VM3COP01.2
Historic Documents & Records

ISO 9001, ISO 13485 and the MDD Council Directive 93/42/EEC including many of its derivatives require a document and/or a record.

Historically

The documents and records were located in Red Binders (still available)
With the advent of Paperport documents were scanned filed in Paperport files and transferred regularly to CD's
ID Doc 2167
ID Doc 2168
ID Doc 9017
ID Doc 3760
ID Doc 9565
ID Doc 9690

Paperport is an electronic filing and storage system.
Imagine a Filing cabinet with drawers and individual files.
Some files can be opened by anyone in the company others are restricted.
In Paperport the files open to all start with a letter (A)
Electronically there can be more levels of filing than in a paper system
e.g.
Take ISO.
All our ISO files are found (D) ISO Information   Level 1
There can be many or few major groups of files in Level 1
In the ISO system we will usually have 6 or 7
(D) BSI information   This contains basic information on BSI
(D) ISO Quality Manual   This contains the latest and most current Viamed company Quality manual
(D) ISO EN Documentation   This contains the actual BS : EN ; & ISO standards
(D) ISO 9000 Current (year) This contains all the current company procedures
                    Manufacture
                    Repairs
                    Administration
                    QA procedures
                    Office procedures
                    Vandagraph procedures
(D) Management reviews   This contains the Management review minutes
(D) ISO 9000 2000 ISO 13485 This file will change its name as standards change. It the update file when the procedures are amended but are are yet included in the current procedures
All the groups (A) >> follow a similar format + means there is another level of files

New information & Upgrades

Files in an electronic system can easily be modified and erroneous information inserted without traceability. For this reason all the open Files are read only. Upgrades and new information can only be added by a director.

New information

New Information should be scanned into pp update

Upgrades

To upgrade a file first duplicate it in Paperport
Add a postnote with the modification or highlight the errors and add text.
Print the modified page to Paperport either black & white or colour.

CHECK The graphic is set to 200 dpi or 300 dpi

Once the information is in Paperport duplicate the documents as paperports documents, stack, rename, and delete the original image.
Most the product files available on CD are still available as backups.
New CD's or DVD's can be made from existing Paperport files.

Personal Filing
Every member of the staff who has a need to store information has a Folder on T drive.
These are backed up regularly and stored in remote locations.
Documentation can be printed out to be used on <u>a once only basis</u>. Any modifications can be added by the user but must then be submitted for confirmation and updating by senior personnel into the system.

Intrastats
Itrastats program was written to solve an EU Intrastat requirement of regularly documenting sales for EU & Non EU areas.
The success of this program led to the expansion, to include documentation and procedures etc.
It soon became obvious that "Intrastats" could Document, Record, and control the main elements required by the company. It not only includes QMS but also HSE. Marketing & Sales etc.

Co-incidentally with the introduction of "Intrastats " documentation and communication by email become the norm. All the communications are records stored in either system. They are recoverable even though Goldmine our Contact and communication system was outgrown and emails were replaced with Gmail.

Paper records for this era do not necessarily exist. Some of the important documents have been converted into Intrastats for speedy delivery to the MHRA as samples if an incident ever occurred.

Conclusion

The original documents are still in existence. The Intratsat system is a live evolving system that is paper free.
ID Doc 21696

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