1.0 Purpose

This procedure describes the process necessary for evaluation, approval and re-assessment of critical vendors in accordance with cGMP. It will ensure the performance capabilities of vendors and maintain the internal controls for appropriate vendor selection and on-going vendor re-assessment.

2.0 Scope

This procedure applies to vendors of products, materials and services that directly affect the quality of product. Critical vendors are those that their products or materials become part of (raw materials) or are in direct contact (packaging) with product. Critical service vendors may service equipment (calibration) or provide test results (outside laboratory) used for making quality decisions.

3.0 Responsibility

- Personnel involved with selecting a new critical vendor or changing a critical vendor is responsible for following this procedure.
- Personnel receiving materials/service is responsible for notifying Quality Assurance of any issues.
- Quality Assurance is responsible for performing an initial evaluation of a potential critical vendor, evaluating the vendor's quality system, as appropriate, assigning vendor status ('approved" or "not approved"), reporting vendor quality performance on a continuous basis and establishing and maintaining individual critical vendor archival files.

4.0 Safety Considerations

Safety is a condition of employment. Employees are not authorized to work in an unsafe manner and are prohibited from harming the environment of the facility or community.

5.0 Materials/Equipment

N/A

6.0 Procedure

Vendor Selection

1. Select potential vendor(s) for the products or services needed.

2. Define the requirements/specifications to be met by the vendor. Vendor must agree to pre-warn Giles of any changes to specifications/source of raw material prior to receiving new stock.

3. Determine if the vendor is a critical or non-critical vendor. Critical vendors must be approved by Quality Assurance; these vendors will be evaluated to determine the capability of their quality systems or programs (if any).

4. Submit *New Vendor Request* form *(Q12-PR-100-023a)* to Quality Assurance to begin the vendor evaluation process.

5. If changing the source of supply/vendor of critical materials, the change will also be treated according to the change control system. Submit a *Change Control* form *(Q13-PR-100-027)* with the *New Vendor Approval Request* form.

Vendor Evaluation and Approval

1. Quality Assurance will determine the need for and extent of qualification for the vendor in question based on the risks associated with the material or service. If it is determined that a vendor must be qualified, Quality Assurance will determine what level of qualification is necessary. Depending on the level of qualification necessary, either a *New Vendor Qualification Letter (Q12-PR-100-F023b)* and *Vendor Assessment Survey* form *(Q12-PR-100-F023c)* will be sent to the vendor or a Quality representative will conduct an on-site audit using the *Vendor Site Quality Audit* form *(Q12-PR-100-023d).*

2. At the successful completion of the qualification, Quality Assurance will send a *Vendor Approval Letter (Q12-PR-100-F023e)* to inform the vendor that Giles has accepted them as an approved/qualified vendor. Copies of the letter will be sent to the Accounting/Purchasing department and to the individual who initially submitted the *New Vendor Approval Request* form.

3. Quality will maintain a list of qualified critical vendors on an *Approved Vendor List (Q12-PR-100-F023f).* The A*pproved Vendor List* will be circulated to the appropriate personnel

anytime there is any change made to the list. Critical materials will only be purchased against agreed upon specifications from the qualified vendors on this list.

4. Current vendors that have been in use since before the effective date of this procedure may be considered qualified based on past performance. A retrospective qualification will be accepted where it is determined that risk of failure is low. The following criteria must be met:

    a. Used the vendor for at least one (1) years
    b. Product quality and service history have been acceptable
    c. CoA results have been consistently confirmed when periodically checked

Vendor Re-assessment

1. Quality will perform a vendor re-assessment at a minimum of every two (2) years or when a trend in quality issues arise for all vendors on the *Approved Vendor List* that are suppliers of quality critical materials. The re-assessment will be documented using the *Vendor Re-assessment* form *(Q12-PR-100-023g)*. If there have been less than four purchase orders placed with a vendor during the two year period, Quality Assurance has the option of not performing the re-assessment. If re-assessment is deemed unnecessary, it will be documented on the *Vendor Re-assessment* form.

2. Quality will send a *Vendor Self-Assessment Survey (Q12-PR-100-F023c)* every two (2) years to approved vendors that are suppliers of critical materials to evaluate the continued effectiveness of their quality systems. It will be requested that the survey be completed and returned within two weeks of receipt.

3. Quality will schedule an on-site vendor audit as required based on vendor performance and re-evaluation data obtained from vendors. The frequency of the audit should be dynamic and depend on a rating. For example:

    - Completely satisfactory: 5 years
    - Mainly satisfactory: 3 years
    - Partially satisfactory: 1 year

    The frequency should be maintained until the performance improves to a higher level. If the vendor shows a low performance for more than one year, their approval/qualification should be re-evaluated.

    The on-site audit will be conducted according to the *Vendor Site Quality Audit* form *(Q12-PR-100-023d).*

4. Quality will follow-up on any audit finding to ensure appropriate CAPAs have been implemented and are effective.

5. Quality will use the above audit and follow-up information to determine the qualification status of the vendor as either continual approval or disqualified.

6. Testing of quality critical materials (raw, packaging) may be reduced depending on the performance of the vendor over a period of time and the criticality of the material.

Vendor Disqualification

Vendors not responsive to Corrective Action Requests or unable to correct problems with delivery or quality may be disqualified and removed from the *Approved Vendor List*. The vendor will be contacted to inform them of the disqualification.

Record Keeping

Quality will prepare and maintain a vendor file for each vendor on the *Approved Vendor List* that supplies quality critical materials. Vendor files will be stored in the cGMP Library and retained for a period of at least three (3) years. The *Approved Vendor List*, re-assessments and surveys for the current year will be kept in the *Critical Vendor Qualification* binder.

7.0 Reference Documents

New Vendor Approval Request	*(Q12-PR-100-F023a)*
New Vendor Qualification Letter	*(Q12-PR-100-F023b)*
Vendor Self-Assessment Survey	*(Q12-PR-100-F023c)*
Vendor Approval Letter	*(Q12-PR-100-F023d)*
Vendor Re-assessment	*(Q12-PR-100-F023e)*
Vendor Site Quality Audit	*(Q12-PR-100-F023f)*
Approved Vendor List	*(Q12-PR-100-F023g)*
Change Control	*(Q13-PR-100-027)*

8.0 Change Information

Expanded detail of original procedure to incorporate more requirements from 211 and Q7. Placed on new template using new format and numbering.