areas.

Training

Refer to VOP 12.

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. These will all be recorded in the training Records. 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, VST, 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, if any risks are identified at the time, these will be highlighted and addressed.

For Responsibilities to end level Employees use Intrastats, Employee Menu.

<p style="text-align: center;">VOP</p> <p style="text-align: center;">Operating Sub Process</p> <p style="text-align: center;"><u>Personnel and Responsibilities, Staff and Staffing Issues, Training, Roles and Tasks</u></p>			
Created:	27/03/06	VOP 02	Issue 1
		See the Route Map for related ISO Standards.	Page 7 of 7

For Complete List See:

Employee Roles and Titles → Roles Titles Processes and Procedures ADMIN - click Overview for complete break down.

For Individual Employee

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

In the event that a member of staff is absent from work. The person covering their role, is able to carry out the task as well as complete the audit task. It is expected this will be for a limited time. If this absence is going to be prolonged, the task will be reassigned to another user.

EFFECTIVENESS

Effectiveness of staff is assessed by regular meetings with supervisory staff, in the form of office and warehouse reviews, these can be face to face or over Zoom.

Staff effectiveness will be monitored through the Roles and Tasks system where areas of concern can be flagged up, monitored and reviewed.

Review of issues pertaining to staff and their effectiveness within the company and the processes they use and are part of. Including the non conformance review of errors and issues. Annual appraisals when possible depending on any national or international crisis, e.g. Covid 19 pandemic. Management Review and Board meetings.

Effectiveness of training is assessed by regular meetings and communications with supervisory staff, in the form of office and warehouse reviews. Discussing requirements and performance where relevant. Review of issues pertaining to staff and their effectiveness within the company and which refer to training gaps or training that may not have been fully effective.

The effectiveness of staff training can be monitored through the Roles and Tasks system where areas of concern can be flagged up, monitored and reviewed.

Training is discussed in the Annual appraisals, done when and where possible depending on any national or international crisis, e.g. Covid 19 pandemic. The Effectiveness of training is reviewed in the Management Review and Board meetings.

Effectiveness of the systems is assessed by regular meetings with supervisory staff, in the form of office and warehouse reviews. Discussing requirements and performance of the system. Review of issues pertaining to the system and their effectiveness within the company errors and issues. These may refer to gaps or areas that may not be fully effective. The systems are discussed in the Management Review and Board meetings, where any risk and effectiveness is reviewed.