DCVMN Workshop Exercise 2

Underlined/red words are directions or notes for completing this exercise. In this scenario, you are the author.

This is not a test. This is an exercise to get people thinking and discussing their approaches to Assay Validation.

Validation Plan (This document is based on NIBSC's approach to assay validation)

Indicate here the analytical procedure that you are validating _____

Title	
Document Reference	
Division/Study Area	

Document Approval

For items 1, 2 & 3, list who else in the quality management chain should approve this Validation Plan

Author			
Name	Position	Signature	Date
1			
Name	Position	Signature	Date
2			
Name	Position	Signature	Date
3			
Name	Position	Signature	Date

Contents

1. Introduction

Provide an outline and context for the validation i.e. what is being validated and why.

2. Scope

Describe the method to be validated including details of the products / samples to which it is applied, summary of the assay / test performed along with details of the equipment and software used.

Note:

- *for new methods state whether it is replacing another method and summarise any method development work*
- *for modifications to existing methods describe the modifications being made the reasoning behind making the changes and the impact of the modifications on the performance of the method*

Include references to SOPs, published papers, monographs, investigation reports, previous validation work.

3. Validation Plan

3.1 Validation Approach

Provide rationale for the validation approach to be taken based on the method to be validated e.g.

- *Pharmacopoeial (compendial method)*
- *Validated/approved method of a manufacturer or other laboratory*
- *Non compendial published method*
- *Method of a first manufacturer to be used for a product of a second manufacturer*
- *Method for an active substance to be used for a medicinal product*
- *Methods to reduce, refine or replace animal use (3Rs)*
- *New in-house procedure*

Refer to PA/PH/OMCL (13) 82 2R for further guidance

3.2 Validation Parameters

Provide details of parameters which will be tested during the validation exercise e.g.

- *Accuracy*
- *Precision*
  - *Repeatability*
  - *Intermediate Precision*
- *Specificity*
- *Detection Limit*
- *Quantitation Limit*
- *Linearity*
- *Range*

Refer to ICH Guideline Q2(R1) for further guidance

3.3 Format of Validation Procedure

Describe the design of the validation exercise e.g.

- *Type of samples to be tested, whether previous results are available from a previously validated method*
- *How many samples / plates / assays to be tested*
- *How many replicates will be included*
- *Whether multiple operators will carry out the testing*
- *What controls and reference samples will be included*
- *What critical equipment will be utilised*
- *Which software packages will be utilised*

Include a summary table if useful:

Samples to be tested (e.g. number and type)	**Source of samples**	**Parameter to be tested**

3.4 Validation Criteria

Describe the criteria which must be met for the validation to be deemed successful.

If less than 100% performance is acceptable specify what level of performance is acceptable plus some justification.

In some cases it may not possible to define specific acceptance criteria, instead how a system performs may be sufficient measure, if this is the case describe what validation success would look like so that a conclusion can be drawn on the outcome of the validation exercise.

Include a summary table if useful

e.g.

Test Parameter	**Acceptance Criteria**	**Specification**
e.g. Accuracy	*e.g. 100% of validation data points to fall within XYZ*	*e.g. PhEur N.N.N method X*

Validation Criteria continued

Test Parameter	Acceptance Criteria	Specification

4. Procedure

Describe the procedure to be followed for the validation exercise, either reference SOP highlighting any deviations from the procedure documented in the SOP or provide step by step instructions here.

e.g.

Step	Action
1	*e.g. Prepare 10 samples for assay Y using sample preparation method Z, refer to SOP s/n XXXX*
2	*e.g. Run 2 plates using instrument protocol ABC as described in steps 10 to 18 of SOP s/n XXXX*
3	*e.g. Transfer raw data to form s/n XXXX and perform statistically analysis*

Step	Action
1	
2	
3	
4	
5	
6	Etc.

5. Impact of Validation

Document your assessment of the impact of the validation exercise:

- *what documents will need revising e.g. SOPs, forms, study plans*
- *what records need creating or updating e.g. equipment records, training records, critical reagents list*
- *how will staff be trained to the new / modified method and ongoing competency assessed*
- *how will the performance of the method be monitored*
- *how will the uncertainty of measurement been accessed and documented*
- *what LIMS changes are required*

Appendix A

Appendices can be added and deleted as required to include details of items referred to in the body of the validation plan e.g. specifications of reagents / equipment, flow diagrams.

Or appendices can be added to contain results tables to be populated during the validation exercise.

Sample ID	Test parameter	Observed result	Acceptance criteria (Pass / Fail)
e.g. 123456	*e.g. Accuracy*	*e.g. 2.2 RPU*	*e.g. Pass*
etc			

Who in the quality management chain should complete and check this Validation Plan prior to authorisation?

Completed by			
Name	Position	Signature	Date
Checked by			
Name	Position	Signature	Date

Postscript

This exercise is based on NIBSC's approach to assay validation planning in its role as a National Control Laboratory. NIBSC does not manufacture biological medicines and so does not operate under a GMP quality management system. List below any additional items that a Manufacturer's QC laboratory would document when writing a Validation Plan for this assay.