1.0 Purpose

To validate equipment, methods and processes affecting the critical product attributes of the final product.

2.0 Scope

Outline of the steps for various validations.

3.0 Background

Validation is an element of Giles' Quality Assurance program used to ensure that Giles' processes, methods, tests, and equipment are capable of producing the desired product under normal circumstances and conditions.

4.0 Procedure

Validation, in simple terms, is documenting that a piece of critical equipment, production process, cleaning procedure, analytical method, in-process control test procedure, or computerized system is capable of "doing what you want it to do" under normal circumstances and that any output produced under normal circumstances is acceptable. The general steps to complete a typical validation are below:

1. Identify the desired outcomes. These can be identified in terms of asking what the equipment or process is supposed to do. This should probably include:

    - Defining the product in terms of its critical product attributes
    - Identifying process parameters that could affect the critical quality attributes of the product
    - Determining the range for each critical process parameter expected to be used during routine manufacturing and process control

2. Write a validation protocol. At a minimum, the protocol will include specifics of what parameters will be tested, the acceptance criteria, and the number of process runs. The protocol will be reviewed and approved by the Quality Department and other affected areas (i.e. Production).

3. Document the qualification of equipment and systems. Qualification is usually carried out by conducting the following activities, individually or combined:
    a. Installation Qualification (IQ): documented verification that the equipment or systems, as installed or modified, comply with the approved design, the manufacturer's recommendations and/or user requirements
    b. Operational Qualification (OQ): documented verification that the equipment or systems, as installed or modified, perform as intended throughout the anticipated operating ranges
    c. Performance Qualification (PQ): documented verification that the equipment and ancillary systems, as connected together, can perform effectively and reproducibly based on the approved process method and specifications

4. Gather and document required data for each qualification step. Note and correct deviations from the requirements or explain why the requirement is not being fulfilled.

5. Write a report based on the protocol that summarizes the results, comments on any deviations, draws appropriate conclusions, and includes any recommended changes to correct deficiencies.

5.0 Validation Review

During the Management Product Quality Review, the need for re-validation of equipment or processes based on the data will be determined and assigned through the CAPA list generated at that meeting.

6.0 Re-validation

All critical equipment should be re-validated at least every 4 years. When any process critical equipment is modified (i.e. changes in physical size, nature of operation, or sequence in the overall process) a new validation should be performed if the Change Control risk assessment determines that it should.