manufacturing site.

All Master Formulae are based on Chemistry, Manufacturing and Control (CMC) information registered in the markets that will be supplied with the API or formulated drug product.

In the case of products manufactured within a market for supply only to that market, i.e. local products, this CMC data may be supplied by the regulatory department of the local marketing company.

4 Responsibilities

4.1 It is the responsibility of Dossier Management Group (DMG), to produce CMC documentation that describes the manufacture and packaging of each commercial Active Pharmaceutical Ingredient (API) and formulated drug product or by a contractor on behalf of the contract giver site, that is consistent with the information approved by regulatory authorities in the markets for which the product will be supplied.

Note: CMC documentation does not include information about printed packaging components. For products manufactured within a market for supply only to that market, i.e. local products, this responsibility is with the marketing company concerned.

4.2 It is the responsibility of Dossier Management Group (DMG), to make the currently approved CMC documentation available to manufacturing sites and packaging sites, by the controlled distribution of the documents.

For products manufactured within a market for supply only to that market, i.e. local products, this responsibility is with the market concerned.

4.3 It is the responsibility of the contract giver to supply CMC information to the contractor(s) it manages.

4.4 It is the responsibility of the manufacturing sites and packaging sites to prepare local, i.e. site specific, master formulae that are consistent with the CMC documentation and use these as a basis for the creation of master batch documents.

4.5 It is the responsibility of the manufacturing sites and packaging sites to document all manufacture and packaging on batch specific copies of their master batch documents, in line with cGMP requirements and expectations.

5 Guideline

5.1 Chemistry, Manufacturing and Control (CMC) Documentation

5.1.1 Contents

Master Batch Packaging Record must be produced by e.g. photocopying or computer printing. The actual batch number must be entered on all pages of the copy.

The amount of materials for an intended quantity to be packaged must be entered on this copy. The accuracy of this copy must be confirmed. The individual responsible for preparing the batch specific copy should confirm by signing, the hard copy or by an electronically sign off if a validated computerized system is used, that the correct Master Batch Production Record has been copied/printed, that correct quantities of material and correct batch number and expiration date (if applicable) have been entered and that the copy/printout is completely legible before the Batch Production Record is given to the production department.

5.2.6.2 Use during Packaging

The guidance given in Section 5.2.5.2 is applicable to the use of batch specific copies of the Master Batch Packaging Records.

Specimens of container labels should be attached to the Batch Packaging Records, including those applied to containers used for storage and transportation of APIs, intermediates, and bulk/finished drug products.

5.3 Retention and Disposal

All Documentation identified in this Guideline falls within the definition of 'GMP Documentation' and its retention and disposal must be managed in accordance with approved procedure.

5.4 Documentation of Manufacture by means of Computerized Systems

When computerized systems are used, entirely or partly, for documentation of manufacturing the following additional prerequisites must be satisfied.

5.4.1 The instructions and recording of the manufacturing procedures must give the corresponding information as a paper-based system according to Section 5.2 above.

5.4.2 Traceability of materials used and recall of the history of the manufacturing must be equivalent to those exhibited by a paper-based system.

5.4.3 The personal responsibility for data entered into the documentation must be secured (by combination of password and identification number interlocked to each other or by other means of the same security).

5.4.4 It must not be possible to change or delete data entered into the system after the acceptance by the person entering it. Any correction thereafter must be recorded and previous entry must be readable and traceable.

