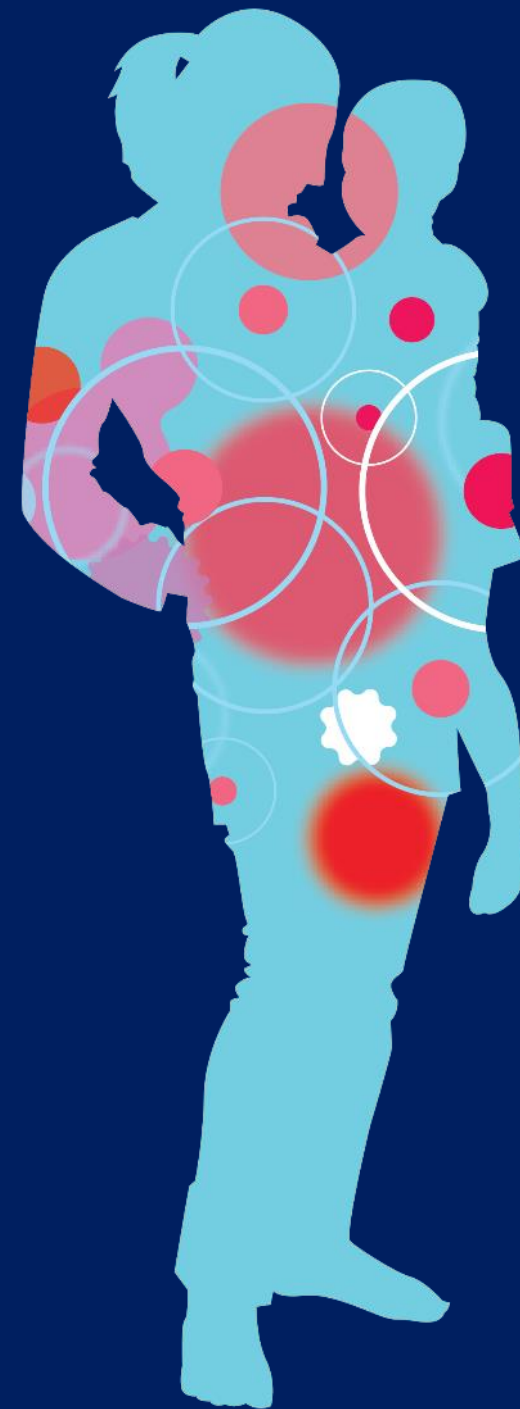


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Applicable Accreditations in the Tissue Banking Sector



Nothing is inevitable. Anything is possible.

What is a Tissue Bank and Accreditation



- A tissue bank is an establishment that collects and recovers human cadaver tissue for the purposes of medical research, education and allograft transplantation. A tissue bank may also refer to a location where biomedical tissue is stored under cryogenic conditions and is generally used in a more clinical sense.
- Accreditation is the independent, third-party evaluation of a conformity assessment body against recognised standards, conveying formal demonstration of its impartiality and competence to carry out specific conformity assessment tasks.

The Need for Accreditation



- The concept of standardisation and quality management has gained increasing importance in tissue banking.
- There are several reasons for this development:
 - increasing demand for human and other biological tissue;
 - increasing risk of viral infections;
 - progress in medical, pharmaceutical and technical sciences related to tissue banking;
 - centralisation in tissue banking;
 - international co-operation and networking;
 - international harmonisation by standards and guidelines.
- The General and Specific Standards for Tissue Banking cover national and/or international requirements and are accompanied by technical manuals related to methodology of tissue banking (donor selection, processing, preservation, sterilisation, storage, and distribution). These standards and technical manuals ensure the quality of tissue banking. Such a quality system is very specific.
- To establish a quality framework that covers the specific methodology as well as general aspects of quality management (research & development, design control, education and training, documentation, traceability, management control, corrective action, etc.), tissue banks can use international standards.

Applicable Accreditations



Principles of a QMS



ISO 9001



ISO 20387



Different notified bodies that provide accreditation



- BSI - are among the most respected and reputable management systems certification bodies in the world and are accredited by around 20 local and international bodies including:
 - American National Standards Institute - American Society for Quality National Accreditation Board LLC (ANAB)
 - LRQA The China National Accreditation Board (CNAB)
 - Raad voor Accreditatie (RvA) in the Netherlands
 - United Kingdom Accreditation Service (UKAS)
 - South African National Accreditation System (SANAS)
- LRQA - are recognised by over 30 accreditation bodies
- SISCert - SIS Certifications is basically one of the leading certifying organizations which provide international management system certification services to all types of organizations regardless of their type, size, and processes, by using all the right processes. We are accredited by International Accreditation Forum (IAF), International Organization for Accreditation Services (IOAS), and International Accreditation Service (IAS).
- DEKRA - DEKRA Certification South Africa is an Accredited Certification Body under the German accreditation body DAkkS
- DAkkS – German accreditation-based company

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Thank you

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