Section13:Validation Master Plan

ScinoPharm Taiwan has established a comprehensive Validation Master Plan to identify and coordinate the various activities (Product / Process Development, Engineering, Maintenance, Computer Systems, QA, QC, Validation, etc.) necessary to successfully validate our API Facility. This high level plan was written in accordance with ScinoPharm's Facility Basis of Design Document and provides a roadmap for implementing various QA and validation programs as required by U.S. cGMP requirements. Basically, this plan:

* Describes ScinoPharm's validation philosophy, commitment, and approach.
* Defines validation responsibilities.
* Identifies and defines elements of the various validation programs.
* Describes various individual validation plans, protocols, and activities that will be used to validate the API facility.
* Defines general requirements for the format, execution, review, and approval of vali dation documentation.
* Defines the supporting systems and infrastructure necessary to maintain the facility in a validated state.
* Provides a set of validation lexicon that will be applicable to all validation activities in the company.

The ongoing validation programs at the ScinoPharm Facility include the following:

* Facility and Support System Validation (including Equipment Qualification).
* Computer System Validation (including plant automation and ERP systems).
* Analytical Method Validation.
* Manufacturing Process Validation.
* Equipment Cleaning Validation.
* Water System Validation

Document Management System

In ScinoPharm's new API facility, formal documents are produced and used to control daily operations in accordance with cGMP requirements. These documents themselves must be controlled (i. e., maintained in a secure repository, protected by restricted access, with change managed by a formal review and approval process) per established SOPs. Some controlled documents are hardcopies, signed in pen and stored under physical security. Others such as Policies and Standard Operating Procedures (SOP's) are used daily and will be retained in electronic format using validated computer systems. Controlled documents are typically generated using Microsoft's Office Word processing software, with graphic and scanned images embedded as necessary.

Examples of controlled documents include:

* Policies and Guidelines.
* Standard Operating Procedures.
* API, Starting Materials, Raw Materials, and Components Specifications.
* QC Laboratory Test Methods and Procedures.
* Instrument Calibration Procedures.
* Maintenance Procedures and Records.
* Computerized Systems Specifications and Test Procedures.
* Change Control Requests and Records.
* Validation Plans, Records, and Reports.
* Audit Reports - FDA, Local Authorities, Material Vendors, Client's and ScinoPharm's QA Compliance Audits.
* Personnel Qualification, Training Curriculum and Records.

The Document Control Module of the plant's Enterprise Resource Planning (ERP) central computer system will handle generation and maintenance of documents in electronic format. This module will be equipped with GMP and security features including access authorization and records, revision history, and audit trail for each document. After the system is established, document control can also be extended to on-line management of batch sheets used by pilot scale and full scale manufacturing facilities.

A formal change control procedure details the process of document management. There are also separate change control procedures for managing process changes, physical changes, changes to computerized systems, calibration and maintenance procedures, Material Vendors specifications and analytical test methods. Typically controlled change begins with a change request, submitted on a standard form for review and approval. The various change control related documents are all controlled within the Document Control Module of the ERP system.

SOP System

It is SPT policy to maintain current, written policies and procedures (SOPs) that define all critical systems and activities performed on the plant site. SOPs are intended to impose standardization and consistency and serve as both training and guiding documents.

SOPs will be established for all cGMP-related systems and operations as well as environmental, health, safety and other business-related activities. SOPs will be used to define the requirements of compliance systems as well as the format and control of other necessary documents such as forms, reports, and sub-procedures.

Regulatory Compliance

An integrated systematic approach will be taken to address the need for regulatory compliance all the way from Process Development throughout Scale-up, Validation, and Product Introduction. The requirements include:

* CGMP Requirements.
* Environmental Regulations.
* Safety Regulations.
* Government and Local Codes.
* Community Requirements.
* Responsible Care Requirements.

Summary

ScinoPharm has comprehensive validation programs in place to achieve FDA's cGMP compliance as well as meeting the company's objectives for high product quality and unsurpassable customer satisfaction. The validation activities are also designed to facilitate and streamline R&D activities and help establish an integrated quality system.