

Procedure for Quality Management of Contractors

be fully transferred from procurement group to the Lead Site by the end of the establishment phase unless agreed otherwise by the Lead Site involved. In the case of ongoing involvement of procurement group in the maintenance phase, the agreed split of responsibilities shall be documented.

A Lead Site shall be identified for each material/product manufactured by a particular Contractor. These will be assigned using the following criteria and recorded in the vendor assurance and Contractor Database:

Category	Contractor Activity	Basis for Lead Site Assignment
1	API intermediate/Starting Material	Site assigned to receive and further process the material
2	API	Site assigned to receive, or carry out final processing stage of, API.
3	Formulated Product Processing	Site with current or previous history of manufacture of a product (preferred), or product type.
4	Formulated Product Packing (only) for designated markets <ul style="list-style-type: none">• Regional supply• Local Supply	Focus Packing Site for region. Local Site with current or previous history of packing product (preferred), or Focus Packing Site for region
5	Contract Laboratory conducting in-process testing/release testing/stability testing (only)	As Category 2. for API/Intermediate/Starting Material As Category 3. for Formulated Product Processing and Packing.

When more than one Lead Site option is identified by using these criteria, geographical proximity, technical knowledge and involvement in the supply chain of the product shall be considered to finalise the assignment of Lead Site.

3.5 Quality Assurance Agreement

A written and binding agreement between a Contract Giver and Contract Acceptor that clearly defines the roles and responsibilities of the Contract Giver and Contract Acceptor in the provision of a service, product, project or study.

3.6 Quality Assurance Agreement Co-ordination Site

The site assigned by Supply and Capability (S&C) to co-ordinate GMP related interactions and issues between an established contractor and Sponsor when the contractor supplies different materials/products assigned to more than one Lead Site.

In some cases, the role of the Quality Assurance Agreement Co-ordination Site may be

5.3.1 Contractor Status (Quality and Compliance Systems)

Contractor Status shall be assessed/assigned by the Quality Assurance Agreement Co-ordination Site. This status may be:

- Acceptable (approved) - no or minor issues only
- Major issues and concerns with the contractor that are being addressed.
- Disapproved/recommendation to find alternative supply or suspend supply until significant improvements are made.

The 'Contractor Status' is determined by the Quality Assurance Agreement Co-ordination Site and reviewed annually as a minimum, taking into account all activities performed by the contractor and any issues arising during liaison meetings, audits and ongoing product supply – see also Section 5.3.3

Note: This overall assessment may be sub-classified by manufacturing stage, e.g. API intermediates, APIs, Formulation and Packing.

5.3.2 Material/Product Certification/De-certification

The sponsor site(s) receiving the material/product, in consultation with coordination Site and Lead Site shall decide the certification status of a material/product. If no sponsor site receives the material/product, the Lead Site shall decide the certification status. .

To be certified, a material/product must have been manufactured by contractor site that has both:

- Acceptable quality and compliance systems in place to assure that the manufacturing steps undertaken by the supplier contractor site are under control
and
- Demonstrated that it can consistently manufacture the material/product within its pre-determined specifications and quality attributes.

These criteria may already have been met by the end of the establishment phase.

The contractor shall provide to the site receiving the 'certified' material/product, on a batch by batch basis:

- A Certificate of Analysis conforming to the agreed format;
- A Certificate of Manufacturing/cGMP Compliance (this may be combined with the Certificate of Analysis); and
- Deviation reports where there are excursions outside the acceptable ranges given in the Batch Record.
- OOS investigation reports, including those conducted as a result of post-production surveillance programs, e.g. commercial stability studies.

The above information is a minimum. Other documents may be requested, e.g. specimen batch sheets and executed documentation shall be requested on a needs basis e.g. for submission to Regulatory Authorities.

6 Appendices

6.1 Appendix I –Guidance on the process for contractor selection

The Lead Site should be represented on the project team that is responsible for selection of a contractor.

The Lead Site should assign both Technical Support staff and QA staff to this team. This team should:

- Review the contractor database to determine if there is a contractor that is currently used which will meet the requirements for outsourcing
- Provide a rough-cut estimate of the sponsor resources that are required for this phase
- And review the history of the contractor including GMP status to generate a preferred candidate list.

The Lead Site should consult the Quality Assurance Agreement Co-ordination Site (if already assigned to the contractor) to get a detailed assessment of contractor history and status at the start of the Selection Phase and should keep the Quality Assurance Agreement Co-ordination Site informed on the progress of the Selection Phase.

The team should also take into account other considerations e.g. cost, supply performance etc.

After agreeing a preferred candidate list, the team should determine the technical and QA capability of the contractor and establish a sub-team for final selection of the contractor.

The team should also undertake the following activities:

- Ensure that a secrecy agreement is completed before the release of confidential information to the contractor
- Draft supply and QA agreements for use in their discussions with the candidates; establish what information needs to be transferred to the candidates including technical information e.g. process, analytical methods, and International Procedures/Guidelines.

For contractors not previously used to manufacture, supply and/or test sponsor products, the team should then conduct a formal assessment including GMP standards of the contractor at the contractor facilities and log the information on the Contractor Database.

The Project Team will make a recommendation on the choice of contractor to Operations Senior Management (APIs and formulated products marketed internationally) or Site Management (formulated product packing or products for local marketing) who will make the final decision on whether to use the contractor.

When the contractor to be used has been confirmed the composition of the Project Team should be reviewed and shaped as appropriate, for the establishment phase. The resources required for the establishment phase should be determined at this point and the agreements referred to above should be finalized. A Project Manager, if different from the selection phase, should also be appointed.