MANUFACTURING & QUALITY AUDIT DIVISION
CENTRE FOR DRUG ADMINISTRATION

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GUIDANCE NOTES ON
PREPARATION OF VALIDATION MASTER PLAN

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GUIDANCE NOTES

Subject: PREPARATION OF VALIDATION MASTER PLAN

1.0 Principle

1.1 Validation in general requires a meticulous preparation and careful planning of the various steps in the process. In addition, all work involved should be carried out in a structured way according to formally authorised standardised working and administrative procedures. In addition validation is characterised by:

- **Multidisciplinary approach**: A specific characteristic of validation work is that it requires the collaboration of experts of various disciplines such as pharmacists, technologists, metrologists, chemical analysts, microbiologists, engineers, experts on Q.A. validation etc.

- **Time constraints**: Generally validation work is submitted to rigorous time schedules. These studies are always the last stage prior to taking new processes, facilities into routine operation.

- **Costs**: Validation studies are costly as they require time of highly specialised personnel and expensive technology.

1.2 The above factors require a well organised and structured approach that should be adequately described in a Validation Master Plan (VMP).

2.0 Purpose and Definition

Purpose

2.1 The VMP should present an overview of the entire validation operation, its organisational structure, its content and planning. The core of the VMP being the list / inventory of the items to be validated and the planning schedule.

2.2 A VMP helps management:

- to know what the validation programme involves with respect to time, people and money, and to
- understand the necessity for the programme;

A VMP helps all members of the validation team:

- to know their tasks and responsibilities.

A VMP helps GMP auditors:

- to understand the firm's approach to validation and the set up and organisation of all validation activities.

3.0 Definition

3.1 A Validation Master Plan is a document that summarises the firm's overall philosophy, intentions and approach to be used for establishing performance adequacy.

4.0 Scope

4.1 All validation activities relating to critical technical operations, relevant to product and process controls within a firm should be included in a VMP. This includes qualification of critical manufacturing and control equipment.

4.2 It should comprise all Prospective, Concurrent, Retrospective Validations as well as Re-validations.

4.3 In case of large projects like the construction of a new facility, often the best approach is to create a separate VMP. (In such situations the VMP should be part of the total project management.)

5.0 Format and Content

5.1 The VMP should be a summary document and should therefore be brief, concise and clear. It should not repeat information documented elsewhere but refer to existing documents such as Policy Documents, SOP's and Validation Protocols/Reports.
The VMP should be agreed by management.

5.2 A VMP should contain data on the following subjects / proposed chapters.

Introduction:

5.2.1 Firm's validation policy, general description of the scope of those operations covered by the VMP, location and schedule (including priorities).

Organisational Structure of All Validation Activities:

5.2.2 Personnel responsibility for

- the VMP,
- protocols of individual validation projects,
- validation work,
- report and document preparation and control,
- approval / authorisation of validation protocols and reports in all stages of validation processes,
- tracking system for reference and review,
- training needs in support of validation.

Plant / Process / Product Description:

5.2.3 Provides a cross reference to other documents. A rationale for the inclusion or exclusion of validations, for the validation approach and the extent of validation should be included.

Note: *A common principle in validation studies is to challenge processes, systems etc. The rationale behind any challenge and or "worst case" situation should be explained. Consideration can be given to the grouping of products / processes for the purpose of validating "worst case" situations. Where "worst case" situations cannot be simulated, the rationale for the groupings made should be defined.*

Specific Process Considerations:

5.2.4 Under this heading specific characteristics / requirements of the plant / process etc. *that are critical for yielding a quality product and need extra attention* may be briefly outlined here.

List of Products / Processes / Systems to be Validated:

5.2.5 All validation activities comprised in the VMP should be summarised and compiled in a matrix format. Such matrix should provide an overview and contain:

- all items covered by the VMP that are subject to validation describing the extent of validation required [i.e. IQ, OQ and/or PQ]. It should include validation of analytical techniques which are to be used in determining the validation status of other processes or systems,
- the validation approach, i.e. Prospective, Retrospective or Concurrent,
- the Re-validation activities,
- actual status and future planning.

Key Acceptance Criteria:

5.2.6 General statement on key acceptance criteria for the items listed under (5.2.5) above.

Documentation Format:

5.2.7 The format to be used for protocols and reports should be described or referred to.

Required SOP's:

5.2.8 List of relevant SOP's should be presented.

Planning & Scheduling:

5.2.9 An estimate of staffing (including training needs), equipment and other specific requirements to complete the validation effort should be described in the VMP. A time plan of the project with detailed planning of subprojects. This time plan could be included in the above mentioned matrix (5.2.5). A VMP requires regular updating.

Change Control:

5.2.10 A statement of the company's commitment to controlling critical changes to materials, facilities, equipment or processes (including analytical techniques), should be included.

6.0 References

PIC/S document PI 006-1 : Recommendations on Validation Master Plan, Installation and Operational Qualification, Non-Sterile Process Validation, Cleaning Validation.

END OF DOCUMENT

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REVISION HISTORY

Rev No.	DCC Ref No.	Author	Date of Revision	Remarks of Revision
001	-	-	01 Jan 2000	New.
002	-	-	03 Aug 2001	Change of organisation name
003	-	Terrance Ong	09 Dec 2002	Update document format.
004	209	Terrance Ong	01 Mar 2004	1) Change 3D HSA logo to 2D HSA logo. 2) Change Centre name to Centre for Drug Administration 3) Detached Revision History from Guidance Notes.
005	257	Terrance Ong	06 Sep 2004	1) Re-located Revision History to the main document.