1.0 Purpose

The purpose of this procedure is to define the conduct of Management Reviews. The purpose of Management Review is to verify the consistency of the process, to assess trends, to determine the need for changes in specifications, production, manufacturing, and/or control procedures and to evaluate the need for revalidation.

2.0 Scope

A range of reviews exist discussing certain aspects of the Quality System at different levels and parts of the organization at different times. This frequency allows time to gather useful data, take actions between reviews and allows for the results of these actions to be evaluated at the next review.

3.0 Responsibility

At Giles Chemical, Management owns the Quality System and must ensure its continuing suitability, adequacy and effectiveness. It is their role to provide a vision, be clear on its direction and control the resources needed to achieve objectives. For the Quality System to remain aligned with business needs, Management Review provides the opportunity for Management to review their Quality System.

The Quality Unit's role is to operate the system independently on a daily basis and collect the data required for an effective Management Review. The Quality Unit will coordinate and manage program.

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

Daily Batch Records
Daily Process Control Charts
Monthly Trend Charts
Monthly Operations Report
Management Review Manual

6.0 Procedure

A consolidation of available data that may be provided as inputs for review includes, but is not limited to, the following:

- The appropriateness of the quality policy and objectives *[Are these still suitable for the organization?]*
- The results of audits and other assessments *[Internal and External audits as well as inspections by authorities. Any areas of concern? Any areas to praise? Anything to learn?]*
- Customer feedback, including complaints, returns, recalls, investigations *[Are our customers satisfied with the product and service?]*
- Analysis of data trending results *[Data on process performance and product conformity. Any positive or negative trends? Risk Assessments? Re-validations? Utilization and Yields?]*
- The status of actions to prevent a potential problem or a recurrence *[Corrective Actions and Preventive Actions closed and effective?]*
- Follow-up actions from previous management reviews *[Recommendations for improvement?]*
- Changes in business practices or environment that may affect the quality system (such as the volume or type of operations) – Change Control or Deviations *[Is anything going to change soon? New shift patterns, new equipment, new customers, etc. Impact of these on the Quality System and business?]*
- Product characteristics/conformity *[in-process and critical test results, Non-conformances, OOS, changes in stability]*

6.1 Daily Management Reviews – Every morning the Production Management Team reviews productions numbers, batch records and process charts. Applicable inputs listed above are discussed. Resolution of any issues noted the prior day is evaluated. The Production Management Team consists of management from Operations, Manufacturing, Repackaging, Quality, Engineering and Maintenance.

6.2 Bi-weekly Management Reviews – Twice a month, schedules permitting, the Leadership Management Team conducts an abbreviated Management Review. Applicable inputs listed above are discussed. The Leadership Management Team consists of the President and management from Operations, Manufacturing, Repackaging, Quality, Customer Service, Human Resources, Accounting and Sales.

6.3 Monthly Management Reviews – There are two formats for Monthly Management Reviews.

6.3.1 ***Quality Trend Charts*** are reviewed by the Production Management Team every month. Data is discussed in detail and Corrective Action Plans developed and

documented if necessary. An attendance/CAPA roster and copy of the Trend Charts reviewed are kept in the Management Review Manual.

6.3.2 ***Operations Report*** is distributed to Ownership and the Leadership Management Team monthly. This report includes all the inputs listed above from each of the areas represented on the Production Management Team. A copy of this report is kept in the Management Review Manual.

The output from the Management Review should include any decisions and actions taken relating to:

- Improvements to the quality system and related quality processes *[From the information that has been discussed – where are the areas that worthwhile improvements can be made?]*
- Improvements to manufacturing processes and products *[Are there any improvements that can be made to the processes and products?]*
- Realignment of resources *[In order to make the improvements stated above, what resources are needed to achieve these?]*

The results of a review should be evaluated and an assessment made of whether corrective action or any revalidation should be undertaken. Reasons for such corrective action should be documented. Agreed corrective actions should be completed in a timely and effective manner. Corrective Actions generated from the Monthly reviews will be recorded on the *Management Review (Q12-PR-100-F007)* form. If any investigations are determined to be necessary, they will be recorded within the CAPA system.

The current year of the documents described above will be kept in the Management Review Manual. Thereafter, the Quality Unit will file these documents in the cGMP Library for four years.

7.0 Reference Documents

Management Review (Q12-PR-100-F007)

8.0 Change Information

Procedure was re-written to incorporate the philosophies of the FDA's Quality System Model and ICH Q10; including new format and numbering.