

Implementation of ISO 9001 in biobanks as a milestone towards ISO 20387 accreditation

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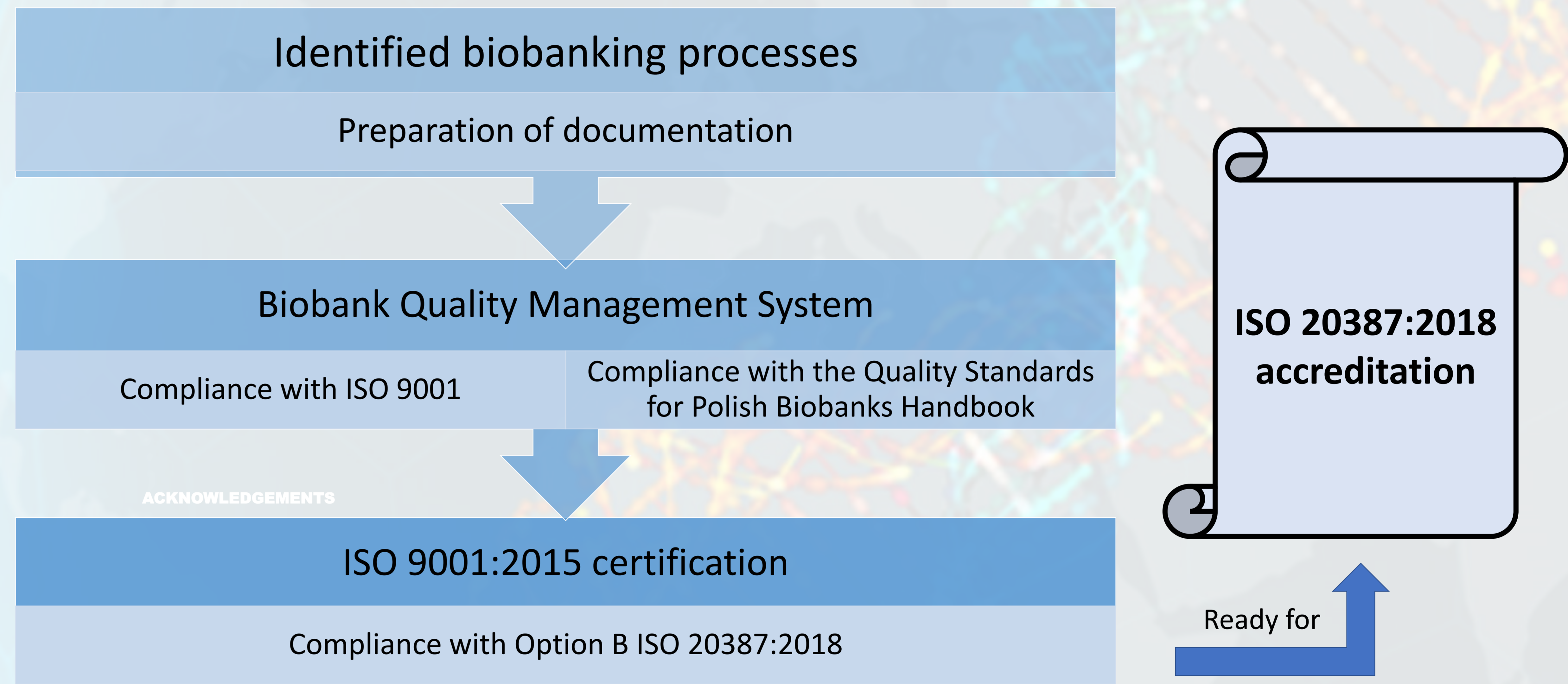
INTRODUCTION

ISO 9001 is a general standard, dedicated to each organization, where quality is very important. ISO 20387 provides guidelines for QMS and complies with ISO 9001 in this respect while referring to more detail biobanking processes. Thus, ISO 9001 implementation seems to be reasonable decision for QMS introduction in Biobank from the perspective future ISO 20387 accreditation.

METHOD

The ISO 20387:2018 standard indicates two options A and B for requirements implementation. According to option B, Biobank where QMS is in accordance with ISO 9001 in clauses 4 to 7 also fulfills the intent of the QMS specified in 8.2 to 8.9. Moreover, clause 8.1.3 pointed out the consistent fulfillment of specific requirements for biobanks captive in the section. Option A is dedicated to biobanks that implement minimum requirements of a quality management system in a biobank. For ISO 9001:2015 certification process preparation, the Quality Standards for Polish Biobanks Handbook (QSPB) played a significant role. QSPB is convergent with ISO 9001, 20387, OECD, IARC recommendations and ISBER Best Practices. As a supporting tool, QSPB help to create, implement, and continuously improve Wrocław Medical University Biobank (WMU Biobank) QMS.

RESULTS



WMU Biobank, as the first biobank in Poland, holds certificate No: FS 708094 and operates a Quality Management System which complies the requirements of ISO 9001:2015 for the following scope: Biobanking of biological material for scientific, educational, research and development purposes.

CONCLUSIONS

The ISO 9001 requirements don't interfere with the shape of the specific procedures of the biobank but integrate them with all biobank activities and complements technological details of ISO 20387 standard.

REFERENCES

1. ISO 20387: 2018 *Biotechnology — Biobanking — General requirements for biobanking* <https://www.iso.org/obp/ui/#iso:std:iso:20387:ed-1:v1:en>
2. ISO 9001: 2015 *Quality management systems — Requirements* <https://www.iso.org/obp/ui/#iso:std:iso:9001:ed-5:v1:en>

ACKNOWLEDGEMENTS

The project is supported by the Polish Ministry of Science and Higher Education (DIR/WK/2017/2018/01-1).

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