Regulatory Basis:
FDA Quality Systems Regulations

1. Purpose

The purpose of this guideline is to provide guidance on the preparation of Validation Master Plans (VMP).

2. Scope and Applicability

All functions, departments and manufacturing sites within the sponsor or its contractors operating under GMP regulations or guidelines. This guideline applies to all existing and new drug compounds. It covers the planning of validation activities related to the manufacturing and control of the registered stages of Drug Product or Active Pharmaceutical Ingredient (API) for clinical use, validation or sale.

All manufacturing activities concerned with:

- The receipt and establishment of new Drug Products or API's.
- Major processing changes to existing Drug Products or API's.
- The construction of new manufacturing or related facilities.
- Major alterations to existing manufacturing or related activities.

Should be carried out in accordance with approved procedures for validation. Where a project consists of a range of different validation activities then a Validation Master Plan (VMP) should be prepared. Different major projects carried out in one facility may each have it's own VMP. Activities should be planned and prepared for by local management who should approve essential documentation prior to starting validation activities.

3 Definitions

3.1 Active Pharmaceutical Ingredient, (API)

Any substance or mixture of substances intended to be used in the manufacture of a drug (medicinal) product that when used in the production of a drug becomes an active ingredient of the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.

Note: Also known as Bulk drug or Drug Substance.

3.2 Drug Product

The dosage form in the final intermediate packaging intended for marketing.

3.3 Validation

impact assessments) should be carried out to identify items requiring qualification.

5.2.4 The content of the VMP should reflect the complexity of the extent of the validation activities to be undertaken. At minimum the VMP should address the following:

i. Title, statement of commitment and approval page.
ii. Summary description of the project and its scope.
iii. A statement of validation policy and the objectives of the validation activity
iv. References to other existing validation documents.
v. A description of the organization and responsibilities for validation
vi. The validation strategy to be adopted opposite Facilities and Systems (process equipment and services including automated systems), Materials, Quality Control, Personnel including training.
vii. The intent in respect of Process Validation and Cleaning Validation for each of the drug product range.
viii. The documentation management and control system to be used.
ix. A description of the validation change management process.
x. An indicative relative timescale plan.
xi. Clear acceptance criteria against which the outcome of the validation exercise will be judged.

5.2.5 The requirements for the above should be reflected in a completed Responsibility Chart for all deliverable documentation.

5.2.6 Appendix 1 illustrates the inter-relationship of validation documents, as an example for a major project.

5.2.7 For large projects involving many materials, a Materials Validation Plan may be used. For smaller projects, a Materials Validation Plan is optional. The VMP (Validation Master Plan) or lower tier documentation alone may cover the qualification of materials.

5.2.8 The headings of the VMP may be based on the above list. A project may be organized in different ways, however, depending on the character of the project.

5.2.9 The VMP should demonstrate that the validation activities have been considered and are being organized in a structured manner.

5.2.10 A VMP should be presented as a formal document which is suitable both as an internal guide and for scrutiny by a member of a regulatory inspectorate. It should therefore be concise, easy to read and not excessively duplicate text from documents held elsewhere in the Quality System.

5.3 Reporting

5.3.1 Each VMP should result in a report confirming that all validation activities have been completed satisfactorily.

Appendix 1