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BIOBANKING FOR GLOBAL CHALLENGES

Quality Standards for Polish Biobanks Handbook

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INTRODUCTION

BBMRI.pl QMS team has performed many activities and prepared supporting tools to help biobanks from Polish Biobanking Network (PBN) to form and improve their quality systems to fulfill the requirements of high quality samples and data for scientific cooperation purposes and exchange. In cooperation with ELSI and IT experts from BBMRI.pl Quality Standards for Polish Biobanks Handbook (QSPB Handbook) have been prepared (2018) and evaluated (2020).

AIM

We have observed a continued increasing expectations of researchers of both access to high quality biological material and the quality of associated data, regardless of the specific scientific purposes. The handbook is the first such a tool in the biobanking science area, which allows any biobanking entity to create, implement and continuously improve their QMS

METHOD

The structure of the document consists of 15 chapters, where all QMS aspects regarding biobanking are determined according to the best knowledge based on the dedicated for biobanks ISO standards and *Best Practices*. The configuration of the document are as follows: Admission, Dictionary, and 15 chapters covering the areas: 1. Management of Biobanks; 2. Quality management; 3. Documentation and records; 4. Human Resources Management; 5. Ethical and legal aspects; 6. Supplies, materials management; 7. Equipment; 8. Traceability; 9. Environmental and staff hygiene; 10. Biobanking processes and quality control; 11. Deviations, nonconforming product/data, or service; 12. Audits; 13. Improvement; 14. Biobank cooperation in the scientific, research, and development area; 15. Safety and security.

QSPB Handbook is convergent with ISO 20387:2018, ISO 9001:2015, ISO 19011:2018, ISO 27000:2014 and ISO 27002:2013. It is compatible with the recommendations of the OECD, IARC, and ISBER *Best practices.*

RESULTS

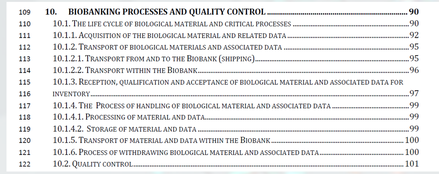
QSPB is currently the only publication on the international field of biobanking. Most importantly it is compliant with the standard ISO 20387:2018 *Biotechnology - Biobanking - General requirements for biobanking.* Thanks to creative approach it describes all the requirements contained in the standard in a more detailed, descriptive, and practical way. Any user planning the implementation of quality standards in biobanking can easily understand and then implement the requirements, thereby preparing for the accreditation process for compliance with the standard.

A good example is the best practices section under the following requirements are placed with Frequently Asked Questions (FAQ) part.

Authors of this Handbook not only present the requirements that must be met to maintain the correctness of the scientific and research process, but also precisely explain and suggest how you can implement the given clause.

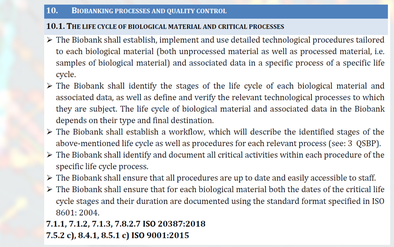
QSPB can be a significant international resource for the implementation of the highest quality standards for biobanking units of human biological material and related data, in accordance with the guidelines of ISO 20387:2018. The manual can be used by any biobanking unit regardless of the biological material with which the biobank operates and biobank networks to which it belongs. Good QMS can be both helpful for achieving scientific targets and also help in cooperating with the private's sector.

First version of QSPB has been published in polish language in 2019. Now 2nd version is prepared to be published in English and Polish language.



The most common practices:

! Important technological processes at the Biobank are usually:
– the process by which the Biobank acquires biological material and associated data, e.g. by:
  - the procurement of material at the Biobank or under the responsibility of the Biobank,
  - the transfer of material and data to the Biobank, e.g. based on a cooperation agreement. In such a case, the Biobank is not responsible for the procurement of the material,
  - taking responsibility for the supervision over the material and data entrusted to the Biobank as well as related data. In such a case, the Biobank is not the owner of the material and data.
– the process of transport of biological material and associated data to the Biobank;
– the process of reception, qualification and acceptance of biological material and associated data for the inventory of the Biobank;
– the process of handling of biological material and associated data in the Biobank, including:
  - the process of processing of material and data,
  - the process of storage of material and data,
  - the process of transport of material and data within the Biobank.
– the process of withdrawing of biological material and associated data from the Biobank by:
  - the process of distribution (issuing) of material and data as well as the process of their transport from the Biobank,
  - the process of the disposal of material and data.


10. BIOBANKING PROCESSES AND QUALITY CONTROL

10.1. THE LIFE CYCLE OF BIOLOGICAL MATERIAL AND CRITICAL PROCESSES

- The Biobank shall establish, implement and use detailed technological procedures tailored to each biological material (both unprocessed material as well as processed material, i.e. samples of biological material) and associated data in a specific process of a specific life cycle.
- The Biobank shall identify the stages of the life cycle of each biological material and associated data, as well as define and verify the relevant technological processes to which they are subject. The life cycle of biological material and associated data in the Biobank depends on their type and final destination.
- The Biobank shall establish a workflow, which will describe the identified stages of the above-mentioned life cycle as well as procedures for each relevant process (see: 3 QSBP).
- The Biobank shall identify and document all critical activities within each procedure of the specific life cycle process.
- The Biobank shall ensure that all procedures are up to date and easily accessible to staff.
- The Biobank shall ensure that for each biological material both the dates of the critical life cycle stages and their duration are documented using the standard format specified in ISO 8601: 2004.

7.1.1, 7.1.2, 7.1.3, 7.8.2.7 ISO 20387:2018
7.5.2 c), 8.4.1, 8.5.1 c) ISO 9001:2015

Frequently asked questions:

? **May the Biobank refuse to accept biological material and associated data, and, if yes, when?**
The Biobank may refuse to accept the material and data. Such activity has to be included in the Biobank's internal procedures and the external entities supplying the material and data have to be informed in advance about such possibility, e.g. such possibility is included in the written information for the material procurement unit or in the cooperation agreement with such a unit. Both above-mentioned procedures as well as information for the entity / contained in the contract with the entity should clearly specify the situations in which the Biobank refuses to accept the material and the further course of action in such a case.

? **What could be the reasons for refusing to accept biological material and related data at the Biobank?**
The reason for refusing to accept biological material and associated data at the Biobank may be, for example, an irreversible damage to the transport packaging or incorrect transport conditions that result in an irreversible damage to biological material.

CONCLUSIONS

QSPB Handbook has been identified as a positive, thoroughly researched, carefully structured, readable and highly valuable document. It can empower local biobanks to dive into QM for the processes improvement and security assurance in knowing they are adhering to european and international standards.

QSPB Handbook as comprehensive and consecutive solution for uniform QMS implementation and improvement in PBN is the first such a tool in the biobanking area, which allows any biobank to create, implement and continuously improve their QMS. It may be a well-organized, self-control and regulation tool enables biobanks to do their job properly. Finally, the implementation of a new ISO standard 20387:2018, dedicated to biobanks is also easier to perform with QSPB Handbook.

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