

Intrastats

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The Processes, documentation and records are now moving to be electronic in preference to failure. Massive failures of the server systems due to outside forces and the speedy re-installation without loss of data and the holding of off-site backups has been proven.

This is based on a system of electronic databases linked to frequently held “Management meetings.” The term meetings can be one person following up one item on the agenda. This updated item will become available at the next management meeting.

There are fixed meetings held regularly

Stock Meeting

Sales & Marketing Meeting

Project Meeting

There are sub meetings which can be part of any of the above or can be isolated and held separately. When held separately they are available for viewing either by individuals who can re-act to issues raised or they can become part of one of the main meeting

Issues raised can only be cleared by the initiator signalling they are satisfied with the answer given. Failure to close an issue allows that issue to remain open and be presented at subsequent meetings until it is cleared

See Intrastat Charts

Compliance with Standards

Each clause of the required standard ISO, MDD, CND CAS etc is linked electronically to the relevant documents or records.

e.g

- 6.2.2d All employees will be made aware, during their induction, of their contribution to, and the importance of, their activities within the company’s system.

VOP/12 QC40 HS 01 Induction

- 6.2.2e A Training Record will be raised for each employee, which details the training, which has been provided and will be signed on satisfactory completion.

Training will be planned, carried out and recorded in accordance with company operating Procedure, **VM/COP/12.**

By choosing 6.2.2d the operator is presented with the option of viewing

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The sub process the company employs for training VOP/12
The procedure VM3/COP/12
The training record
The guidance document QC40 HS01 Induction
Training record form QC07
And the training audit Audit 16

Some of these documents can be updated by the user most are read only

Interacting with the system

All employees can interact with the system from there own workstation or any other workstation in the company, Remote access from outside the company can be made available

e.g.

They can select the section Training

View their personal Training record QC07 and update it or correct it

The interaction is permanently recorded and logged against the user who accessed it via passwords

Documentation

Documents are either created in a word processor e.g. Word or an equivalent.

Read only documents are preferably P.D.F but can be photographic or scanned documents.

The electronic library is Folder/Directory L:/ where documents are stored in P.D.F.

Original documents are stored in Folder/Directory S:/ in their original format

This can be Word processing, Spreadsheets, or Databases

Every live as opposed to read only document in S:/ is dated when last opened

Records

Records are kept of all interactions

Hard copies of records can be created when required by all users at most workstations

Audits

Audits are timed controlled and are flagged at weekly meetings

The auditor is chosen and informed

He/she has access to the Audit , Procedures ,Audit advisory documents

When the audit is complete it is recorded and NCF any non-conformances noted.

At the next management meeting the audit will be either

Left open

Marked as complete

Non-conformances will be viewed and added to the NCF file.

This is available for viewing and all management meetings and can only be closed by Being completed

Actions minuted

Signed off by meeting

The history of NCF's is held centrally and can be accessed at any time.

Many audits by an individual auditor are now becoming superfluous as audits can be executed more regularly , by a group

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e.g.

Suppliers need to supply Viamed with certain documentation including but not restricted to ISO certification.

CE information

FDA information

This can be reviewed regularly as out of date information flags RED.

The supplier is emailed and submits the information in PDF format automatically into the system.

Old versions are archived and retained indefinitely.

Meetings / Issues

The term meeting does not necessarily imply several people sitting around a table discussing in real time.

A Viamed meeting can be one person reacting to the system and completing or advancing an outstanding issue.

There are many issues, which occur in day to day execution of processes that require another person or sections input.

These can be added to a general issue for discussion at a future meeting or can be a specific issue raised with only one or more persons. These issues are logged and documented.

It is the aim to document all meetings and interactions (classed as meetings) in order to document and record topics discussed and decisions made.

The minutes and records record the progress of any decisions taken

Several main meetings are held weekly and are designated Management meetings

Management Meetings

Management meetings are held at least week/monthly under the titles

Stock

Production

Sales & Marketing

Projects

These meetings have a basic fixed agenda and decisions of past meetings are available and outstanding issues can be called up discussed and reviewed

They are interlinked e.g. so that during a stock meeting for example NCF's and customer complaints can be viewed, discussed and progressed

All other meetings can also visit the NCF's and check on updates or actually update

All changes are minuted, identified and recorded

Processes requiring Routine attention

All processes that require routine attention e.g.

Training: Audits: Supplier documentation: Maintenance: are flagged in Red once an expiry date has passed

e.g.

Suppliers need to have up to date certification.

All New suppliers are automatically added to the Suppliers register in RED

If they do not require grading or certification they are tagged and change to Grey

Each Supplier has the following possible requirements amongst others

ISO9000

EN46001

ISO13485:2003

CE Certification

These will be flagged RED

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When the information is received it is dated and the flag turns Grey until the expiry date is exceeded.

This can be used for all processes that must be viewed and examined on a regular basis. Although always available at every meeting the meeting can decide to skip the topic and not discuss it.

The time period a topic has not been reviewed is presented to the meeting

When it is opened all outstanding issues on that subject are made accessible

Statistics

A range of statistics is available continuously e.g .Turnover, Outstanding orders, repairs

Follow up actions

Many processes require follow up action

These topics can be called up as part of another meeting

e.g. A fall in sales could be related to NCF's of product

or they can be separate meetings

Process Procedures for Production/Repair/QA/Administration

All processes in the company from Administration to Repair may have detailed procedures and instructions. These are held in PDF and can be accessed by all personnel at the workstation. They cannot be modified. Hard copies can be taken and hand modified for future changes to the procedure or process

All company documentation is available through the same channels including

Company manual

HSE

Reference documentation

Linked processes

As the processes throughout the organisation are linked and interrelated "Intrastats" has similarly been linked with interrelating processes e.g.

Telephone enquiries can now call up

Customer data

Customer buying history

Current stock levels

Current prices

Technical and sales data on the products being requested

This can also be linked to current and historical repairs and customer problems