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Biobanking and Accreditation:

Enabling Trusted Scientific Research

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INTERNATIONAL STANDARD FOR BIOBANKING

ISO 20387:2018

Biotechnology – Biobanking – General Requirements for Biobanking

It specifies general requirements for the competence, impartiality and consistent operation of biobanks including quality control requirements to ensure biological material and data of appropriate quality.

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SCOPE:

- Applicable to **biobanks** storing biological materials from humans, animals, plants, and microorganisms.
- Ensures **quality** and **competence** in biobank operations.
- Covers:

Governance and organizational structure

Personnel Competence

Facilities and environmental conditions

Equipment and traceability

Documentation and records

Process control (collection, acquisition, preparation, preservation, storage, and distribution)

Ethics and confidentiality

Financial stability

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Accredited biobanks are biorepositories that meet specific **international quality and competence standards**, typically through **third-party assessment**.

Accreditation confirms that a biobank:

- Has robust **quality management systems.**
- Follows **standard operating procedures (SOPs).**
- Ensures **traceability, sample integrity**, and **data security.**
- Complies with **ethical and legal standards.**

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ACTIVITIES OF BIOBANKING COVERED

Sample Collection

Sample acquisition & reception

Sample Processing & Storage

Data Management

Ethical & Legal Considerations

Distribution & Use

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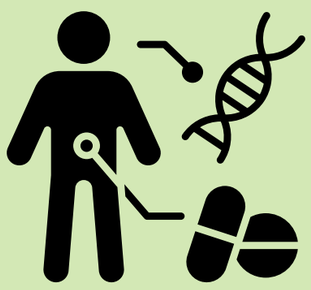
Importance of Biobanking

1

Medical Research

Enables discovery of disease mechanisms and biomarkers.



2

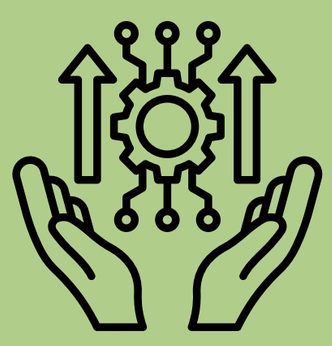
Personalized Medicine

Biobanks play a vital role in personalized medicine by enabling researchers to study how individual genetic makeup and other factors influence disease susceptibility and response to treatment.

3

Public Health

Facilitates large-scale studies (e.g., COVID-19 biobanks).



4

Advancing Research

Biobanks are crucial for advancing medical and scientific research by providing researchers with access to high-quality biospecimens and associated data.

5

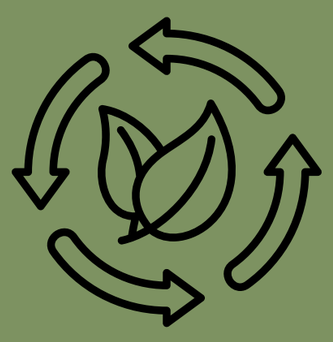
Understanding Diseases

Help scientists understand the causes and mechanisms of diseases, leading to the development of new diagnostic tools, therapies, and preventive strategies.

6

Drug Development

Support the development of new drugs and therapies by providing the necessary biological materials for preclinical and clinical trials.



7

Plants Material

Acting as a vital safeguard for genetic diversity and a resource for future adaptation and recovery efforts.

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TYPES OF BIOBANKS

- **Population-based**: General public (e.g., UK Biobank).
- **Disease-specific**: Focused on conditions like cancer or Alzheimer's.
- **Hospital/Clinical**: Linked to ongoing patient care.
- **Virtual Biobanks**: Coordinate samples/data across locations via digital systems.
- **Others**: Biobanks for biological materials from animals, plants, and microorganisms.

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INTRODUCTION TO APAC

APAC 's primary role is to manage and expand a mutual recognition arrangement (MRA) among accreditation bodies in the Asia Pacific region. The MRA facilitates the acceptance of conformity assessment results (e.g. test reports, calibration certificates, inspection reports, and certification) across the region and with other regions around the world.

Conformity assessment results that are produced by conformity assessment bodies (CABs) that have been accredited by one APAC MRA signatory are accepted by all the other APAC MRA signatories. This mutual recognition and acceptance of conformity assessment results reduces the need to undertake duplicate testing, inspection or certification, thus saving time and money, increasing economic efficiency and facilitating international trade.

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