exceptional circumstances should a document be manually signed.

The vast majority of markets and customers will accept an electronically signed document.

5.4 Exchange of Certificates between QA units

When materials are made at one manufacturing site and then shipped to another site, for further processing, two key pieces of information must be transferred between the QA units of the sites involved:

The analytical results.

The confirmation that the batch has been made in full compliance with GMP and Marketing Authorization/ NDA requirements.

Analysis of the drug substance or finished product usually takes place at the manufacturing site and is not repeated at the subsequent processing site.

Analytical results are transferred to the next site in the processing chain either via a Raw Material CofA for transfers of drug substance or via an Internal CofA for transfer of finished product.

The Internal CofA must not contain acceptance criteria for more than one market. If at the time of manufacture of the bulk finished product the final destination market is unknown the material should be supplied with an Internal CofA suitable for the country of the receiving packing site. Once the final destination is known and if the original Internal CofA is not suitable then a market specific Internal CofA should be requested.

The QA unit at the manufacturing site ensures manufacture has taken place according to GMP and regulatory license requirements. Confirmation of batch compliance is then given on the Raw Material CofA or the Internal CofA.

The product is suitable for use in all markets unless a market restriction applies. Any such restriction must be given on the Raw Material CofA or Internal CofA using either:

‘Suitable for use in ……..’

or

‘Marketing Authorization excludes supply to market(s)……..’

When an External CofA is required. The packing site attaches the Internal CofA to a document that links the manufacturing and packing steps. Primarily this is a document stating both the bulk batch number and the packed batch number.

Together the Internal CofA and the linking document make up the External CofA that is delivered to a customer.

Any deviations from this guideline should be justified.

5.8 Market Specific Requirements Database

MRAs are in place between the European Union and Australia, Switzerland, apan, Canada and New Zealand. The MRA CofA therefore only applies to materials supplied between these countries and the EU. Without an MRA materials should be supplied with one of the other CofA as appropriate.

