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Biotechnology — Biobanking — General requirements for the validation and verification of processing methods for biological material in biobanks

Biotechnologie — Biobanques — Exigences générales pour la validation et la vérification des méthodes de traitement du matériel biologique dans les biobanques

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 276, *Biotechnology*.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Biobanks, producing viable and non-viable biological materials (human, animal, plant, microbial) for research purposes, within biotechnology, use processing methods. Many biobanks include processing laboratories where processing methods are performed and biological materials are produced as an output. Examples of widely used processing methods, applied by biobank laboratories, include DNA, RNA and protein extractions from blood, tissue, seeds, bacteria, or other biological material, or primary cell cultures. An example for the validation of a processing method is provided in Reference [27]. Biobank laboratories are not always equipped to perform testing methods, which are required for annotation or qualification of the biological material output.

This document sets out specific requirements for validation of processing methods. It is intended to help biobank laboratories who perform processing of biological materials, whether they perform themselves testing activities on the biological materials they have produced, or not. It enables validation of processing methods, complements the quality management system of any biobank laboratory performing processing of biological materials and gives more credibility to such an organization. It is understood that while the term "method" used in ISO/IEC 17025 corresponds to "testing method" or "calibration method", a fundamental distinction exists between "processing methods" where the output is a biological material and "testing methods" where the output is a test result (see Annex A). It is understood that validation of processing methods performed by accredited testing laboratories, who test the biological material output themselves, is already included in their accreditation scope.

Validation of a processing method encompasses confirmation of the fitness for purpose of the output biological material, assessment of the homogeneity and stability of the biological material, and assessment of the reproducibility and robustness of the processing method. This validation requires testing in order to assess/measure the qualitative or quantitative properties of the biological material. This testing will lead to the assessment of the fitness for purpose, the reproducibility, and the robustness of the processing method. Examples of such properties are: viability, purity, pluripotency, molecular integrity, concentration, growth capacity, etc.

Biotechnology — Biobanking — General requirements for the validation and verification of processing methods for biological material in biobanks

1 Scope

This document specifies the validation and verification requirements applicable to a biobank to be able to demonstrate that it operates its processing of biological materials with validated and/or verified methods that are fit for purpose.

This document is intended for use in the implementation and validation of processing methods for biological materials.

This document covers method validation and verification for the production of all biological materials. This document does not apply to biological material intended for food/feed production, laboratories undertaking food/feed analysis, and/or therapeutic use.

Reference material production is not covered in this document. For the production requirements for reference materials, see ISO 17034.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 20387, *Biotechnology — Biobanking — General requirements for biobanking*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 20387 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
aliquot
portion of a quantity of biological material which has been divided into separate parts at the same time under identical conditions

Note 1 to entry: The aliquot is representative of the biological material with respect to the property or properties being investigated.

Note 2 to entry: The term aliquot most commonly refers to liquid or semi-liquid biological materials.

3.2
biobank laboratory
processing (3.15) laboratory under the control of a biobank where *processing methods* (3.16) are performed for the output/production of biological materials