

SOP

IMPROVEMENT MANAGEMENT



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A. GENERAL INFORMATION

A1. SCOPE

This SOP provides insight into the Biobank (BB) continual improvement, which drives an efficient and effective Quality Management System.

The BB Quality Policy is a document approved by the BB Management; it reports the quality objectives that drive the BB.

The Management Review process requires BB management to review the QMS periodically to ensure its suitability, effectiveness, and alignment with the BB strategy and the Quality Policy. The purpose of the Management Review process is the continual improvement of the QMS of the BB.

A2. OBJECTIVES

- › Ensure that the BB QMS is continually evaluated and improved.
- › Ensure that the BB operates within legal, ethical, societal, and professional requirements are fulfilled.
- › Ensure that the BB Quality Policy and the quality objectives are always appropriate and suitable via periodical suitability reviews.
- › Ensure that the BB Quality Policy and the quality objectives are shared with the personnel.

A3. ABBREVIATIONS AND DEFINITIONS

For this document, the following abbreviations apply.

BB = Biobank

BIMS = Biobank Information Management System

CAPA = Corrective Action / Preventive Action

QMS = Quality Management System

QR = Quality Representative

SBP = Swiss Biobanking Platform

SOP = Standard Operating Procedure

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

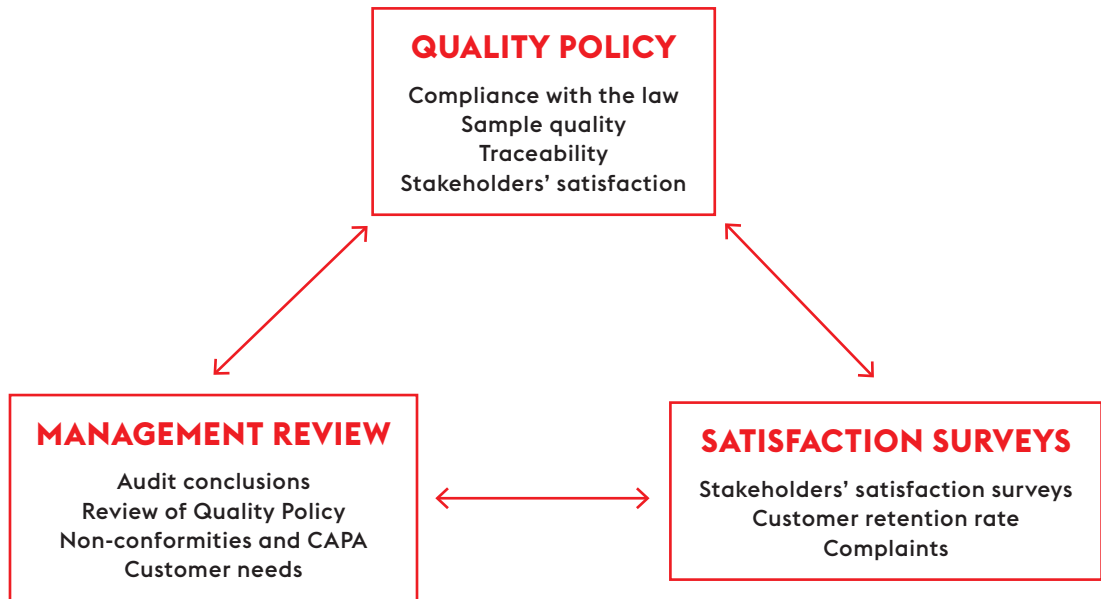
B1. ROLES AND RESPONSIBILITIES

BB personnel	Responsibility / role
Strategic and Operational Management	<ul style="list-style-type: none"> › Defines the Quality Policy › Reviews and updates the Quality Policy › Performs periodical management reviews
Qualified personnel	<ul style="list-style-type: none"> › Contribute to the continual improvement of the BB › Carry out the Stakeholders' Satisfaction Surveys › Are aware of the BB Quality Policy
BB Director/Manager	<ul style="list-style-type: none"> › Defines the Quality Policy › Reviews and updates the Quality Policy › Performs periodical management reviews › Writes the Management Review Report › Implements the Quality Management System › Communicates the reviewed Quality Policy and objectives to the personnel
QR	<ul style="list-style-type: none"> › Defines the Quality Policy › Reviews and updates the Quality Policy › Communicates the reviewed Quality Policy and objectives to the personnel › Analyses the Stakeholders' Satisfaction Surveys › Performs Quality Control

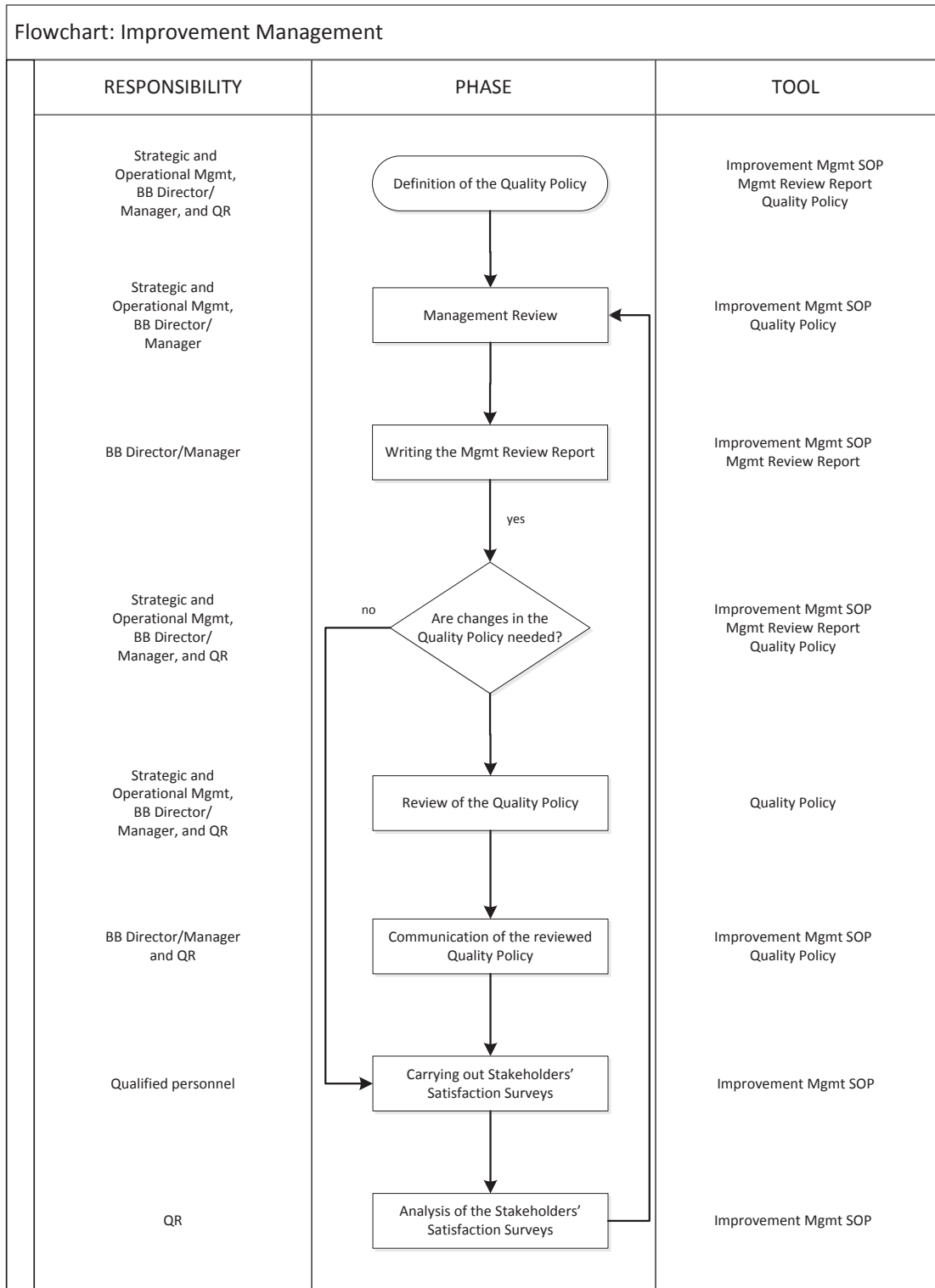
C. PROCESS MANAGEMENT

CI. PROCEDURES

This diagram displays the interdependencies of the Quality Policy, Management Review process, and Satisfaction Surveys.



This flowchart describes the phases leading to the improvement of the QMS of the BB.



C1.1. Defining a BB Quality Policy

- A BB Quality Policy shall at least include the following four objectives:
 - 1a. Compliance with the law achieved by fulfilling the minimal legal and ethical requirements.
 - 1b. Reliable traceability of samples, documents, and resources management, achieved by implementing a BIMS and a Document Management System.
 - 1c. Stakeholders' satisfaction achieved through the analysis of the stakeholder surveys. The BB should build a profitable relationship with the customers. The management of participant's complaints, handled as defined in the Safety and Complaints SOP (Document 1.01.004), should be included in the Quality Policy as well.
 - 1d. Continual improvement, including sample quality improvement. The continual improvement is achievable via the implementation of CAPA and good biobanking practices.
- Strategic and operational management, the BB Manager/Director, and the QR shall define the objectives of the Quality Policy. Precise descriptions of procedures, processes, and initiatives concerning these objectives shall be included.
- The Quality Policy, the quality objectives shall be maintained as documented information and should be readily accessible for audits, as further explained in the Internal audit SOP (Document 1.04.004).

C1.2. Conduction BB Management Review process

- The frequency of the reviews is defined in the QMS.
- Minutes of the management reviews shall be documented through the Management Review Report (Document 2.04.005).
- The management review process shall focus on:
 - 1a. Satisfaction of stakeholders, as the result of the stakeholders' survey analyses.
 - 1b. Audit results.
 - 1c. Occurred non-conformities and the corrective and preventive actions undertaken.
 - 1d. Possible changes that might affect the QMS, including changes to the Quality Policy and quality objectives.
- The management review outputs should include QMS improvement actions and revised BB Quality Policy.
- The Management Review Reports shall be maintained as documented information and should be readily accessible for audits, as further explained in the Internal audit SOP (Document 1.04.004).

C1.3. Review of the Quality Policy

- The Quality Policy shall be updated and the quality objectives modified in agreement with the Management Review Report.
- Strategic and operational management, the BB Manager/Director, and the QR shall review the Quality Policy.

C1.4. Internal communication

- The BB Manager/Director and the QR shall communicate the changes to the Quality Policy to the personnel.
- All personnel shall be aware of the Quality Policy changes and contribute to the continual improvement of the BB
- All personnel shall be trained in the continual improvement of the BB, including the understanding of the Quality Policy and objectives.

C1.5. Assessment of the satisfaction of the BB Stakeholders

- Stakeholders' satisfaction surveys shall be conducted by phone call or through questionnaires.
- Qualified personnel shall conduct stakeholders' satisfaction surveys.
- Customer retention rate (percentage of customers retained at a certain period compared to the number of customers at the beginning of this period) is another indicator that measures the satisfaction of the customers and, indirectly, the quality of the samples and of the services the BB offers.
- Employees' satisfaction surveys provide to the BB management the knowledge and the tools to build a positive work environment.
- Employees' engagement surveys shall be conducted as well. They measure the commitment of the employees toward the BB goals. Engaged employees share responsibility and are eager to work together toward mutual success objectives.
- Complaints shall be included in the overall assessment of the BB QMS, as established in the Safety and Complaints SOP (Document 1.01.003).

C1.6. Analysis of the satisfaction of the BB Stakeholders

- The QR shall perform the analysis of the stakeholders' satisfaction surveys. The analysis outcomes shall be part of the objects of the next management review.

C4. QUALITY CONTROL

- › The QR controls that personnel are qualified and committed to contributing to the overall improvement of the BB and its QMS.
- › The QR controls that personnel, who are responsible for the improvement management, 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).
- › Every time the QR performs quality control on the process outputs, quality control details (date of QC, outcomes) shall 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

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]
- › ISO 9001:2015

E2. REFERENCE TO OTHER SBP DOCUMENTS

- › 1.04.001 Document Management SOP
- › 1.02.001 Personnel Management SOP
- › 1.01.003 Safety and Complaints 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
- › 2.04.004 Quality Policy
- › 2.04.005 Management Review Report

E4. REVISION HISTORY

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