

3.2 Lead Audit Team/Site (for Vendors)

The site/function that is accountable for conducting quality audits of suppliers.

3.3 Certification

Is the act of approving (accepting) quality control results provided by the supplier in relation to a specific material, thereby eliminating the need to undertake some or all laboratory tests on receipt of that material at gmp site unless specifically required to meet regional/local GMP and/or import regulations.

3.4 Material

A material is an Active Pharmaceutical Ingredient (API), intermediate, raw material, packaging component, excipient, formulated product or packaged product.

3.5 Certified materials

A certified material is a material provided to receiving site, by a supplier, that is released by sister site, or released by a contractor directly into site's distribution chain, without repeat laboratory testing by the receiving site or an independent laboratory approved by the receiving site, unless such testing is necessary to meet cGMP requirements, e.g. identity testing and/or local import regulations.

A certified material may undergo additional laboratory testing by the receiving site, or an independent laboratory approved by the site, if the supplier does not perform all tests required to release the material.

3.6 De-certified material

A de-certified material is a material that has had its 'certified' status revoked.

3.7 Vendor

A supplier of commercially available materials and/or services to the site.

3.8 Contractor

A person or entity agreeing to provide the sponsor site with a service or material according to site's specified requirements and intellectual property.

3.9 Supplier

An umbrella term that covers both Vendors/Contractors.

3.10 Lead Site (for Contractors)

The Lead Site is the site reflected in the Vendor and Contractor Database to be accountable for conducting specified material related QA activities. If no Quality Assurance Agreement Coordination site is assigned, the Lead Site would be responsible for GMP related interactions and issues, conducting audits, and development of the Quality Assurance Agreement.

## 4 Responsibilities

Certification is ultimately the responsibility of the Quality Assurance Department of each site receiving the material directly from the supplier site (Receiving Site).

### 4.1 Lead Audit Site/Lead Site/QAAC Site

The Lead Audit Site for Vendors and the Lead Site for Contractors should make a recommendation to the Receiving Sites on the certification status of materials delivered by a Supplier based on the outcome of the audit(s) it has conducted.

The appropriate QAAC site co-ordinates GMP related interactions and issues between an established Supplier and the site and is responsible for the preparation and negotiation of the Quality Assurance Agreement (which maybe a stand alone agreement, may be combined with a business contract, or may be called a Certification Agreement).

The QAAC site decides the overall 'supplier site status' and enters it into the supplier database.

### 4.2 Receiving Site Supplier Certification Team

The Receiving Site Supplier Certification Team for each Receiving Site is responsible for deciding/reviewing the certification status of all materials received by the site according to established quality criteria, taking into account the relevant Lead Audit Site/Lead Site/QAAC Site's recommendations. If multiple sites receive the same material, the receiving sites should share information as to the acceptability of the material/supplier.

## 5 Guideline

The general process for awarding a certified status to a material from a specified supplier site is based on the following items.

- Quality Assurance Agreement (or for vendors only, a Supply Agreement containing a section detailing quality related requirements)
- Periodic Audit
- Quality Review/Risk Assessment by each Receiving Site considering the following items:
  - A review of analytical methods, specifications, etc., used to determine any potential impact upon Regulatory registrations.
  - Approved Technology Transfer to the supplier by the site.
  - Identification of the supply chain for the material (i.e. how the material will be delivered to the Receiving Sites).
  - A review of material quality and supply performance based upon data/information generated by the Supplier and the site. This can be from other materials received by the site from the supplying site.

NOTE: To maintain a status of 'certified', materials should be subject to a documented

- Regulatory Compliance
- Quality Agreement Compliance
- Service Performance
- Non-Conformities/Complaints
- Certificate of Analysis/Conformity
- Last Audit/Questionnaire
- Supplier Analytical Method Review
- Received Batches Analytical and Clearance Status Review
- Recommended Testing Protocol
- Change Control
- Trend Analysis (when applicable)
- Compliance confirmation of full testing (performed at appropriate intervals)
- Progress with audit observation closure
- Compliance Status of Supplier
- Periodic testing of the certified material. (This is only performed when required by the local GMPs of the receiving site).

If appropriate, the certification status of the material shall be downgraded to ‘decertified’ (see Section 5.5) or may stay ‘certified’ (see Section 5.4). This revised status shall be periodically reviewed. An updated version of the “Certification Report’ should be issued to include the latest status.

Each Receiving Site should send a copy of their updated “Certification Report’ to other sites receiving the same material from the same supplier site together with the Lead Audit Site so they may be aware of any new issues with the supplier.

#### 5.4 Criteria for Maintenance of Certification Status

If no critical defects were observed during the latest audit, no serious problems or observations were noted with the monitoring program, and no serious observations were noted during the periodic quality review, the Receiving site may make the recommendation that the supplier shall maintain their status of “Certified Supplier” for use at site operations.

#### 5.5 Criteria for De-certification

During the routine review period of certification status, the Receiving Site may determine that the material no longer meets the criteria for certification. Note: This may occur outside of the normal frequency of assessing the Supplier. The Receiving Site Supplier Certification team, using the following criteria, should determine the severity and scope of non-compliance by the supplier for assessing if de-certification is warranted. If areas were identified during the on site audit, monitoring program or in the historical quality review that poses a vulnerability for site operations, the Receiving Site Supplier Certification team should make the recommendation that the supplier shall be de-certified.

- Poor or failing historical quality review
- Critical citations or observations from the presiding regulatory agency that severely limits the supplier’s ability to fulfill its contractual obligation with