

SOP

VALIDATION OF METHODS

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A. GENERAL INFORMATION

A1. SCOPE

Validation is the process by which a method is ensured to be repeatable, reproducible, precise, and accurate. This SOP provides guidance in the development and validation of methods, when no standardised methods are available or when standardised methods are modified to extend their intended purpose.

This SOP does not cover safety procedures for using equipment and handling reagents; personnel shall follow institutional safety guidelines.

A2. OBJECTIVES

- › Ensure that BB methods selected, modified, or developed are appropriate for the intended use.
- › Ensure that BB methods are appropriate, validated, and properly documented in the Methods list (Document 2.03.005) and/or in the Document Management System or BIMS.
- › Ensure that personnel, who will apply the newly validated methods, are qualified to perform the task.
- › Ensure that each method applied has suitable facilities, equipment, and consumables with appropriate metrological monitoring.

A3. ABBREVIATIONS AND DEFINITIONS

For this document, the following abbreviations apply.

BB = Biobank

BIMS = Biobank Information Management System

Mgmt = Management

QR = Quality Representative

SBP = Swiss Biobanking Platform

SOP = Standard Operating Procedure

See SBP Glossary for definitions.

The SBP SOPs are based on Good Biobanking Practices to ensure an optimal setup for the biobanking activities.

Additionally, the SBP SOPs can serve as a reference for BBs to develop site-specific Work Instructions.

B. PERSONNEL MANAGEMENT

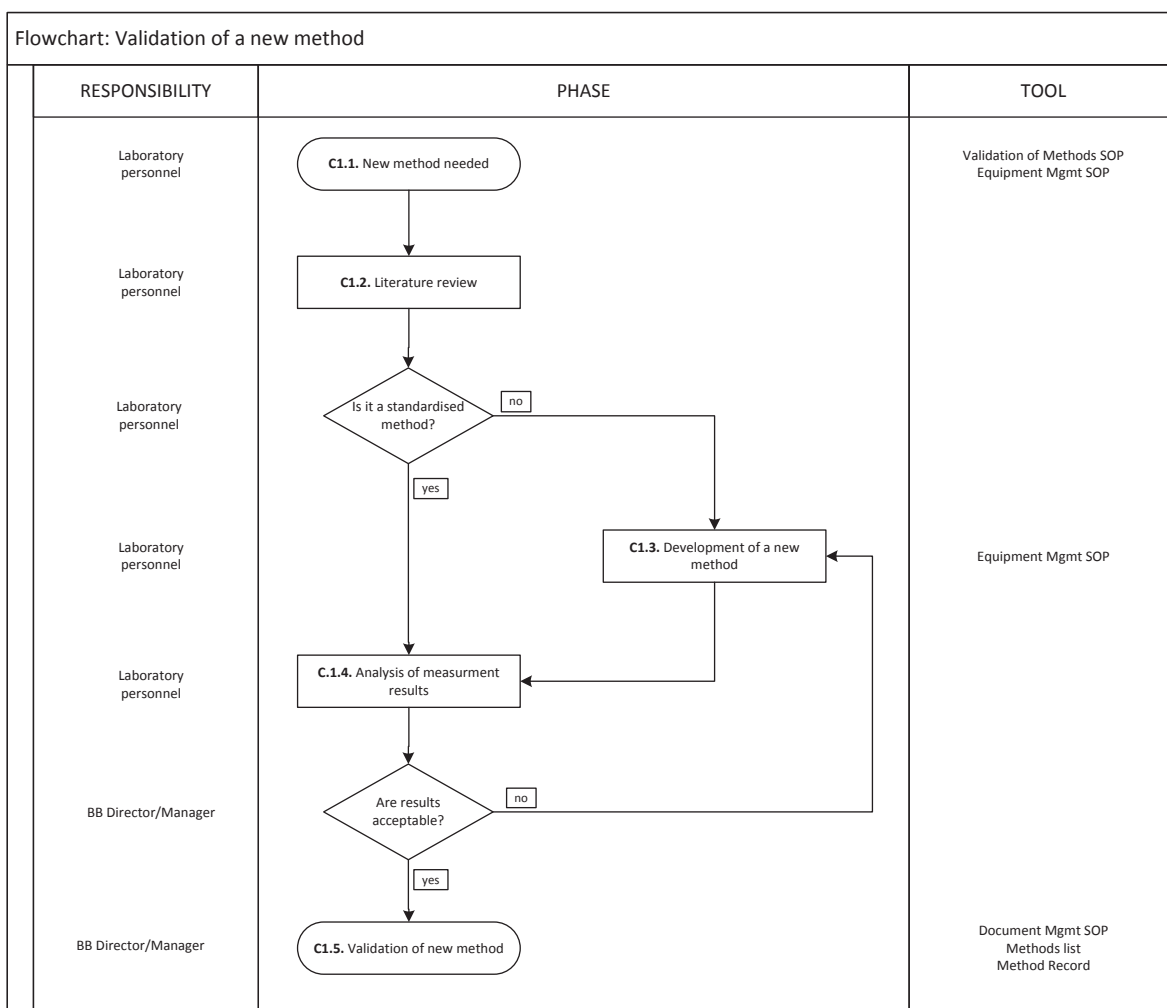
B1. ROLES AND RESPONSIBILITIES

BB personnel	Responsibility / role
BB Director/Manager	› Validates and approves newly developed methods
Laboratory personnel	› Identification of new methods › Literature review › Development of new methods › Carrying out of measurements › Acceptance or rejection of measurement results › Writing of new Work Instructions
QR	› Validates new Work Instructions › Performs Quality Control

C. PROCESS MANAGEMENT

C1. VALIDATION OF METHODS

The following flowchart represents the steps to follow to develop a new method or validate an already existing one.



C1.1. Need of a new method

- > New methods shall be developed or adapted when no standardised methods are available or when a modification of a standardised method is required.

C1.2 Literature review

- > Before developing new methods, an accurate and in-depth literature review, concerning the new methods that the BB personnel want to apply, shall be conducted.

C1.3 Development of a new method

- > The laboratory personnel shall develop and optimise the selected method.
- > The laboratory personnel shall carry out the test experiments with the developed method.

C1.4. Analysis of measurement results

- The laboratory personnel shall analyse the new method measurements to ensure that the requirements for the intended purpose are met. Data and statistical treatments on the measurement results should be used to determine whether the methods can be accepted or must be rejected. The following criteria should be fulfilled: Repeatability, Reproducibility, Accuracy, and Precision.
- In the presence of any non-conformities, the laboratory personnel shall follow the procedures described in the Non-conformity Management SOP (Document 1.04.002).

C1.5. Validation of the method

- The BB Director/Manager shall evaluate if the new method can be accepted and, therefore, implemented or not, based on the analysis of measurement results.

C1.6. Documentation of the new methods

- Upon acceptance of the new method, laboratory personnel shall write BB Work Instructions for the new method.
- The BB Director/Manager shall validate the BB Work Instructions for the new method.
- When a new method is validated, a new Method record (Document 2.03.004) shall be created and maintained. The method record should contain the following information: title of the method, short description of the method, source of the method, parameters or quantities or ranges to be determined, equipment requirements, consumables required, description of the methodological step-by-step protocol, any safety measures to be observed, criteria for approval, the uncertainty estimated for the new method results.
- A Methods list (Document 2.03.005) containing all methods validated shall be maintained as well.
- The Method list (Document 2.03.005) and the Method record (Document 2.03.004) shall be recorded in the Document Management System or BIMS and should be readily accessible for audits, as further explained in the Internal audit SOP (Document 1.04.004).

C2. QUALITY CONTROL

- The QR controls that personnel, who are responsible for the validation of methods, are qualified for the task, as reported in the Personnel file (Document 2.02.001), as established in the Personnel Management SOP (Document 1.02.001).
- The QR controls that the report and the documentation concerning the new methods is compliant with standard requirements.
- Quality control outcomes should be recorded in the Quality Control Results (Document 2.04.009).

D. RESOURCE MANAGEMENT

D1. MATERIALS AND EQUIPMENT

The materials and equipment in the following list are recommendations only and may be substituted by alternative/equivalent products more suitable for the specific task or procedure.

Materials and equipment
Consumables
Equipment

D2. PROTECTIVE WEAR AND SAFETY EQUIPMENT

Personnel shall follow institutional safety requirements at all times.

Safety equipment/protective wear
Safety equipment for equipment calibration and maintenance

E. REFERENCES

E1. REFERENCE TO LAWS, REGULATIONS, AND GUIDELINES

- › SBP - Ethical, legal and professional compliance list for human research biobanks applicable in Switzerland [Status as of 1 March 2018]

E2. REFERENCE TO OTHER SBP DOCUMENTS

- › 1.04.001 Document Management SOP
- › 1.02.001 Personnel Management SOP
- › 1.02.002 Equipment Management SOP
- › 1.04.002 Non-conformity Management SOP
- › 1.04.004 Internal audit SOP

E3. APPENDICES

- › 2.04.009 Quality Control Results
- › 2.02.001 Personnel file
- › 2.03.004 Method record
- › 2.03.005 Methods list

E4. REVISION HISTORY

Document number	Revision date	Author	Details of revision
1.03.002		SBP	Initial release