1 Purpose

The purpose of this procedure is to describe the process for Quality Assurance (QA) Agreement regarding the supply of active pharmaceutical ingredients, bulk formulated products, part finished packs and finished packs to be followed by a pharmaceutical operation.

The QA Agreement supports the arrangements defined within the Supply Agreement and should complement the Supply arrangement by defining the responsibility of each party regarding Quality Control and Quality Assurance.

2 Scope and Applicability

Applicable to all GMP related activities between Operations manufacturing (including packing) sites. For sites that supply other areas agreements shall be generated on a needs basis. Both bipartite and tripartite contractual relationships are covered.

Transfer of raw material and packing material between sites are not covered by this guideline.

The QA Agreements required for batch certification within the EU by a Qualified Person are included in this procedure.

3 Definitions

3.1 Quality Assurance Agreement (QA Agreement)

A written agreement covering QA aspects of manufacture between Contract Giver and Contract Acceptor that shall clearly define the roles and responsibilities of each party. If relevant it will also include the Toll Principal.

3.2 Contract Acceptor (Contractor)

A person or entity who agrees to provide a sponsor with a service, product, project or study according to the sponsor's specified requirements. The terms 'Lead Site' or 'PROCESSOR' are also used.

3.3 Contract Giver

A person or entity, who on behalf of the company, commissions a project or study, and/or supports the acquisition of a service or product. The terms 'Receiving Site' or 'BUYER' are also used.

3.4 Products

Products include API, bulk formulated product, part-finished and finished product.

4.4 It is the responsibility of each Receiving Site to support the generation and to approve QA Agreements for supply to their sites.

4.5 The Toll Centre, Lead Site and Receiving Site are responsible for representing the legal entities in the country in which they are located.

5 Procedure

5.1 Role of QA Agreement Manager

The QA Agreement manager's role must include:

(i) Generation of draft agreements with proper index code from QA.

(ii) Circulation of draft agreements for comment; e.g. Receiving Site, local Legal Affairs and Finance (including Toll) as appropriate.

(iii) Obtaining approval of the agreement from the appropriate QA managers.

(iv) Establishing local procedures for the writing, distribution, control and archiving of QA Agreements.

(v) Amending and reviewing agreements in accordance with requests from other contract parties, e.g. Service Agreements, Distribution Agreements.

(vi) Interface with the QA & dossier management co-coordinator to ensure rapid and effective resolution of issues.

(vii) Training of local staff in local procedures.

(viii) Ensuring agreements meet company's legal and regulatory obligations, e.g. tolling.

(ix) Supporting the establishment and updates of the QA-Agreement templates.

5.2 Role of QA & Dossier Management Group in Supply & Capability

The QA & DMG co-coordinator's role must include:

(i) Involving Legal Affairs Department in discussions regarding agreements.

(ii) Ownership of Information technology resource to support the QA Agreement process e.g. Lead Site web site where for example the list with all QA agreement Managers can be found.

(iii) Maintenance and development of Internal QA Agreement templates.

5.6.2.1 Letter Code

Bi-partite

Site references (allocated by QA)	PROCESSOR	BUYER
	A	B

There are some letter coding of sites containing two letters and those codes are set within brackets for example A(AA) 1.1.

Tri-partite

Site references (allocated by QA)	PROCESSOR	SELLER	BUYER
	A	C	B

5.6.2.2 Number code (x.y)

The first number (x) is an incremental number to make a unique code starting at 1. The second number (y) is the version number and the first version starts at 0.

When various products between two sites are included in one agreement as long as the responsibilities for each of the products are the same then versions are controlled e.g. AB 1.0, AB1.1, AB1.2, …….AB 1.11 etc.

When the responsibilities between sites are not the same for all of the products then several different QA Agreements are required. Each is allocated a separate number e.g. if the responsibility for QA release is different for different product groups then agreements will be AB1.0, AB2.0….AB12.0 etc.

It is not permissible to make statements in an existing QA Agreement to the effect that a clause does not apply to a particular product.

For example if PROCESSOR Operations supply both bulk (letter code Q) products and finished packs to BUYER (letter code I) then two agreements must be set up. The first one concerning the bulk products and have therefore the code QI 1.0 and the second agreement regarding QP release is assigned index code QI 2.0.

5.6.3 Dating

The normal expiry date of a QA Agreement should be 5 years from the date on which the last party signed.

5.6.4 Originals

Originals should be prepared for each of the signatories and one for QA.

5.7 Document Approval

