If the transfer is to another development facility, then the transfer may be less formal but nonetheless should still be documented appropriate to the stage of development and competency by the receiving site to undertake the work should be established and/or documented.

In-process control tests should be defined where necessary and methodology supplied.

For analytical testing, procedures for investigating Out of Specification results should be defined.

5.9 Responsibilities for Review/Approval/Archiving of and Packaging Documentation

Responsibilities for the preparation, review and approval of master and executed Documentation for manufacture and packaging, should be defined.

Duplication of reviews and approvals should be avoided wherever possible, for example, review of an executed batch record by QA in addition to the QA of the service provider, whether the giver site or external contractor should be only be undertaken if there are specific quality and business needs to do so.

Responsibilities for archiving of the original documentation and copies, if taken, should be defined.

5.10 Product Release

Responsibility for product release of an API or investigational product destined for R&D purposes, lies with QA. If a commercial product, released by Operations QA for sale and is to be used for R&D use, it should be released by QA. Responsibilities for release of an API intermediate, normally destined for a sales product, should be defined in the Agreement and would normally be done by Operations QA.

Within the EU where different manufacturing steps for the manufacture/assembly of an Investigational Medicinal Product are conducted at different EU sites, responsibilities of each Qualified Person for each step, as required by Annex 16 of the EU GMP, should be defined in the Agreement, which should be approved by a Qualified Person at the respective sites.

5.11 Shipment and Distribution

Requirements for shipment and distribution where appropriate, including storage conditions of the finished material (intermediate stage of an API, the API or investigational product) to its destination, whether returned to the giver site or elsewhere in the supply chain should be defined.

5.12 Reconciliation/Unused/Rejected Materials

Requirements for reconciliation of materials should be defined as appropriate.

