Description of Sample Validation Documentation

This following represent the primary components of a sample FDA required Validation that has been prepared for a typical MISys user company. These documents include:

1. **Test Protocol** – this is the primary document for the Validation Protocol. The principal sections include such topics as purpose, scope, references, descriptions of the primary user environment and test environment, responsibilities, data migration plan, the Trace Matrix and acceptance criteria. The Trace Matrix is the critical section of this document and defines the specific requirements and test cases that will be performed during the actual "Validation Process." It is important to recognize that these requirements may vary from one company environment to another. **Note:** there is no section **6** in the sample document.

   The requirements listed in the Trace Matrix section have been sequenced to provide for a logical flow and buildup of data in the test database beginning with the loading of items, BOMs and suppliers, transacting inventory, processing purchase and manufacturing orders and ultimately confirming the accuracy of the resulting lot tracking data. At the end is a section for testing the system and user security setup.

2. **Test Cases –** several sample Test Case documents are provided. In the actual validation, there are separate Test Case documents for each of the "Requirement" listed in the Test Matrix. These documents define the specific "Test Steps" to be performed in satisfying the requirement defined in the Trace Matrix. In addition, they describe the "Expected Results" for each step and provide space for recording the "Actual Result," "Disposition" and "Tested by" data. At the end of each document is space for final sign - offs, approvals, etc.

3. **Input Documents –** these documents are included (typically for each Test Cases) to list specific data (Item numbers, descriptions, etc.) to be entered when performing the Test Case. Again a sample document has been provided here.