NIBSC

Inactivated Viral Vaccines (IVV)
Division of Virology

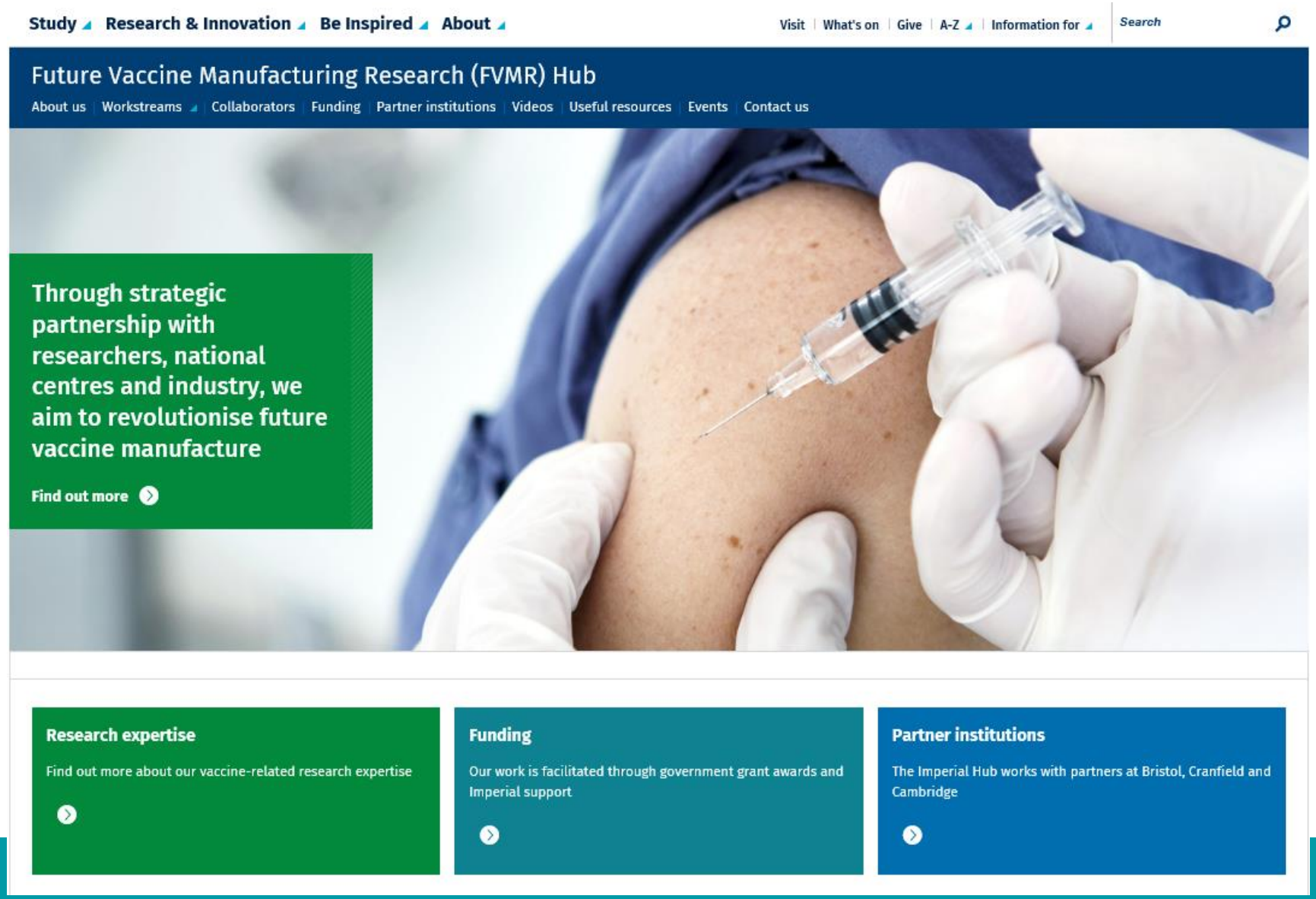
Analytical Method Validation for Vaccines, Biopharmaceuticals and other Bioproducts

Dianna Wilkinson



Medicines & Healthcare products Regulatory Agency

FVMR Hub https://www.imperial.ac.uk/future-vaccine-hub/



FVMR Hub

NIBSC

Partner institutions

Aimei Hissen Vaccine (Dalian) Co., Ltd.
Find out more

Developing Countries Vaccine Manufacturers Network (DCVMN) - Nuon Switzerland
Find out more

GSK Vaccines Institute for Global Health (GVGH) - Siena, Italy
Find out more

Incepta Vaccine Ltd. - Dhaka, Bangladesh
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MSD Wellcome Trust Hilleman Laboratories Pvt. Ltd. - New Delhi, India
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Ugandan Virus Research Institute (UVRI) - Entebbe, Uganda
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VaBiotech - Hanoi, Vietnam
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Future Vaccine Manufacturing Research (FVMR) Hub

About us | Workstreams | Collaborators | Funding | Partner institutions | Videos | Useful resources | Events | Contact us

Workstreams

- RNA manufacturing platforms
- Quality assurance and control
- Membrane antigens
- Baculovirus expression
- Platform improvement
- Demonstration and design
- Yeast platforms
- Eliminating the cold chain

General enquiries

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Department of Health & Social Care
Department of Health & Social Care
Our key funding partner

EPSRC
Engineering and Physical Sciences Research Council
Our key funding partner

Home / Research groups / Future Vaccine Manufacturing Research (FVMR) Hub / Workstreams

Workstreams

Our research expertise at the Hub is categorised along eight key research programmes. Follow the links below for further information:

RNA manufacturing platforms

Development of novel manufacturing platforms for RNA vaccines

Quality assurance & control

Facilitating development of common QA methodology and regulatory convergence

Membrane antigens

Generalised modules for membrane antigens

Baculovirus expression

Insect cell-baculovirus expression system

Platform improvement

Integrating life science and engineering to improve existing platforms

Demonstration and design

Platform industrialisation, demonstration and design projects

Yeast platforms

Re-engineering next-generation yeast platforms

Eliminating the cold chain

Rethinking formulation, delivery and adjuvants to eliminate cold chain and maximise efficacy

FVMR Hub workstream

NIBSC
Confidence in Biological Medicines

Quality assurance and control

Challenge and opportunity

Often Quality -Assurance / -Control of vaccine qualification together with regulatory approval provides the greatest rate-limiting step for rapid vaccine deployment, hence streamlining these processes will be a key aspect of the program.

Through our partnership with National Institute for Biological Standards and Control (NIBSC), we will provide access to reference material and assays designed to help convergence in the QA of existing and new vaccine products and their regulatory approval.

NIBSC deals with all quality aspects of vaccines and works in collaboration with external stakeholders performing prequalification (PQ) testing on behalf of the World Health Organization (WHO) to ensure the quality of vaccines purchased by United Nations (UN) agencies for use in developing countries.

Key contributors

- Imperial College London
- NIBSC
- GSK Vaccines Institute for Global Health (GVGH, Italy)
- Cambridge
- NHS BT-CBC
- LMIC partners

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NIBSC
Confidence in Biological Medicines

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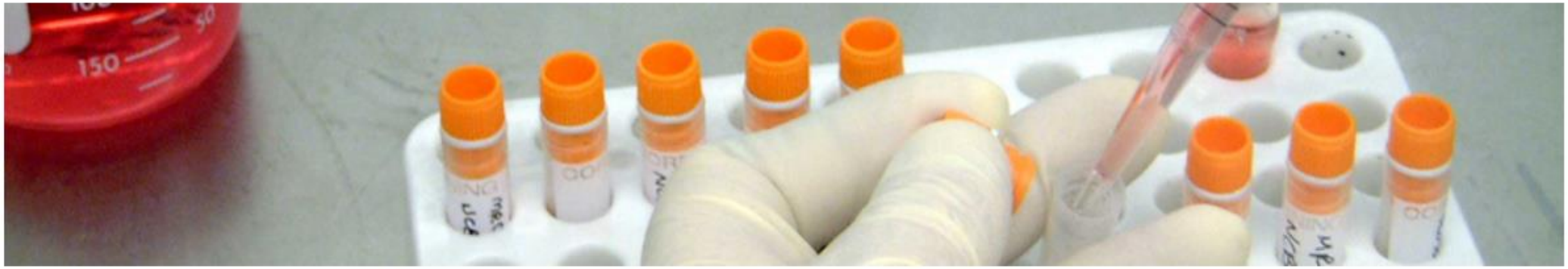
OCABR batch release price list

Home / Control testing



Control testing

https://www.nibsc.org/

Control testing activities at NIBSC

NIBSC has the capability to test a wide range of biological medicines including:

- vaccines against bacterial, viral and parasitic infections
- toxins and antitoxins
- albumins
- therapeutic antibodies
- blood clotting and anti-clotting factors
- plasma pools
- cytokines
- hormones and growth factors

Control testing activities at NIBSC

- NIBSC serves as the UK's Official Medicines Control Laboratory (OMCL) for biological medicines
- We perform official control authority batch release (OCABR) testing of blood products, vaccines and other biotherapeutics for the European market following guidelines of the European Directorate for the Quality of Medicines (EDQM)
- We test some biological medicines used outside the EU and perform prequalification testing (PQ) on behalf of the World Health Organisation (WHO) to ensure the quality of medicines purchased by United Nations (UN) agencies for use in developing countries.

Control testing activities: Inactivated Viral Vaccines group (IVV)

- EU Batch Release of HPV Vaccines

- Testing purified VLP **bulks** for Purity and Intact Monomer by SDS-PAGE and densitometry
- Testing unpackaged **vaccine** for in vitro relative potency, Appearance by visual inspection, and MPL content by GC (if applicable)
- Reviewing the protocols for the manufacture of the vaccine lot
- Reviewing packaging documentation
- Confirming details of the request for release
- Providing a signed certificate for the release of the batch

- Other EU Batch Release testing

- Therapeutic IgG in vitro Potency testing by ELISA (anti-HBS, -VZV, -HepA)

Control testing activities: IVV cont.

- Testing of WHO PQ vaccines [HPV Vaccines and HepB Vaccines (monovalent and combined)]
  - Assessment of Purity of non-adjuvanted monovalent bulks by SDS-PAGE and densitometric analysis (if requested)
  - In vitro relative potency of final container vaccine by ELISA (HPV and HepB)
  - In vivo relative potency (HepB if requested)
  - Appearance of final container vaccine by visual inspection
  - Protocol information
  - Completion of test report to WHO

Aim of Presentation

- Presentation is limited to NIBSC's approach to Analytical Validation only

  - Explain
    - What validation is
    - Key guidance and standards used at NIBSC
    - Analytical validation
    - NIBSC's approach to analytical validation
    - Validating an assay from another laboratory

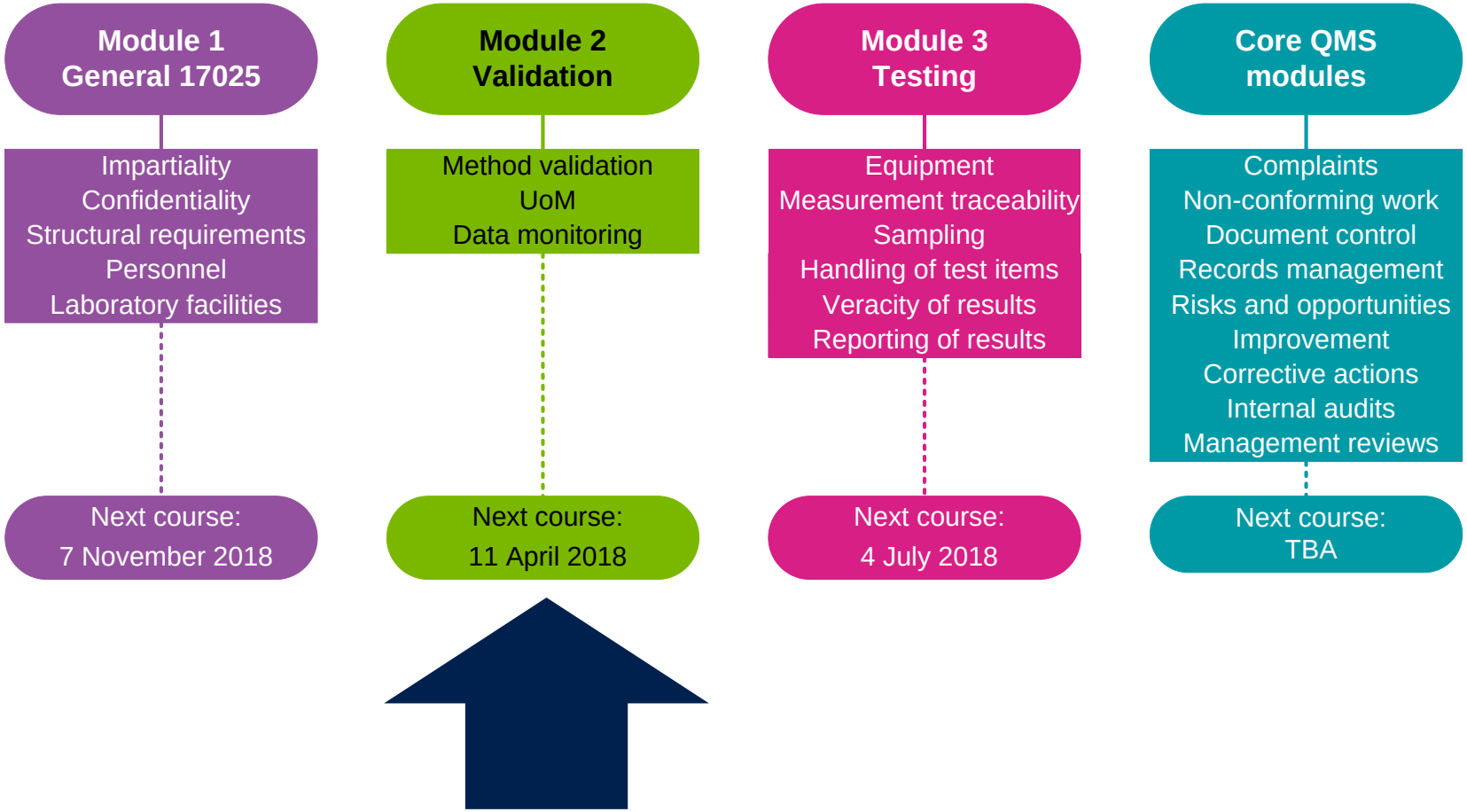
ISO 17025: Module 2 Validation, ~~UoM & Data Monitoring~~

NIBSC Quality Assurance Presentation to Study Areas

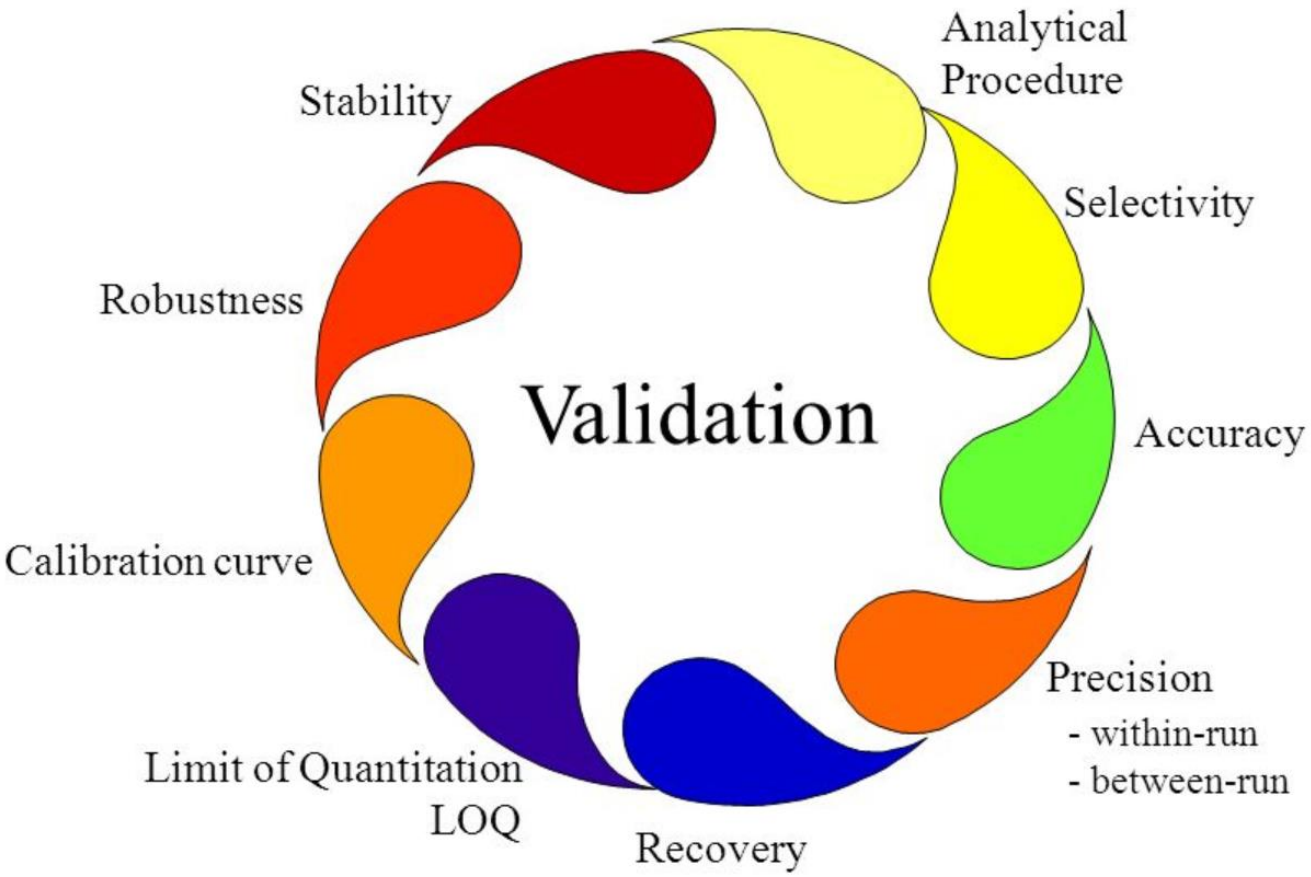
11 April 2018

Medicines & Healthcare products Regulatory Agency

NIBSC Internal Training programme



Validation


Validation
Analytical Procedure
Selectivity
Accuracy
Precision
- within-run
- between-run
Recovery
Limit of Quantitation
LOQ
Calibration curve
Robustness
Stability

Definitions of Validation

ISO/IEC 17025:2005 clause 5.4.5.1

Validation is the confirmation by examination and the provision of **objective evidence** that the particular **requirements** for a specific **intended use** are fulfilled.

ISO/IEC 17025:2017 terms and definitions

Verification – provision of objective evidence that a given item fulfils specified requirements (Post-DCVMN meeting note: For clarification, where NIBSC's training module uses the term "system suitability checks", a v**erification may be required depending on the extent of the impact of the change on the validation).**

Validation – where the specified requirements are adequate for an intended use

ICH Guideline: Objective of validation is to demonstrate that the procedures is suitable for its intended purpose

OMCL (PA/PH/OMCL (13) 82 2R): Data should demonstrate that the proposed testing and acceptance criteria are sufficiently under control to guarantee reproducible quality of the products at release and adequate control during shelf-life

Purpose of validation

To demonstrate that method is:

- Fit for its intended purpose
- Sufficiently under control that results are reliable and reproducible

During validation the following are defined:

- Type of sample that can be used
- Limits within which test can be performed
- Controls developed and assessed
- Test validity criteria
- Estimates for measurement uncertainty

Why validate?

ISO/IEC 17025:2005

…shall validate…methods…to confirm that the methods are fit for intended use…

…validation shall be as extensive as is necessary…

…shall record results obtained…procedure used…and a statement as to whether the method is fit for the intended use…

ISO/IEC 17025:2017

Re-Validation

Same intent as 2005 version plus

…when changes are made to a validated method, the influence of such changes shall be determined and where found to affect original validation, new method validation shall be performed…

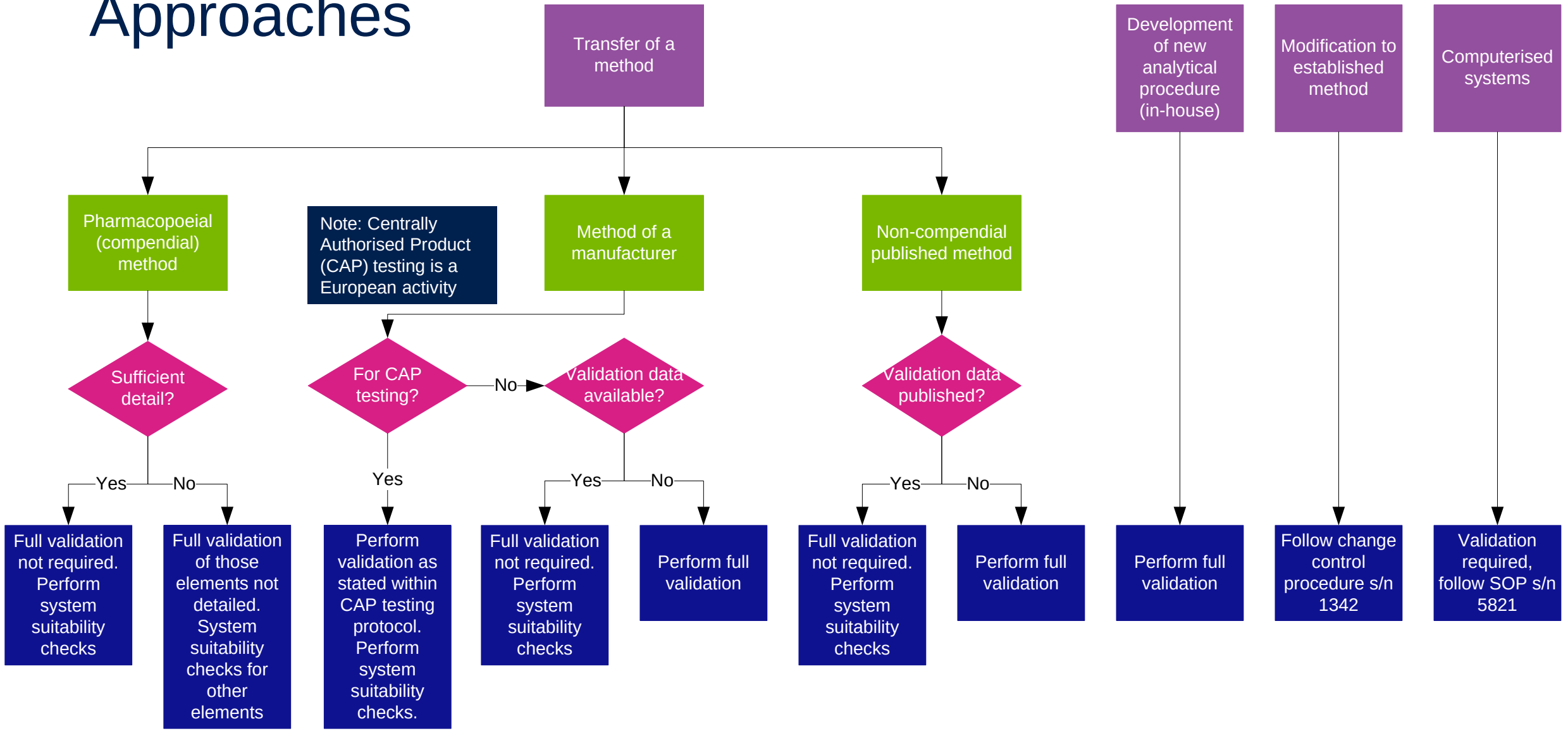
OMCL guideline

PA/PH/OMCL (13) 82 2R Validation of Analytical Procedures

This document is a note for guidance, which provides detailed recommendations of the extent of the validation exercise dependent on the category of the analytical procedure.

Based the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Guidelines

Approaches



(**Post-DCVMN meeting note**: For clarification, where NIBSC's training module uses the term "system suitability checks", a v**erification may be required depending on the extent of the impact of the change on the validation).**

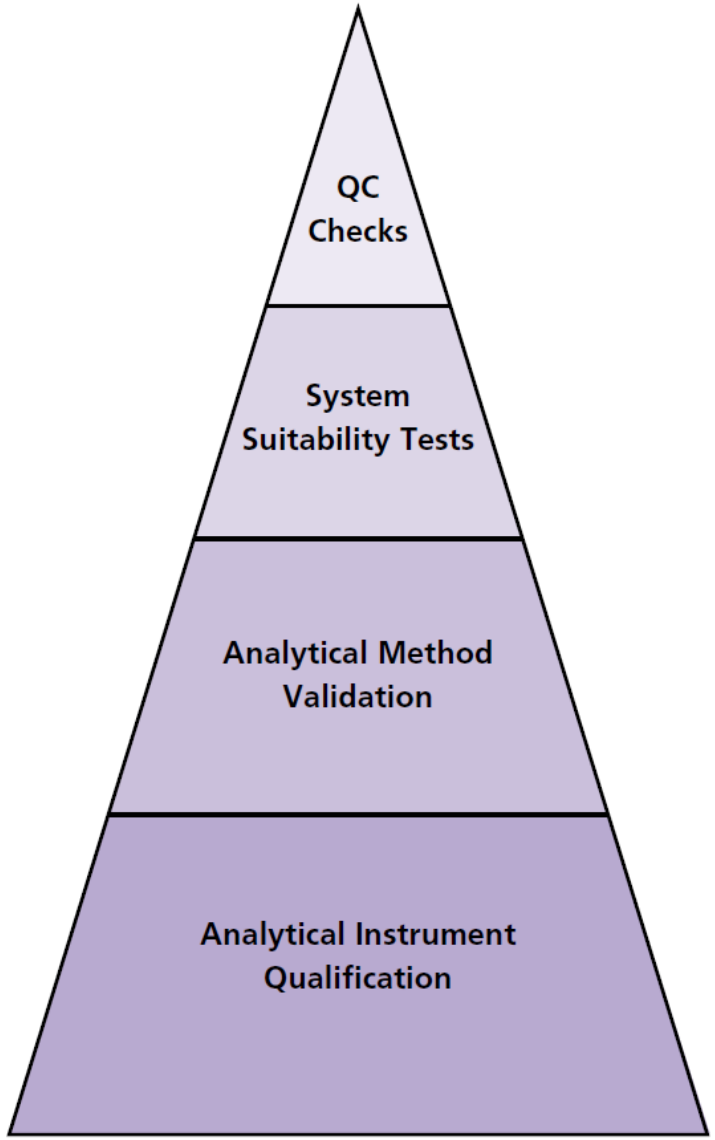
System suitability tests

Based on concept that equipment, electronics, analytical operations and samples constitute an **integral system** that can be evaluated as such.

- Provides assurance that system is working properly
- Ensures method and instrument are performing within expectations
- Should be assessed when there are changes in equipment or critical reagents

The test parameters to use for system suitability tests/verification are established based on the procedure being assessed.

Data quality triangle



Instrument or Method?	When Performed?	Controls What?
Method	• During an analytical run	• System drift over the time of the analytical run and over time of all runs • Can identify system-to-system bias
Method	• On the day of analysis • Before committing samples for analysis	• Confirmation that the system (instrument and method combination) functions within predefined limits
Method	• Before application of the method	• Confirmation of method operating parameters • Sample preparation • Operator-to operator bias • Instrument-to-instrument bias • Method transfer between laboratories
Instrument	• At initial instrument set up • At regular intervals thereafter • Following major maintenance	• Instrument capability • Calibration of instrument independent of method or operator and traceable to national standards whenever possible

DCVMN Workshop Exercise **1**
Validation Requirements

Exercise 1 Validation Scenarios

Scenario Details	
A	European Pharmacopoeia 9th Edition (9.3) includes a revised, fully described method: 2.7.4 Assay of Human Coagulation Factor VIII. This method is fully documented in NIBSC SOP-”Potency estimation of Factor VIII by the chromogenic method.
B	Manufacturer B would like NIBSC to perform batch release testing of their plasma pools with Next Generation Sequencing (NGS) of HCV. This test will be added to NIBSC’s standard process for release testing of plasma pools. This method is documented in Qiu et al. PLOS One, 04/2015, Volume 10, Issue 4.- HCV Genotyping from NGS Short Reads and its Application in Genotype Detection from HCV Mixed Infected Plasma.
C	The Polio study area has developed a new method for in vitro testing of the potency/identity testing of polio type 3. The development of this method is fully documented in the laboratory books.
D	Manufacturer A has developed a new vaccine VacJab and would like NIBSC to perform batch release testing of the product. Manufacturer A has provided their full validation data pack and proposed a method transfer exercise.
E	An in-house spread sheet which automates the relative potency calculation needs to be revised as the manufacturer has updated the method of calculation.

Exercise 1 Complete the columns based on the scenario

Scenario	Type of Validation required	Reason
A		
B		
C		
D		
E		

Exercise 1

NIBSC’s responses on next slide

Exercise 1

Scenario	Validation required	Reason
A	Follow change control	Modification to existing method (falls within current validation)
B	Perform full validation	Published method with incomplete validation data included
C	Perform full validation	In-house developed method
D	Full validation not required, system suitability tests or verification	Transfer of manufacturer's method where full validation data is available
E	Validate as detailed in NIBSC SOP s/n 5821	Computerised system, spreadsheet is performing calculations directly impacting test results.

Extensive as necessary

Accuracy	Trueness, closeness of agreement
Precision - Repeatability - Intermediate precision - Reproducibility	Degree of scatter between series of measurements - Within a run/assay - Within a laboratory - Between laboratories
Specificity	Ability to assess unequivocally the analyte
Detection limit	Lowest amount of analyte which can be detected
Quantitation limit	Lowest amount which can be quantitatively determined
Linearity	Ability to obtain results proportional to concentration
Range	Upper and lower concentration of analyte for which suitable level of precision, accuracy and linearity have been demonstrated

Which parameter to test

Characteristic	Identification	Test for Impurities Quantita.	Limit	Content/potency
Accuracy	-	✓	-	✓
Precision - Repeatability - Intermediate precision	 - -	 ✓ ✓/-	 - -	 ✓ ✓/-
Specificity	✓	✓	✓	✓
Detection limit	-	-	✓	-
Quantitation limit	-	✓	-	-
Linearity	-	✓	-	✓
Range	-	✓	-	✓

Planning validation

Prior to embarking on validation work the following need to be defined and documented:

- context i.e. what is being validated and why
- scope of the validation i.e. sample/product type, method, equipment, software
- validation approach to be taken and rationale for decision
- parameters to be tested i.e. accuracy, specificity
- experimental design i.e. how many samples / assays, no. of replicates, controls to use, no. of operators
- acceptance criteria i.e. what would validation success look like

NIBSC SOP (s/n 2951) Validation of tests

- v10 issued 16/03/2018
- Section added to describe method development / optimisation phase
- **Clarification that changes to existing methods needs to follow change control procedure (s/n 1342)**
- Added instructions on what a model validation plan / protocol should include
- Added instructions on what a model validation report should include

Validation plan template

1. Introduction

XXX...

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

2. Scope

XXX...

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

XXX...

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

- *Pharmacopoeial (compendial method)*
- *Method of a manufacturer*
- *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 s/n 2951 and PA/PH/OMCL (13) 82 2R for further guidance

3.2 Validation Parameters

XXX...

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 s/n 2951 and ICH Guideline Q2(R1) for further guidance

3.3 Format of Validation Exercise

XXX...

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	Source of samples	Parameter to be tested
e.g. 10 vaccine vials	*e.g. Reference batch 12345*	*e.g. Reproducibility*
e.g. 10 DNA extracts	*e.g. PTS EDQM 2014*	*e.g. Specificity*
e.g. 3 plates	*e.g. previously released batches from NoMA*	*e.g. Detection limit*

3.4 Validation Criteria

XXX...

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

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*

4. Procedure

XXX...

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.

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*
4	
5	
6	

5. Impact of Validation

XXX...

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, refer to s/n 2406*
- *how will the uncertainty of measurement been accessed and documented, refer to s/n 16*
- *what CT-LIMS changes are required, refer to s/n 7169*

Validation acceptance criteria

- Objective of validation is to demonstrate fitness for purpose
- Need to define what validation success looks like
- Devise validation criteria and state them in validation plan
  - Product release specifications
  - Measures to demonstrate expected outcome
- Where possible state the source of each criterion

e.g.

Test parameter	Acceptance criteria	Specification
Repeatability	95% of calculated content values to fall within 0.83 and 1.27µg/µL	PhEur 9.8.6.7 method 12345

Documenting validation

Validation process needs to be documented in reports:

- context and scope of validation, in line with validation plan
- acceptance criteria, in line with validation plan
- assessment of performance against each acceptance criterion
- concluding statement regarding methods fitness for purpose
- recommendation to implement validation method
- commentary on impact of validation i.e. uncertainty of measurement, data monitoring processes, document updates

Validation report template

1. Introduction

XXX...

Provide an outline and context for the validation i.e. what was validated and why. [Can copy from the Validation Plan]

2. Validation Criteria

XXX...

Re-state the validation criteria described in Validation Plan. [Can copy from the Validation Plan]

3. Assessment of Performance Against Criteria

Include detailed results with a section for each validation acceptance criteria.

3.1 Acceptance Criterion 1 [edit heading]

XXX...

Each section should include results tables and discussion related to the specific criterion. If any aspect is not fully met this must be discussed with appropriate actions and/or recommendations made.

Sample ID	Observed results			±3SD
	Replicate 1	Replicate 2	Replicate 3	
e.g. 123456	*e.g. 28.2*	*e.g. 33.1*	*e.g. 37.4*	*e.g. 21.3 – 39.7*

XXX...

Reference to the location of original raw data should be included e.g. report appendix, hard copy file locations, soft copy network drive locations.

XXX...

Conclude each section with a statement on whether the acceptance criterion has been met

Acceptance criteria [XXXX] – **Pass/Fail**

3.2 Acceptance Criterion 2 [edit heading]

XXX...

Each section should include results tables and discussion related to the specific criterion. If any aspect is not fully met this must be discussed with appropriate actions and/or recommendations made.

Sample ID	Observed results			±3SD
	Replicate 1	Replicate 2	Replicate 3	
e.g. 123456	*e.g. 28.2*	*e.g. 33.1*	*e.g. 37.4*	*e.g. 21.3 – 39.7*

Sample ID	Observed results			±3SD
	Replicate 1	Replicate 2	Replicate 3	

XXX...

Reference to the location of original raw data should be included e.g. report appendix, hard copy file locations, soft copy network drive locations.

XXX...

Conclude each section with a statement on whether the acceptance criterion has been met

Acceptance criteria [XXXX] – **Pass/Fail**

3.3 Acceptance Criterion 3 [edit heading]

XXX...

Each section should include results tables and discussion related to the specific criterion. If any aspect is not fully met this must be discussed with appropriate actions and/or recommendations made.

Sample ID	Observed results			±3SD
	Replicate 1	Replicate 2	Replicate 3	
e.g. 123456	*e.g. 28.2*	*e.g. 33.1*	*e.g. 37.4*	*e.g. 21.3 – 39.7*

XXX...

Reference to the location of original raw data should be included e.g. report appendix, hard copy file locations, soft copy network drive locations.

XXX...

Conclude each section with a statement on whether the acceptance criterion has been met

Acceptance criteria [XXXX] – **Pass/Fail**

4. Conclusions

XXX...

Conclude whether all validation acceptance criteria have been met. If not what has not been fulfilled? What impact does that have on the validity of the assay and the veracity of results? e.g. will a particular sample type be invalid or does the whole test method need to be further optimised / re-designed?

Include a concluding statement on the fitness for purpose of the test method

All validation acceptance criteria have been met and [test method] deemed fit for purpose for the [identification of X/determining the relative potency of Y/...] for use within the [Study Area/Group] of [Division].

5. Recommendations

XXX...

Describe any actions which need to be taken as a result of the validation exercise, number the recommendations to aid identification and subsequent follow-up.

No.	Recommendation	Target Date	Assigned To
1	*e.g. 28.2*	*e.g. 01/01/2020*	*e.g. John Doe*
2			
3			
4			

Suggest including a general statement approving the implementation of the validated test method.

The validation exercise has been successfully completed and following [close-out of the above recommendations and] authorisation of this report the validated test method will be implemented for routine use following change control procedures.

6. Impact of Validation

XXX...

Based on the impacts stated in the Validation Plan describe what actions have been taken:

- *what documents have been revised e.g. SOPs, forms, study plans. Reference CRQ raised and version numbers issued.*
- *what records have been created or updated e.g. equipment records, training records, critical reagents list. Reference storage location of new/updated records.*
- *what training schedules have been created/updated, which staff have undergone (re)training.*
- *has a review of data monitoring method taken place and been documented. Reference location of authorised review*
- *has uncertainty of measurement been re-accessed and documented. Reference location of authorised re-assessment*
- *have required CT-LIMS changes been made. Reference record of changes made.*

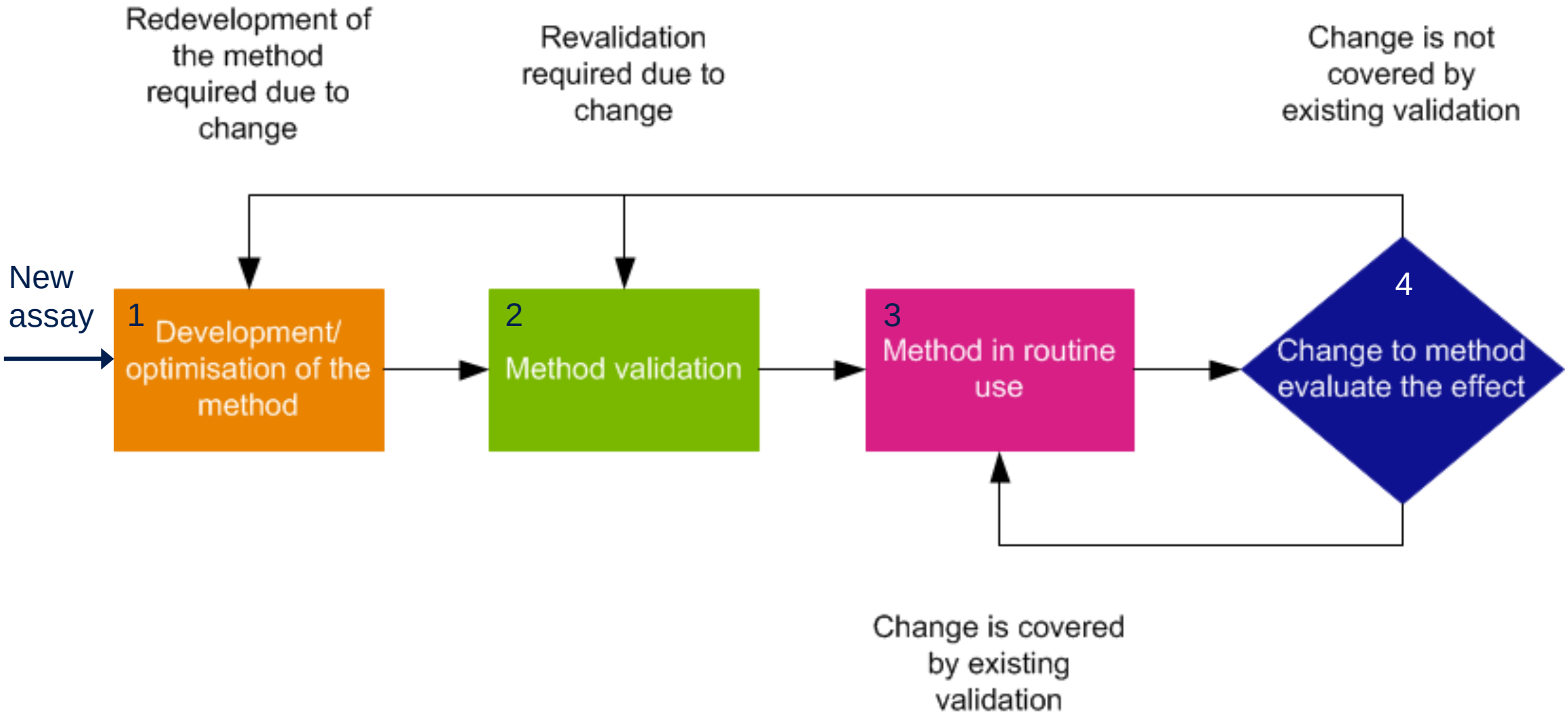
Document attributes

Validation documents are considered technical records and therefore need to have the right document attributes:

- Unique identification
- Pagination
- Version number and traceability of revisions
- Issue/authorisation date
- Author’s name and signature
- Authoriser’s name and signature

Note: Validation plans should be written and authorised prior to embarking on validation work, watch your dates.

Validation lifecycle



Changes to methods

When planning changes to existing methods need to consider the following:

- Details and scope of proposed change
- Benefits of proposed change
- Evaluation of the impact the proposed change will have on the current method including risks and challenges
- Evaluation of the risk of not making the proposed change

Document this on change control record NIBSC form s/n 1509

Summary - Validation

- Validation demonstrates test method is fit for purpose
- Approach taken depends on the primary source of the method
- Devise appropriate validation acceptance criteria based on what validation success looks like
- Develop a validation plan/protocol prior to generating validation data
- Assess impact on validated state when changes are made, re-validate where required.

DCVMN Workshop Exercise 2

Method Transfer Scenario

At Manufacturer A (site ABC), you are a QC officer in a laboratory (site ABC) that undertakes QC/release testing of bulks that go into the manufacture of a well-established, licensed HepB Vaccine (VaccuHep). The tests that you perform on VaccuHep include the determination of 1) **Purity and Intact Monomer of HBsAg Bulks by SDS-Page and Densitometry and** 2) **In vitro Relative Potency of HBsAg Bulks by ELISA.**

Manufacturer A also has a licensed HPV Vaccine (HPVVac) that is manufactured and QC-released at another site (XYZ). The assays at site XYZ for HPVVAc bulks include 1) **Purity and Intact Monomer of HPV Bulks by SDS-Page and Densitometry and** 2) **In vitro Relative Potency of HPV Bulks by ELISA.** The demand for HPVVac is increasing and Manufacturer A wants to expand the QC testing of HPVVac bulks to the laboratory at site ABC.

The 2 laboratories have been asked to initiate the transfer of the above assay methods for HPV bulks (from site XYZ to site ABC). The lab at XYZ will be providing their SOP (including the requirements for assay validity and specifications) and all critical reagents (including the reference materials and controls). Your lab at ABC will be using the same laboratory setup that is used for the testing of HepB bulks (e.g. the same gels, buffers, stain, scanner and densitometer software for assay 1; or the same buffers, plate washer, substrate and plate reader for assay 2).

DCVMN Workshop Exercise 2
Method Transfer Scenario
Drafting a validation plan

Your Task

Working in groups of 2-4, chose either assay 1 (**HPV Bulk Purity and intact monomer by SDS-Page and Densitometry)** or assay 2 (**In vitro Relative Potency of HPV Bulks by ELISA)** to complete the Validation Plan based on the scenario given.

DCVMN Workshop Exercise 2
Method Transfer Scenario
Drafting a validation plan
(pdf)

DCVMN Workshop Exercise 2
Method Transfer Scenario
Drafting a validation report
(pdf)

DCVMN Workshop Exercise 2

Method Transfer Scenario

What do you do if one of the criteria is not met? E.g. One assay is not valid?

What if measurement readouts are running high? E.g high ODs or extra bands in the gel?

Acknowledgments

Inactivated Viral Vaccines Group

- Lindsay Stone
- Emma Summersgill

Future Vaccine Manufacturing Research (FVMR) Hub
https://www.imperial.ac.uk/future-vaccine-hub

NIBSC Quality Assurance

- Penny Carter - Head
- Jennifer Sandle
- Lucy Johns

- Professor Robin Shattock – Director
- Ben Pierce Operations Manager

NIBSC is grateful to the U.K. Department of Health and Social Care for funding the Future Vaccine Manufacturing Hub through the Engineering and Physical Sciences Research Council (EPSRC, grant number: EP/R013764/1)

Future training opportunities

- NIBSC is part of the Hub (https://www.imperial.ac.uk/future-vaccine-hub/)
- DCVMN is also a partner
- Training opportunities from the Hub will become available throughout the Hub's duration likely in 2020

Thank you for your participation