with equivalent, recognized specifications such as talc, lactose or microcrystalline cellulose) may be qualified by alternate means (e.g. risk assessment, paper audit, etc.);

4) Elements of the selection criteria should include whether the supplier is local (may supply a single location) or global, the number of materials supplied (sole source of a unique material vs. multiple source commodity item), as well as the function of the material in the product formulation or design;

5) Any Quality oversight activities (for example surveillance testing, batch record review, audit frequency, on-site visits, etc.) should be determined based on an evaluation of the supplier and the criticality (source of supply, classification of material, safety, etc.) and intended use of the material;

6) Any of the recommendations for a Quality Agreement may be revised or overridden with a documented rationale approved by the Site Quality Team.

Essential Elements of a Quality Agreement:

1) Scope/purpose statement should contain:
   - Description of services expected;
   - Material list (where suitable a table format including materials supplied and services performed may be helpful);
   - Identification of supplier and client (by name and address);
   - Applicable standards (for instance compendia, national/local regulations, laws, guidances, directives, etc.);
   - Permissible use of subcontractors. (If included specify that the supplier is responsible for all management and oversight activities, qualification, Quality Agreement, test or material results, etc. provided by sub-contractor. Typical examples of sub-contractors include contract labs, packagers, warehouses, shippers, etc.);
   - Agreement terms should include effective period and terms for extension or termination. (Be certain to specify requirements for operations that survive the termination of the Agreement such as stability and complaint handling.)

2) Quality responsibilities should include:
   - conformance to agreed upon standards (such as national/local rules & regulations, law, directives, guidances, compendia, etc.)
   - inclusion of a specification describing the material (acceptance criteria, tests, methods, etc.)
   - supplier should have in place an effective change control system that encompasses customer notification, review and approval of changes, impact evaluation of change ; (criteria should be keyed to material

- requirements for supplier to notify client of significant non-conformances (deviations, discrepancies, out-of-specification results, etc.). Supplier needs to have an effective system for investigation of non-conformances to encompass documentation, corrective activities, and tracking. (Requirements for API, critical excipients and drug products.);

- expectations regarding qualification activities and documentation required for production processes, test methods and cleaning. (Applies to API, drug product.); -an effective complaint handling system should be in place to monitor complaints received, any corrective activities and observed trends.
(Required for drug product; may be included via risk-based justification for other materials);

- supplier should have an effective recall system in place which has the capability to identify materials involved and potential recipients of the affected material/lots;

- details regarding the expectations for a buyer site audit of the facilities used in processing, packaging, storage and handling of the purchased material. This requirement may include sub-contractors, if used. Included should be
expectations regarding the commitment for responses to documented observations and prompt attention to corrective activities . (required for API, drug product, critical excipients, primary packaging components and labeling. The confidentiality of proprietary information and processes may impact access to some information and/or facilities.)

3) Contacts:
   - a listing of essential personnel, their title and contact information (address, phone #, e-mail address, etc.) should be included.
4) Approvals:
   - the signatures of identified responsible company officials and the date of approval need be included.

Table: **Essential Elements of a Quality Agreement**

