Accreditation of Biobanks to ISO 20387:2018

An overview of the standard

What is ISO 20387?

- ISO 20387 is a generic standard that accreditation bodies use to assess the competence of Biobanks
- ISO 20387 specifies generic requirements for impartiality, confidentiality, management, resources and the processes of Biobanks including the collection, distribution, storage, maintenance, transport and traceability of biological material
- ISO 20387 was created via ISO committee ISO/TC 276 – Biotechnology
- First published in 2018
- 2023 it will be up for its first 5-year review

Why was it needed?

- Many Biobanks were accredited to other Standards such as:
- ISO/IEC 17025 General requirements for the competence of testing and calibration Laboratories
- ISO/IEC 17034 General requirements for the competence of reference material producers, or
- ISO 15189 Medical laboratories - Requirements for quality and competence
- However, none of these standards covered the crucial aspects of maintaining a biobank. So, ISO 20387 was developed to ensure that the entire range of biobanking functions in mind such as ethics, consent, financial viability

ISO 20387 does not cover…

- The standard does not apply to biological material intended for food/feed production, laboratories undertaking analysis for food/feed production, and/or therapeutic use.

What is a Biobank?

- This is defined in ISO 20387 3.6 as:
- process of acquisitioning (3.2) and storing, together with **some or all** of the activities related to collection, preparation, preservation, testing, analysing and distributing defined biological material as well as related information and data

- Scope of Biobanks: biobanking of biological material from multicellular organisms (e.g. human, animal, fungus and plant) and microorganisms for research and development.

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ISO 20387:2018- Biotechnology - Biobanking General Requirements

- Contains requirements for:
- Competency, Impartiality and Consistent Operation of Biobanks

- Such as:
- Competence of personnel, training, monitoring
- Equipment and calibration
- Collection, transport, reception and distribution of biological material
- Quality Control
- Validation and Verification of methods utilised
- Management of Data and information
- Management of Nonconforming work and complaints
- Quality Management (internal audits, document control etc.)

ISO 20387:2018 - Structure

- In line with other new 17000 series Standards:-
- Structure: “What one needs to be”
- Resource: “What one needs to have”
- Process: “What one needs to do”

- Also:
- Management system requirements to be met by Biobanks using:-
- ISO 20387 directly – Option A
- ISO 9001 – Option B

ISO 20387:2018- Content

- Introduction
- 1 Scope
- 2 Normative references
- 3 Terms and definitions
- 4 General requirements
- 5 Structural requirements
- 6 Resource requirements
- 7 Process requirements
- 8 Quality management system requirements
- Annex A (normative) Documentation requirements
- Annex B (informative) Implementation guidance for Annex A
- Annex C (Informative) Quality Management system Options
- Bibliography

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ISO 20387:2018 - Terminology

- “shall” indicates a requirement;
- “should” indicates a recommendation;
- “may” indicates a permission;
- “can” indicates a possibility or a capability;
- “note” provides clarification of the text, examples and guidance. They do not contain requirements

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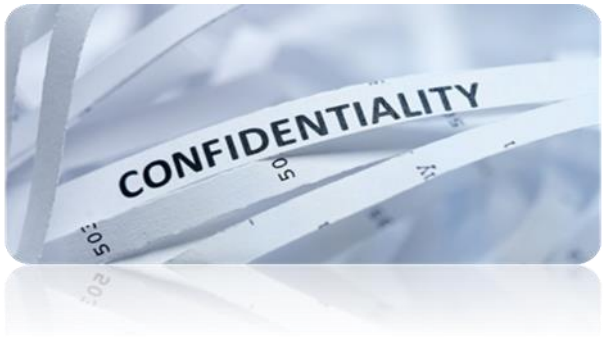
- **Section 4 -** General requirements

- 4.1 General – shall have policies, procedures and information for all activities
- - Mission defined
- - **Ethics, the biobank shall comply with relevant regional, national and international ethical principles for biological material and associated data**
- - Retention time for documented information on all activities
- 4.2 Impartiality
- 4.3 Confidentiality



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- **Section 5.** Structural Requirements - “What one needs to be”
- 5.1 Legal Entity
- 5.2 Top management
- 5.3 Governance body or Advisory Board

- 5.4 The biobank shall be responsible for activities performed in its facilities/dedicated areas
- 5.5 The biobank shall have a course of action to define and address liabilities arising from its activities

ISO 20387:2008

- **Section 5.** Structural Requirements - “What one needs to be”
- 5.6 The biobank shall carry out its activities in such a way as to meet the requirements of this document, its documented agreements and/or legally binding documents, relevant authorities and organizations providing recognition
- 5.7 Define and document range of activities
- 5.8 Governance structure, organisation and management of the biobank, place in parent organisation, relationships between management, technical operations and support services shall be defined along with responsibilities, authorities and interrelationships of personnel who manage, perform, validate or verify work affecting biobanking output
- 5.9 …Shall have personnel performing specific tasks and have specific responsibilities
- 5.10 Management shall ensure that communications with staff, interested parties are performed and understood

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Any Questions?