1. INTRODUCTION AND SCOPE

Instructions: Describe the purpose of the validation master plan and its scope. Give the location of the facility and define the types of validations that are included: facilities and utilities, equipment, processes, and computer systems.

Example: This Validation Master Plan (VMP) is for the XYZ Company facilities located at 100 Main Street, Cupertino, California.

The plan includes all equipment used in the support of GXP activities, including facilities, utilities, environmental monitoring and control equipment, analytical equipment, and computerized business systems.

2. BACKGROUND

Instructions: Define the methodology used to identify the systems and create the plan. If a risk assessment was performed, describe or reference the process used.

Example:

The following method was used in creating the validation master plan.

2.1 A Validation Master Plan Committee (VMPC) was established to create the validation plan. The Committee included:

- *The Director of Quality Assurance*
- *The Director of Information System*
- *The Director of Operations*
- *An external validation consultant*

2.2 The VMPC used the validation policy, VAL001, to determine which functional areas needed to be included in the creation of the VMP. A list of the facilities used by those functions was also developed.

2.3 The consultant provided a form, the Validation Master Plan Item Information Form, to record the information needed to determine if an item had to be validated (including if Part 11 applied) and to establish a priority for validation. The form was adapted and approved as VAL018.

2.4 The utilities, facilities, equipment and computer systems that needed to be validated were identified as follows:

3.3 VAL002: Validation Requirements for Computer Systems

3.4 VAL004: Requirements for Computer System Validation Plans, Protocols and Reports

3.5 VAL018: Validation Master Plan Item Information Form

4. DEFINITIONS

Instructions: Include in the definitions only terms used in the Validation Master Plan that are not common knowledge. Definitions of terms that have already been defined in SOPs should match the definitions given in the SOPs.

Examples are:

GXP: GXP is a generic designation for all FDA regulations for pharmaceutical industry practices, including GLP, GCP, and GMP.

Predicate rule: A predicate rule is a GXP requirement specified in a FDA regulation.

5. ORGANIZATION

Instructions: Provide a description of the organization required to execute the VMP. Define the roles and major responsibilities of the individuals or organizations that will be involved in the execution of the plan.

Examples of functions to include are:

- *Project Manager*
- *Validation Review Board*
- *System Owners*
- *Additional user representatives, if any*
- *IT*
- *QA/Validation*
- *QA*

Define the training that is required based on the roles and responsibilities of the individuals.

Example:

The training requirements for these functional areas, and the consultants working on their behalf, are shown in the following table.