

Standard Operating Procedure

Title: Management of Validation Protocols and Reports

Department	Validation/Technical Services		Document no	VAL-205	
Prepared by:		Date:		Supersedes:	
Checked by:		Date:		Date Issued:	
Approved by:		Date:		Review Date:	

A APPLICATION

To outline the procedure for the management of validation related projects and documentation.

B RESPONSIBILITY AND AUTHORITY

- 1 It is the responsibility of the **Validation Department** to assign a project number to the validation project and to ensure that the progress of the project is kept up to date in the Validation Database.
- 2 It is the responsibility of individual personnel (from outside the Validation Department) in charge of a project which requires validation to work in collaboration with the **Validation Department** on the generation of validation documents.
- 3 It is the responsibility of the **Validation Department** to provide guidance on the [validation requirement](#) of any given project.
- 4 In the case where the expertise of a vendor, contractor or consultant is engaged, it is the responsibility of the **Validation Department** to ensure that all validation documents are prepared according to **GMP site's** standards and procedures.

C SAFETY AND PROCESS SPECIFIC INFORMATION

N/A

D PROCEDURE

1 Validation Project Numbers

- 1.1 When a new validation project is initiated, a validation project number is assigned to the project as follows:
- 1.2 The validation project identification takes the form of a six-digit number:

AA-B-CCC.

Where:

AA = Denotes the last two digits of the year in which the project is initiated/registered, i.e. 11 for 2011.

B = Denotes an automatically generated number. This number has no meaning at this stage

CCC = Denotes sequential number for each year, starting from 001.

2 Registration in Validation Database

- 2.1 The validation database is used to maintain a record of the work undertaken for the purpose of validation and the current validated state of a process (product), equipment or system.
- 2.2 The Validation database has two main sections the first section is the "Validation" section which contains details of the physical equipment, system or process that requires validation. The second section is the "Project" section which contains details of the activities undertaken to demonstrate a valid state. A valid state is considered to be the sum of all projects that are undertaken to demonstrate a "Validation Item" has met defined validation requirements.

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- **Priority Driver** – The priority driver is used to define why a project was undertaken, the importance and link to other GMP activities. For example, if the project was undertaken as a result of change control than “[Change Control](#)” (CC) should be selected and the CC number added to the reference section (below).
 - **Project Manager** – The person who is the project leader and responsible for coordinating the completion of all activities. Where the person selected is a member of the Validation team the project will show up in the “My Projects” section.
 - **Risk Level** – The risk level relates to either a [formal assessment](#) undertaken ([SOP VAL-185](#)) or to that of a more superficial assignment. As the project progresses the nature of risk of the project should be continually assessed.
 - **Life Cycle** – The life cycle option refers to the stage in the life cycle the “Validation Item” is in whilst this project was undertaken. Therefore, the creation of a URS project for a new piece of equipment would be the “Development and Design” stage (See Validation Master Plan [VAL 080](#) for Life Cycle definition).
 - **Validation Area** – Validation Area or type refers to the type of validation project being undertaken and is used in the Master Plan report to group similar projects.
 - **Project Type** – Project type refers to the type of protocol that will be created to document this project.
 - **Commitment** – The commitment attribute of project indicates the group driving the requirement for the project. Where the group is a regulatory body the activity may have been undertaken to meet an audit observation.
 - **Reference** - The reference attribute is used to refer a project to a source event such as a change control or audit observation.
- 4.4 In the Project database record information in the “Project Scope” area to define the scope and activities that were undertaken and any other associated equipment(s) or project(s).
- 4.5 When a new project has been created and the required information has been entered the project needs to be assigned to a “Validation Item” (See Section 3).
- 4.6 Once the project item has been set up in the database, enter the dates for each project stage.
- 4.7 Trace the progress of the project by adding notes progressively.

5 Preparation of Validation Documents

- 5.1 A validation protocol is written for each project. It normally includes the following elements:
- Approval,
 - Objective,
 - Scope,
 - Responsibilities,
 - Background,
 - Validation Rationale,
 - Testing and Methodology,
 - A list of the required validated test methods with the corresponding validation report numbers
 - Acceptance criteria,
 - [Deviation form](#)
 - Interim form
 - Signatories form
- 5.2 A protocol cannot be executed until it is approved by the relevant management representatives.

Appendix 1: Review / Approve Procedure for Validation Documents

Date by which validation execution / close out is planned: _____

Document Identification

Doc type: Protocol / Report / Deviation / Other (specify) _____
Documentation Title: _____ _____
Documentation Number: _____

Document Review / Approval

Protocol	Approve to ensure the proposed validation methodology / acceptance criteria are appropriate. Proposed validation activity complies with the corporate and regulatory requirement. Acceptance of the proposed responsibilities.		
Report	Review and approve on the content and completeness of the report. Agree on the proposed recommendations as appropriate and reasonable.		
Reviewer's name	Title	Return by	Comments