Standards for Stem Cell Services

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Health Policies and Standards Department

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ACKNOWLEDGMENT

The Health Policy and Standards Department (HPSD) developed this Standard in collaboration with Subject Matter Experts and would like to acknowledge and thank these health professionals for their dedication toward improving quality and safety of healthcare services in the Emirate of Dubai.

Health Regulation Sector

Dubai Health Authority

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INTRODUCTION

The Health Regulation Sector (HRS) plays a key role in regulating the health sector. HRS is mandated by the Dubai Health Authority (DHA) Law No. (6) of the year (2018) with its amendments pertaining to DHA, to undertake several functions including but not limited to:

- Developing regulation, policy, standards, guidelines to improve quality and patient safety and promote the growth and development of the health sector.
- Licensure and inspection of health facilities as well as healthcare professionals and ensuring compliance to best practice.
- Managing patient complaints and assuring patient and physician rights are upheld.
- Governing the use of narcotics, controlled and semi-controlled medications.
- Strengthening health tourism and assuring ongoing growth; and
- Assuring management of health informatics, e-health and promoting innovation.

The Standards for Stem Cells aims to fulfil the following overarching Dubai Health Sector Strategy 2026:

- Pioneering Human-centred health system to promote trust, safety, quality and care for patients and their families.
- Make Dubai a lighthouse for healthcare governance, integration and regulation.
- Leading global efforts to combat epidemics and infectious diseases and prepare for disasters.
- Pioneering prevention efforts against non-communicable diseases.
- Become a global digital health hub.

- Foster healthcare education, research and innovation.
- Strengthening the economic contribution of the health sector, including health tourism to support Dubai economy.

EXECUTIVE SUMMARY

The purpose of this standard is to provide a structured regulatory framework that aligns with international best practices and national regulations. These standards outline the essential standards for stem cell practices, ensuring compliance with regulatory and ethical frameworks. It provides structured requirements on governance, donor selection, laboratory infrastructure, quality management, clinical applications, and ethical considerations. By integrating international best practices, these standards aim to enhance patient safety, product efficacy, and regulatory compliance. Key highlights include:

- Ensure the safety, quality, and efficacy of stem cell-based therapies.
- Governance and institutional oversight
- Accreditation and quality assurance requirements
- Donor eligibility and informed consent protocols
- Stem cell collection, processing, cryopreservation, and storage
- Ethical and legal considerations
- Strategic collaborations and research

This framework ensures that stem cell practices operate with the highest levels of ethical conduct, regulatory compliance, and quality assurance, thereby safeguarding patient safety and promoting continuous improvement in clinical outcomes.

DEFINITIONS

AABB (Association for the Advancement of Blood & Biotherapies) is an organization that establishes standards for blood banking, transfusion medicine, and cellular therapy.

Adverse event is any unintended or unfavourable symptom or condition that is temporary and associated with an intervention that may have a causal relationship with the intervention, medical treatment, or procedure

Advanced Therapy Medicinal Product (ATMP) is any cell or gene therapy product or tissue engineered product that has been more than minimally manipulated and/or performs a different function in the recipient than in the donor (non-homologous use).

Allogeneic refers to cells and tissues donated by one person and used to treat a medical condition in another person.

Allogeneic Transplantation is a procedure in which a patient receives healthy blood-forming cells (stem cells) from a donor to replace their own stem cells that have been destroyed by treatment with radiation or high doses of chemotherapy. In an allogeneic stem cell transplant, the healthy stem cells may come from the blood or bone marrow of a related donor who is not an identical twin of the patient or from an unrelated donor who is genetically similar to the patient.

Applicable law refers to UAE Federal and Local regulations governing stem cell practice and related activities.

Autologous refers to cells and tissues taken from, and used to treat a medical condition in, the same person.

Autologous Stem Cell Transplantation is a procedure in which a patient's healthy stem cells (blood-forming cells) are collected from the blood or bone marrow before treatment, stored, and then given back to the patient after treatment. An autologous stem cell transplant replaces a patient's stem cells that were destroyed by treatment with radiation or high doses of chemotherapy.

Biosafety Cabinet (BSC) is a containment device used to handle stem cell cultures under controlled conditions, minimizing contamination risks while protecting the operator from potential risks such as infection.

Chain of Custody is concurrent, permanent, auditable documentation illustrating the guardianship of a cell or gene therapy product from its origin through its final disposition

Chain of Identity is the permanent and transparent association of a cell or gene therapy's unique identifiers from procurement of tissue or cells throughout the full product(s) lifecycle including post treatment monitoring.

Corrective and Preventive Actions (CAPA) are procedures used to investigate and correct quality deviations and prevent recurrence.

Cryopreservation is the process of preserving cells or tissues at extremely low temperatures to maintain viability.

Differentiation is the process by which stem cells develop into specific cell types with specialized functions.

Donor Eligibility Assessment is a set of medical, laboratory, and risk criteria to determine the suitability of a donor for stem cell collection.

Exosomes are extracellular vesicles secreted by stem cells that mediate intercellular communication.

Ethics Committee (EC) is a committee responsible for reviewing and approving ethical aspects of research involving human participants.

Environmental Monitoring are continuous assessment of laboratory conditions such as temperature, humidity, and contamination levels.

FACT (Foundation for the Accreditation of Cellular Therapy) is an international organization that sets standards for cellular therapies and regenerative medicine.

Good Distribution Practice (GDP): The principles and requirements set out in the PIC/S GDP Guide (PE 011-1, 2014), complemented by Good Manufacturing Practice (GMP) requirements specific to Advanced Therapy Medicinal Products (ATMPs).

Good Manufacturing Practices (GMP) is a system ensuring medicinal products are consistently produced and controlled according to quality standards. When used in these standards, GMP refers to the general GMP requirements described by PIC/S GMP Guide (PE 009) complemented with the ATMP specific requirements described in PIC/S Annex 2A – ATMP GMP (2021). DHA also acknowledges EU ATMP GMP (EudraLex Volume 4, Part IV) and US FDA cGMP framework (primarily 21 CFR part 210-211 and 1271).

GMP Certification means the formal certification by a national competent authority that an entity meets the requirements of GMP for production of ATMP or investigational ATMP. For the purpose of stem cell therapies in Dubai, any of the following is considered to meet these requirements: GMP certification for ATMP production by UK MHRA, Australian DoH/TGA,

Swissmedic, or EU/EES national competent authority, and approved BLA or IND phase III for the product in question by FDA.

Graft-versus-Host Disease (GVHD) is a condition in which immune cells from a donor attack the recipient's tissues after transplantation.

Human cells and tissues for medicinal use (HCTs) are human stem cells and tissues containing stem cells that have not undergone more than minimal manipulation and are used to provide the same essential functions in the recipient as they do in the donor (homologous use).

Hematopoietic Stem Cells (HSCs) are Stem cells that give rise to blood and immune system cells.

Induced Pluripotent Stem Cells (iPSCs) are reprogrammed adult cells that behave like embryonic stem cells.

Informed Consent refers to an agreement or permission accompanied by full information on the nature, risks, and alternatives of a tissue donation or medical treatment or procedure before the physician begins the procedure/treatment. Accordingly, the patient or donor either consents to or refuses the procedure/treatment.

Institutional Review Board (IRB) is a body that ensures research involving human participants adheres to ethical and legal standards.

Mesenchymal Stem Cells (MSCs) are multipotent stromal cells capable of differentiating into bone, cartilage, and fat cells.

Minimal manipulation is the concept that cells or tissues do not undergo processing steps that could substantially alter their risk profile (which could include characteristics such

as structural properties and functionality), or that could induce their differentiation, activation, proliferation potential or metabolic activity. Minimally manipulated cells and tissues must not have a systemic effect and must depend on their own metabolic activity for their primary function. Cell or tissue processing steps that are considered minimal include sizing, rinsing and washing, cutting, grinding, centrifugation, freeze-drying, washing, cell suspension, concentration, filtering and cryopreservation, as long as these do not alter the relevant characteristics, functions or structural properties of the cells or tissue.

Quality Management Program (QMP) is a structured system that ensures quality control and continuous improvement in stem cell processing and application.

Reconstitution is defined as the process performed at the administration site that prepares a medicinal product for immediate use.

Regenerative Medicine is a branch of medicine focused on replacing, repairing, or regenerating damaged tissues or organs using cells such as stem cells.

Sentinel Event (SE) is a type of serious incident that is wholly preventable and has caused serious harm to, or death of a patient, and not primarily related to the natural course of the patient's illness or underlying condition. A patient safety event can be, but is not limited to, the result of a defective system or process design, a system breakdown, equipment failure, or human error.

Standard Operating Procedures (SOPs) are written instructions detailing the process or chronological steps taken to accomplish a specific task. Sometimes referred to as work instructions.

Stem Cells are cells with the ability to self-renew and a potential to develop into various more specialized cell types.

Stem cell practice shall mean any individual, partnership, corporation, association, or other legal entity involved in the donation, procurement, testing, processing, preservation, storage, distribution, and administration of human stem cells or tissues meant to be used as HCT or ATMP.

Traceability is defined as the ability to track stem cell products from donor to recipient to ensure safety and regulatory compliance.

ABBREVIATIONS

AABB	:	Association for the Advancement of Blood & Biotherapies
ATMP	:	Advanced Medical Therapeutic Product
BSC	:	Biosafety Cabinet
BLA	:	US Biologics License Application
CAP	:	College of American Pathologists
CAPA	:	Corrective and Preventive Actions
CFR	:	Code of Federal Regulations
DHA	:	Dubai Health Authority
EBMT	:	European Society for Blood and Marrow Transplantation
EC	:	Ethics Committee
EMA	:	European Medicines Agency
FACT	:	Foundation for the Accreditation of Cellular Therapy
FDA	:	US Food and Drug Administration
GMP	:	Good Manufacturing Practices
GVHD	:	Graft-versus-Host Disease
HCT	:	Human cells and tissues for medicinal use
HSC	:	Hematopoietic Stem Cells
iPSC	:	Induced Pluripotent Stem Cells
IRB	:	Institutional Review Board
ISBT	:	International Society of Blood Transfusion

ISCT	:	International Society for Cell and Gene Therapy
ISO	:	International Organization for Standardization
JACIE	:	Joint Accreditation Committee- ISCT and EBMT
LN2	:	Liquid Nitrogen
MSC	:	Mesenchymal Stem Cells
QMP	:	Quality Management Program
QMS	:	Quality Management System
SOP	:	Standard Operating Procedure
WHO	:	World Health Organization

BACKGROUND

Stem cells have emerged as transformative fields in modern healthcare, offering innovative solutions for various medical conditions, including genetic disorders, degenerative diseases, and tissue regeneration.

Stem cell-based therapies have shown significant potential in treating chronic and life-threatening conditions. The increasing global interest in these therapies necessitates a structured regulatory approach to ensure patient safety and treatment efficacy. These standards encompass governance, ethical considerations, laboratory infrastructure, accreditation, donor eligibility, and clinical applications, ensuring compliance with globally recognized benchmarks such as FACT, AABB, GMP, and ISO 15189.

This document covers both autologous (self-derived) and allogeneic (donor-derived) stem cell applications and includes provisions for ex vivo processing, cryopreservation, and clinical administration.

The primary purpose of these standards is to:

- Ensure the safety, quality, and efficacy of stem cell-based therapies.
- Establish ethical and governance principles for stem cell research and clinical applications.
- Provide accreditation and quality assurance mechanisms for stem cell laboratories.
- Standardize donor eligibility and informed consent protocols.
- Enhance collaboration among regulatory bodies, healthcare institutions, and research organizations.

1. SCOPE

1.1. Human stem cells services in DHA licensed health facilities.

2. PURPOSE

2.1. To ensure provision of the highest levels of safety and quality of stem cells services in Dubai Health Authority (DHA) licensed health facilities.

3. APPLICABILITY

3.1. These standards apply to all health facilities involved in handling a HCT or an ATMP, or human cells or tissues to be used in such therapies, which include:

3.1.1. Conducting a part of the donation process; from donor identification, informed consent and evaluation, to labelling and handling of donated tissue or cells.

3.1.2. Administration of HCT or ATMP to humans.

3.1.3. Conducting laboratory analyses, processing, manufacturing, labelling, transporting, cryopreservation and storing.

4. STANDARD ONE: LICENSURE AND GOVERNANCE FRAMEWORK

4.1. All health facilities providing stem cell therapy shall adhere to related UAE Federal and Local Laws and Regulations.

4.2. Facilities providing stem cell-related services shall declare their full activity scope at the time of licensing. Approval for each activity shall be granted as part of the facility license.

4.2.1. The permitted activity scopes include, but are not limited to:

a. Stem Cell Banking

   i. Fulfil the requirements of the cabinet decision no (6) of 2020 concerning the regulation of the practice of the cord blood and stem cells banking centres.

   ii. All clinical use or research involving stem cells are subject to approval for IRB and DHA ethical committee prior to applying for license.

b. Processing and Manufacturing - Facilities requesting a license for a stem cell manufacturing facility contact Emirates Drug Establishment (EDE) directly or to submit the request through the following link: https://smartservices.moh.gov.ae/wps/portal/mohap/login/

c. Clinical Applications:

   i. Where processing, testing or manipulation is required, facilities shall have a contract with an accredited laboratory that complies with GMP standards.

   ii. Obtain EDE approval for the products related to the service.

   iii. Use a clinically tested treatment to prove its efficacy, safety, and quality and has received approval from the Medical Research Ethics Committee

   iv. After obtaining the above, the facility shall submit to DHA for licensing registration.

4.2.2. A facility may apply for more than one scope, as long as it demonstrates the capability, infrastructure, and compliance to safely perform each approved activity.

4.3. Facilities applying for stem cell banking shall fulfil the requirements of the Cabinet Decision no. (6) of 2020 concerning the regulations for the practice of cord blood and stem cells banking centres and applications to the higher committee for Umbilical Cord Blood and Stem Cells must be submitted through DHA.

4.4. Facilities providing stem cell-related services shall obtain approval for all declared activities as part of their facility license. Licensing shall cover the full chain of services, including but not limited to the following:

4.4.1. Donor eligibility assessment,

4.4.2. Collection,

4.4.3. Processing or manufacturing,

4.4.4. Labelling, testing,

4.4.5. Storage,

4.4.6. Transport,

4.4.7. Distribution,

4.4.8. Clinical administration, and

4.4.9. Final disposal.

4.5. Facilities that outsource any declared activity shall maintain written agreements and ensure oversight and traceability for all contracted functions.

4.6. All applications for stem cell banking, processing, or clinical application services shall be submitted through the DHA Licensing system.

4.6.1. Applications forwarded to the Higher Committee for Umbilical Cord Blood and Stem Cells shall include but not limited to the following:

a. Evidence of governance structure,

b. Technical readiness,

c. Traceability systems,

d. Standard operating procedures (SOPs),

e. Compliance with GMP and ethical standards.

4.6.2. Approval from the Higher Committee shall be obtained prior to commencing any stem cell-related activities requiring such oversight.

4.7. All clinical use or research involving stem cells shall receive prior approval from both an Institutional Review Board (IRB) and the DHA Ethics Committee.

4.7.1. Facilities shall maintain active approvals throughout the activity period and report protocol deviations and adverse events in accordance with approved procedures and timelines.

4.8. Facilities shall verify that all medical devices, biological materials, and advanced therapy medicinal products (ATMPs) used are registered and authorized by MOHAP before use, storage, or administration.

4.8.1. A documented procedure for product recall or withdrawal shall be maintained.

4.9. Licensed stem cell practices shall be restricted to the clinical use of autologous cells and products that are minimally manipulated, unless specifically authorized under a DHA-approved clinical trial or stem cell transplantation program.

4.9.1. The use of allogeneic stem cell therapies for non-transplant or regenerative purposes is prohibited. Exceptions may only apply when all of the following conditions are met:

a. The product is used under a DHA-authorized clinical trial or has received approval from MOHAP; and

b. The procedure is conducted within a FACT- or AABB-accredited transplant program; and

4.9.2. Commercial, aesthetic, or wellness-based use of stem cells is strictly prohibited outside these approved pathways.

4.10. Health facilities shall ensure governance and oversight for stem cell practices as follows:

4.10.1. Facilities shall establish a documented governance framework with clearly assigned accountability for all stem cell-related activities.

a. This shall include identification of key Responsible Persons, such as the Medical Director, Processing/Manufacturing Director, and Quality Manager, with defined authority across medical, scientific, and administrative domains.

4.10.2. A comprehensive Quality Management Program (QMP) shall be implemented to govern all activities related to stem cell collection, processing, analysis, storage, transport, distribution, and clinical application. The QMP shall include but not limited to the following:

a. Internal and external audits to ensure compliance.

b. Deviation management and Corrective and Preventive Action (CAPA) systems.

c. Change control and documented risk management processes.

d. Supplier qualification and ongoing vendor oversight.

e. Controlled documentation and version control.

f. Structured competency-based training and ongoing performance evaluation.

g. Continuous compliance with applicable local, national, and international regulations and standards.

4.11. Health facilities shall ensure compliance with regulatory and ethical standards as follows:

4.11.1. All stem cell practices shall comply with applicable local and national laws, regulations, and DHA licensing conditions.

4.11.2. Stem cell practices should align with recognized international guidelines, including WHO guidance on ethics, safety, and human cell and tissue practices, where applicable.

4.11.3. All stem cell-related procedures shall be conducted in accordance with ethical principles approved by the relevant Institutional Review Board (IRB) or Ethics Committee, and facilities shall maintain valid approvals throughout the duration of the activity.

4.11.4. Participation as a donor shall be voluntary and free from coercion.

a. Written informed consent shall be obtained in both Arabic and English prior to any donor-related procedure.

b. Facilities shall perform and document donor eligibility assessment and infectious-disease screening prior to collection and retain associated records in accordance with DHA data retention policy.

4.11.5. Participation as a patient/recipient shall be voluntary and free from coercion in accordance with established ethical and regulatory requirements.

4.11.6. Written informed consent shall be obtained prior to any clinical use of stem cells or HCT-related procedure, in line with local consent requirements and approved protocols.

4.12. Health facilities shall ensure quality assurance and monitoring as follows:

4.12.1. Regular internal and external audits shall be conducted to assess compliance with applicable regulations, accreditation standards, and institutional policies.

4.12.2. A formal system shall be in place for reporting, investigating, and resolving adverse events, non-conformances, and product deviations related to stem cell practices.

4.12.3. Reportable events shall be submitted to DHA within established timelines.

4.12.4. For data management and documentation, facilities shall ensure the following:

a. A biovigilance and traceability system shall be established to ensure complete traceability of cellular products from donor to recipient through unique identifiers.
b. All procedures, test results, approvals, and associated documentation shall be accurately recorded and securely maintained in accordance with data integrity and DHA data-retention requirements.
c. Facilities shall maintain an established recall procedure for stem cell products and materials.
d. Facilities shall participate in the DHA central traceability registry, where applicable.
e. Clinical outcomes shall be continuously monitored to assess the safety and effectiveness of therapies

4.13. Health facilities shall conduct internal monitoring and self-evaluation as follows:

4.13.1. Facilities shall perform regular internal audits and self-assessments to verify ongoing compliance with these Standards and applicable regulatory requirements.

4.13.2. Audit and self-assessment findings shall be formally documented, and corrective actions shall be implemented, monitored, and closed in a timely manner.

4.13.3. Results of internal audits and self-assessments shall be reviewed during management meetings, with actions recorded to support continuous quality improvement.

5. **STANDARD TWO**: HEALTH FACILITY REQUIREMENTS

5.1. Health Facilities Risk based requirements

5.1.1. Facilities shall be designed, constructed, and operated in accordance with recognized good practice standards for cellular and tissue facilities.

5.1.2. Documented and approved facility layout drawings, room classifications, HVAC/airflow schematics, and pressure differential plans shall be retained prior to operation and updated after any facility modification.

5.1.3. Facilities shall perform and document a risk assessment covering cross-contamination, microbial infection, product mix-up, and process deviation.

a. Identified risks shall be mitigated through engineering and procedural controls, verified by the Quality Unit.

5.1.4. Facilities performing ATMP-level manipulation or ATMP manufacturing shall operate within a GMP-certified or GMP-compliant environment and maintain environmental and cleanroom controls in line with Appendix 1.

a. Facilities processing HCT may also be required to implement cleanroom and environmental control measures, based on the level of manipulation and findings from documented risk assessments.

5.2. Facilities shall maintain continuous or periodic environmental monitoring proportionate to risk level, including temperature, humidity, viable and non-viable particulates.

5.2.1. Monitoring data shall be trended, reviewed monthly, and retained for at least 10 years.

5.2.2. Monitoring devices shall be connected to an automated alarm system.

5.2.3. All monitoring and alarm equipment shall be calibrated with traceability to approved national metrology standards, and alarm functionality shall be verified periodically as part of scheduled maintenance and calibration programs

5.2.4. Facilities shall establish temperature and humidity alert/action limits in the QMS. Deviations outside 18–22°C or >60% RH shall trigger documented investigation and CAPA.

5.2.5. HEPA Filtration: HEPA filters shall have a minimum efficiency of 99.97% at 0.3µm, with integrity testing performed at installation and every 12 months thereafter. Alarm systems shall be validated periodically

5.2.6. Facilities shall validate backup power systems and test automatic transfer switches and emergency response procedures at least annually, and after any major maintenance or system modification. Results and any deviations shall be documented and managed within the Quality Management System

5.3. Autologous and Allogeneic Workflow must be separated:

5.3.1. Autologous (patient-specific) and allogeneic (donor-derived) product handling shall be physically segregated to prevent cross-contamination and maintain product integrity,

5.3.2. Areas shall be clearly labelled and supported by color-coded zoning to guide personnel and reinforce segregation controls:

a. Blue zones for autologous processing

b. Green zones for allogeneic processing

c. Red zones for hazardous waste handling

5.3.3. Dedicated air-handling systems or other engineered environmental controls shall be implemented to maintain airflow separation appropriate to the risk level.

5.3.4. A documented personnel movement plan shall be maintained, restricting transitions between zones without appropriate decontamination procedures.

5.3.5. Separate gowning and decontamination areas shall be designated and clearly identified for each workflow, consistent with the level of segregation required.

5.3.6. Facilities shall conduct and document a risk assessment to determine the level of segregation required for autologous and allogeneic workflows and maintain signage and workflow controls accordingly.

5.4. Facilities shall establish and document one-way product and personnel movement maps validated by the Quality Unit to prevent cross-contamination and backflow

5.5. Pass-through autoclaves and validated material airlocks are recommended to minimize manual handling and contamination risks.

5.6. Decontamination stations shall be positioned at all exit points and maintained to ensure effective contamination control and reduce cross-contamination risks.

5.7. Positive pressure differentials shall be maintained in clean zones, with negative pressure areas designated for waste and biohazard containment.

5.7.1. Pressure differentials shall be verified, continuously monitored, and alarmed, with records maintained as part of the facility's environmental control program.

5.8. All stem cell facilities shall adhere to defined cryogenic storage standards to ensure the long-term viability and integrity of cryopreserved cellular products.

5.8.1. Each facility shall maintain approved cryopreservation SOPs and validated stability programs defining acceptable storage conditions, duration, and monitoring requirements for HCT or ATMP products.

5.8.2. Cryogenic storage systems shall be validated, temperature-mapped, and equipped with continuous monitoring and alarm systems.

a. Alarm testing and temperature mapping shall be performed at defined intervals.

b. Temperature and humidity control in the cryogenic storage room.

c. Acceptable temperature ranges and stability criteria shall be specified in controlled procedures.

5.8.3. Refer to Appendix 2 for Liquid Nitrogen (LN_2) cryopreservation requirements.

5.9. Facilities shall maintain controlled environments suitable for the level of processing performed, with documented qualification of cleanroom performance and periodic requalification.

5.9.1. Controlled environments supporting aseptic operations shall meet Grade B–equivalent standards or higher, with annual (or risk-based) requalification and continuous environmental monitoring as part of the quality management system.

5.9.2. Cleanroom requirements shall align with Appendix 1: Cleanroom Classifications.

5.10. Stem cell facilities shall comply with construction and biosafety requirements to ensure a safe, controlled, and contamination-free environment for all laboratory operations.

5.10.1. Construction materials used in critical areas shall be non-porous, chemical-resistant, and easily cleanable, with seamless surfaces for walls, floors, and ceilings.

a. Pressure differentials shall be maintained between clean zones and hazardous waste areas to support aseptic control and containment.

5.10.2. HVAC systems shall be designed with redundancy, humidity control, and validated airflow performance to ensure consistent air quality. Biosafety cabinets (BSCs) and laminar airflow hoods shall be certified and re-validated at least annually.

5.10.3. Oxygen monitoring systems shall be installed in cryogenic storage areas and tested periodically to mitigate asphyxiation risk.

5.10.4. Refer to Appendix 3 for detailed construction and biosafety requirements.

5.11. Laboratory personnel shall follow mandatory PPE requirements, including sterile gowning, gloves, shoe covers, and eye protection, appropriate to the area classification and nature of activities.

5.11.1. PPE shall be donned and removed in designated gowning zones and disposed of in approved containers to prevent cross-contamination and maintain cleanroom integrity.

5.11.2. Cooling vests shall be provided and used when required, particularly in high-temperature or cryogenic storage environments to support staff safety and comfort.

5.12. Facilities shall provide documented LN_2 safety and fire evacuation training for all staff at least once annually.

5.12.1. Training records shall be retained as evidence for DHA audit.

5.13. Facilities shall maintain complete traceability for all stem cell products, linking donor, product, equipment, environmental data, and operator records.

5.13.1. Traceability shall be verified during internal audits.

5.14. Stem cell facilities shall adhere to strict equipment qualification, calibration, and maintenance requirements to ensure accurate, reliable, and compliant operations.

5.14.1. Only approved and validated centrifuges, incubators, cryogenic storage units, and other critical equipment may be used for laboratory processes, in accordance with applicable regulatory requirements.

5.14.2. Critical equipment shall be equipped with appropriate backup or redundancy systems, where required, to minimize operational downtime and ensure continuity of essential functions.

5.14.3. All critical equipment shall be qualified, calibrated, and maintained in line with manufacturer recommendations and metrology standards.

a. Calibration and preventive maintenance schedules shall be documented and followed.

b. Calibration deviations and equipment failures shall be recorded, investigated, and closed through the Quality Management System.

5.14.4. As a reference, pipettes should be calibrated every 6 months, and incubators, freezers, particle counters, and other instruments should undergo calibration and verification at least annually, or more frequently based on risk and manufacturer recommendations.

5.15. Stem cell facilities shall comply with firm waste management and sustainability standards to ensure safe and responsible disposal of biohazardous and chemical waste.

5.15.1. Sharps shall be disposed of in labelled, puncture-proof containers, and all waste handling shall be conducted by Dubai Municipality licensed waste contractors.

5.15.2. For chemical waste, formaldehyde and other hazardous materials shall be neutralized or chemically treated before disposal, in full compliance with Dubai Municipality's Hazardous Waste Regulations.

5.15.3. These measures are essential to protect public health and the environment while maintaining regulatory compliance.

5.16. Clinical Collaboration and MoU Requirement

5.16.1. Hospitals or clinical facilities performing stem cell collection or administration shall maintain a DHA-approved Memorandum of Understanding (MoU) with a DHA-licensed stem cell establishment authorized to process, store, or release stem cell products.

5.16.2. The MoU shall define responsibilities, traceability, data-sharing, biosafety controls, and compliance obligations.

5.16.3. Agreements shall define and describe the following:

a. Roles and responsibilities of key personnel.

b. Roles and responsibilities of each facility involved in the procurement, processing, labelling, storage, distribution, or administration of a cellular therapy product to maintain the chain of identity and chain of custody. The permanent and transparent association of a cell or gene therapy's unique

identifiers from procurement of tissue or cells throughout the full product(s) lifecycle including post treatment monitoring.

5.16.4. The agreement shall be executed prior to service commencement, reviewed periodically, and available for DHA inspection at all times.

6. **STANDARD THREE**: HEALTHCARE PROFESSIONAL REQUIREMENTS

6.1. Stem cell collection facility shall be:

6.1.1. Led by a DHA-licensed physician with a specialization aligned to the stem cell source and intended clinical application. Relevant specialties include, but are not limited to:

a. Obstetrics (for cord blood / birth-tissue collection)

b. Haematology (for peripheral blood / bone marrow collection)

c. Transfusion Medicine (for hematopoietic cell collection and donor evaluation)

d. Plastic Surgery or relevant surgical specialty (for adipose-derived cell collection)

6.1.2. The physician-in-charge shall be responsible for oversight of all collection activities, including approval of SOPs, donor assessment and safety, and supervision of trained staff involved in collection procedures.

a. The physician's clinical specialization shall correspond to the stem cell source and procedure type to ensure appropriate clinical oversight and patient/donor safety.

6.2. Licensed physicians shall have a minimum of three (3) years of documented experience with **five (5) or more years considered optimal**, in stem cell collection from one or more of the following sources:

a. Umbilical cord blood

b. Peripheral blood stem cells via apheresis

c. Adipose tissue

d. Placental or other perinatal tissues

6.3. Facilities shall maintain verified logs, competency records, and supporting documentation within the Quality Management System to confirm the physician's qualifications and experience.

6.3.1. Physicians shall complete documented training in:

a. Source-specific stem cell collection protocols and donor eligibility assessment

b. UAE regulatory requirements and applicable international standards (e.g., FACT–JACIE, AABB)

c. Biosafety, aseptic technique, and informed consent procedures

d. Risk management related to stem cell collection, including but not limited to:

i. Maternal haemorrhage (cord/placental collection)

ii. Liposuction-related complications (adipose collection)

6.4. Facilities shall maintain evidence of clinical competency and active practice, including but not limited to:

6.4.1. Documented procedures performed

6.4.2. Participation in supervised or credentialed practice, and

6.4.3. Proof of ongoing professional activities relevant to stem cell collection.

6.5. The following healthcare professionals may participate in stem cell collection activities, provided they hold valid DHA licensure and operate under the supervision of the collection physician:

6.5.1. Registered Nurses

6.5.2. Midwives

6.5.3. Surgical Technicians and Apheresis Technicians

6.6. Staffing levels shall be appropriate to the scope and risk of collection activities to ensure donor safety, regulatory compliance, and continuity of care.

6.6.1. Staff shall be trained in:

a. Cord blood collection (in-utero and ex-utero)

b. Adipose tissue collection (liposuction-assisted)

c. Peripheral blood stem cell apheresis procedures

d. Placental and birth tissue collection

6.6.2. Collection personnel shall demonstrate core competencies in:

a. Aseptic technique and sterile field maintenance

b. ISBT 128 labelling, chain of identity, and chain of custody procedures

c. Emergency response procedures and adverse event reporting

d. Ongoing professional development and documented competency verification, supported by evidence of continued practice and supervisor validation

6.6.3. The stem cells processing laboratory shall be led by a Medical Director who is:

a. A DHA-licensed physician specialized in:
   i. Pathology
   ii. Haematology
   iii. Transfusion Medicine
   iv. Other related field relevant to cellular therapy

b. Experience requirements:
   i. Minimum of one (1) year experience in cellular therapy product processing
   ii. Involvement in at least ten (10) stem cell processing procedures within the past two (2) years

c. Responsibilities include:
   i. Oversight of all processing activities
   ii. Approval of medical SOPs related to processing
   iii. Review of clinical impact and product suitability prior to release
   iv. Oversight of staff training and competency documentation

d. Professional development: The Medical Director shall demonstrate ongoing professional development related to stem cell processing, safety, and regulatory requirements, supported by documented evidence.

6.6.4. A DHA-licensed Laboratory Director may be assigned and shall meet the following requirements:

a. Qualifications: Doctoral degree (PhD, MD, or PharmD) in a relevant scientific field such as:
   i. Cell Biology
   ii. Biotechnology
   iii. Clinical Laboratory Science, Or
   iv. Other closely related field relevant to cellular therapy

b. Experience requirements:
   i. Minimum of (5) year experience in cellular therapy laboratory operations
   ii. Direct involvement or supervisory oversight in at least ten (20) cellular processing procedures within the past two (2) years

c. Responsibilities include, but are not limited to:
   i. Oversight of technical operations, equipment qualification, validation, and calibration programs.
   ii. Supervision and competency development of laboratory staff
   iii. Ensuring compliance with applicable regulations and these Standards

iv. Approval of technical SOPs and laboratory procedures

v. Oversight of nonconformance management and CAPA, ensuring deviations are documented and closed through the Quality Management System

d. Professional development: The Laboratory Director shall demonstrate ongoing professional development relevant to cellular therapy and laboratory operations, with supporting documentation retained within the facility's QMS.

Note: A single healthcare professional may serve as both the Laboratory Medical Director and Laboratory Director, provided all qualifications and role requirements are met and role descriptions are formally documented.

6.6.5. Laboratory Technicians shall be:

a. DHA-licensed.

b. Able to demonstrate competency by completing at least three (3) supervised stem cell processing procedures prior to performing these activities independently.

c. Shall be trained in:

i. Aseptic handling and sterile field maintenance

ii. Core stem cell processing techniques

iii. Cell counting and viability assessment

iv. Operation of key laboratory equipment (e.g., centrifuge, incubator, biosafety cabinet)

v. Environmental monitoring and documentation requirements

vi. Correct labelling, chain of identity, and traceability

vii. Laboratory biosafety and emergency response practices

d. Facilities shall maintain documented evidence of training, supervised practice, and competency within the Quality Management System.

6.7. Health care professionals involved in clinical stem cell administration, such as paediatricians, anaesthesiologists, plastic surgeons, or other relevant specialists, shall:

6.7.1. Have documented training relevant to their role, including stem cell infusion techniques and, where applicable, apheresis-related procedures.

6.7.2. Have a defined scope of practice consistent with DHA licensure and facility SOPs.

6.7.3. Participate in continuing professional education and maintain documented competency in cell therapy administration and management of procedure-related complications.

a. This shall include a minimum of ten (10) CPD hours per year in cellular-therapy-related topics.

b. Have experience in recognizing and managing procedure-related complications, including infusion reactions and liposuction-associated events where applicable.

6.7.4. The healthcare professional performing stem cell administration shall be:

a. A DHA-licensed physician experienced in mesenchymal cell infusion/injection and apheresis where applicable.

b. Able to demonstrate documented competence in infusion techniques and emergency management

c. Required to log all stem cell administration cases, with records maintained within the facility's QMS

6.7.5. Clinical pharmacists shall be DHA-licensed with knowledge in:

a. Adjunct medications relevant to cell therapy, including immunosuppressants where applicable

b. Cryoprotectant properties and potential interactions

c. Proper storage, preparation, and reconstitution of cellular products

d. Verification and documentation procedures prior to product release for administration, including product identity, labelling, and expiry checks

6.8. Stem cell therapy shall only be administered by DHA-licensed physicians with recognized clinical specialties.

6.8.1. Physicians shall perform stem cell therapy strictly within the scope of their licensed specialty, supported by documented training and evidence-based practice.

6.8.2. Permitted clinical specialties include, but are not limited to:

a. Orthopaedic Surgery

b. Haematology

c. Oncology

d. Gynaecology

e. Cardiology

f. Neurology

g. Physical Medicine and Rehabilitation

h. Pain Medicine/anaesthesiology

i. Plastic and Reconstructive Surgery

6.8.3. Stem cell therapy shall align with approved, evidence-based clinical indications relevant to each specialty, as outlined in Appendix 4: Permitted Specialties and Approved Indications.

6.9. Health facilities and physicians are prohibited from offering, advertising, or administering stem cell therapies for clinical conditions outside the scope of their licensed specialty.

6.9.1. Examples of cross-specialty misuse include but are not limited to:

a. General practitioners offering stem cell therapy for autism or immune disorders

b. Ophthalmologists administering stem cell therapy for stroke recovery

c. Dermatologists using stem cells for orthopaedic or spinal conditions

6.9.2. Any observed misuse or non-compliant practice shall be documented and reported to DHA through established incident reporting channels.

6.10. All physicians performing stem cell procedures shall:

6.10.1. Be DHA-licensed in one of the approved specialties as per Appendix 4.

6.10.2. Hold board certification in that specialty from a recognized authority such as:

a. American Board of Medical Specialties (ABMS)

b. Arab Board

c. Royal Colleges, or

d. Any another board recognized by DHA.

6.10.3. Maintain a minimum of ten (10) Continuing Professional Development (CPD) hours per year specifically related to stem cell therapy, regenerative medicine, or cellular therapeutics.

6.10.4. Facilities shall maintain a credentialing file for each physician, including DHA license, board certification, and CPD evidence.

a. These records shall be reviewed annually by the Medical Director and retained within the facility's Quality Management System.

7. **STANDARD FOUR:** QUALITY MANAGEMENT SYSTEM

7.1. The Quality Management System (QMS) shall ensure adherence to all applicable DHA stem cell standards, including referenced external guidelines and standards such as AABB, FACT–JACIE, and GMP. The QMS shall be documented, maintained, and periodically reviewed to support compliance and continual improvement in stem cell practices.

7.2. The QMS shall include, but not be limited to, the following mechanisms:

7.2.1. Prioritize donor and patient safety through risk-based safety controls applied across all stem cell collection, processing, and administration activities, including identification, evaluation, and mitigation of risks to donors and recipients.

7.2.2. Ensure full compliance with all applicable UAE laws, DHA regulations, and recognized international standards governing cellular therapies. Facilities shall maintain documented procedures and conduct compliance reviews as part of management review.

7.2.3. Implement a documented risk-management system that includes hazard identification, risk assessment, mitigation planning, and periodic review. Risk actions and deviations shall be tracked and closed through the QMS corrective and preventive action (CAPA) process.

7.2.4. Establish a structured program for continuous quality improvement, including trend analysis of deviations, feedback evaluation, and process optimization. Outcomes and improvement actions shall be reviewed during management meetings.

7.2.5. Maintain controlled, validated, and secure documentation and data systems ensuring data integrity, traceability, and accountability. Records shall be protected from unauthorized access and retained in accordance with DHA data-retention and confidentiality requirements.

7.3. A clear and structured organizational hierarchy is essential for ensuring QMS compliance and maintaining high operational standards.

7.3.1. Each facility shall maintain an organizational chart defining roles and responsibilities for quality oversight, policy management, and regulatory compliance.

7.3.2. The organizational chart shall be reviewed periodically and approved by senior management.

7.4. Facilities shall appoint a qualified Quality Manager with independent authority to oversee and ensure compliance with the QMS.

7.4.1. The Quality Manager shall have direct access to senior management and shall be responsible for overseeing QMS implementation, conducting internal audits, managing deviations and CAPAs, and supporting continuous quality improvement across all stem cell activities

7.5. Senior management, including the Laboratory Director and key executives, shall define measurable quality objectives, allocate adequate resources, and ensure alignment with regulatory and accreditation standards.

7.5.1. Senior management shall actively foster a culture of quality, transparency, and accountability across the organization, demonstrating leadership commitment and ensuring staff adherence to established quality principles.

7.6. Facilities shall conduct documented management reviews at least quarterly to evaluate Quality Management System (QMS) performance, KPI achievement, and the

status of corrective and preventive actions (CAPA). Review findings and action plans shall be formally recorded.

7.6.1. Evaluation of quality objectives to ensure alignment with organizational goals and regulatory requirements.

7.6.2. Assessment of internal and external audit findings, including regulatory and accreditation compliance status.

7.6.3. Review and analysis of nonconformities, deviations, and CAPA effectiveness.

7.6.4. Review of resource allocation, staffing, and training needs to support operational efficiency and quality improvement.

7.6.5. Assessment of stakeholder and patient feedback to support service optimization and continuous improvement.

7.7. Each facility shall maintain an approved and documented Quality Policy Statement outlining the organization's commitment to patient safety, product quality, and regulatory compliance.

7.7.1. The policy shall be reviewed at least annually and communicated to all staff.

7.7.2. Defines the facility's commitment to patient safety, product quality, and full compliance with applicable regulations and standards.

7.7.3. Establishes measurable quality objectives to support continuous improvement and process optimization.

7.7.4. Ensures alignment with applicable UAE regulatory frameworks and recognized international cellular therapy standards.

7.7.5. Is accessible to all employees and relevant stakeholders to foster awareness, responsibility, and compliance with quality principles.

7.8. All personnel shall undergo mandatory initial and periodic training relevant to their assigned roles, covering theoretical knowledge, hands-on practice, and regulatory requirements. Training shall be evaluated for effectiveness and refreshed annually or when procedures, regulations, or technologies change

7.9. Competency assessments shall be conducted at defined intervals based on job function, with results formally documented. Personnel who do not meet competency requirements shall be restricted from performing critical tasks until retraining and successful reassessment are completed. Training and competency records shall be securely maintained and readily available for audit review.

7.10. Standard Operating Procedures (SOPs) shall be developed, approved, and maintained for all relevant processes. SOPs shall be version-controlled, reviewed at least annually or when processes change, and approved by the Quality Manager and relevant directors. Controlled copies shall be accessible only to authorized personnel to ensure consistent and compliant practice.

7.11. Chain of custody requirements include:

7.11.1. All documentation, whether in paper or electronic format, shall provide a traceable record of the chain of custody, including time-stamped transfers and storage conditions.

7.11.2. A look-back program shall be in place for retrospective donor risk assessment and post-transplant monitoring.

7.11.3. ISBT 128 global standards shall be utilized to ensure complete traceability from collection to transplantation

7.12. Quality Assurance (QA)

7.12.1. Each facility shall maintain a documented Quality Assurance (QA) program responsible for internal audits, management of deviations and non-conformances, and coordination of Corrective and Preventive Actions (CAPA). Laboratories shall participate in external proficiency testing programs to verify analytical accuracy and regulatory compliance.

7.12.2. All QA processes, including verification of adherence to approved SOPs, shall be documented. Records related to QA activities shall be retained in accordance with DHA data retention requirements and made available during inspections.

7.12.3. Facilities shall establish a formal process to collect, analyse, and act upon feedback from healthcare providers, patients, and regulatory authorities. Feedback outcomes and improvement actions shall be reviewed during management meetings to support continual service improvement.

7.12.4. An Annual Quality Review shall be conducted to evaluate QMS performance, including audit results, non-conformity trends, CAPA effectiveness, and

progress toward quality objectives. The review shall be approved by senior management and documented within the QMS.

7.12.5. Facilities shall conduct planned internal audits covering all QMS processes at least annually. Audit findings, corrective actions, and closure status shall be documented and reviewed by management to ensure system effectiveness and regulatory compliance.

8. **STANDARD FIVE:** DONOR ELIGIBILITY, RECRUITMENT, AND CONSENT

8.1. Donor eligibility

8.1.1. All stem cells and tissues containing stem cells used for clinical or laboratory purposes shall be of human origin and collected from legally and ethically approved sources. The collection, use, or storage of embryonic stem cells shall be strictly prohibited

8.2. All donors shall undergo a comprehensive screening process to ensure the safety of both the donor and recipient.

8.2.1. A documented review of medical and surgical history, including relevant family history.

8.2.2. All donors shall undergo a comprehensive screening process to ensure the safety of both the donor and recipient.

8.2.3. A documented review of medical and surgical history, including relevant family history.

8.3. All donors shall undergo a comprehensive screening process to ensure the safety of both the donor and recipient.

8.4. Allogeneic donors shall undergo testing for transfusion-transmissible infections (TTIs) using validated assays, and results shall be documented prior to product release.

8.4.1. HIV-1 and HIV-2 (serology and nucleic acid testing)

8.4.2. Hepatitis B (HBsAg, anti-HBc, and HBV DNA)

8.4.3. Hepatitis C (anti-HCV and HCV RNA)

8.4.4. Syphilis (Treponema pallidum testing)

8.4.5. HTLV-I/II (where required by law or regulatory guidance)

8.4.6. CMV testing for recipient groups where CMV-negative status is required

8.4.7. Additional screening (e.g., West Nile Virus, Zika Virus, SARS-CoV-2) based on regional epidemiology, public health alerts, or outbreak situations

8.4.8. Testing shall be performed on properly collected and stored donor samples to ensure specimen integrity and test accuracy.

8.5. Donor Infectious-Disease Testing Timeline: Donor infectious-disease testing shall be performed to ensure donor eligibility and safe handling of cellular material. Testing timelines shall reflect the donor type and clinical context.

8.5.1. For allogeneic donors, infectious-disease screening shall occur at two time points to mitigate window-period risk:

a. Initial pre-screening conducted 1 to 4 weeks prior to donation; and

b. Confirmatory testing on the day of donation, or within 72 hours (3 days) when same-day testing is not feasible.

c. Test results used for donor eligibility and product release shall not be older than 3 days at the time of cell collection.

8.5.2. Maternal infectious-disease testing shall be performed at the time of delivery. If collection or processing is delayed beyond 72 hours (3 days), or if new risk exposure is reported, repeat testing shall be performed.

8.5.3. Autologous donors shall undergo infectious-disease testing prior to collection. Repeat testing shall be required only when:

a. Collection or infusion is delayed beyond the facility-defined validity period; or

b. New risk exposure or clinical concern is identified

c. Positive results shall not preclude collection or infusion of autologous cells unless required by clinical judgement or regulatory directive and shall be used to determine appropriate biosafety precautions.

8.6. When testing for transfusion-transmissible infections (TTIs), facilities shall consider analytical window periods associated with each testing method. For example, serology-based tests may require up to three (3) months from infection for reliable HIV detection.

8.6.1. In cases where testing window periods apply, a second test shall be performed three (3) to six (6) months after donation, and the cellular product shall remain

in quarantine and shall not be released for clinical use until confirmatory results are obtained and documented.

8.7. Donor eligibility for stem cell therapies shall be determined according to defined medical and regulatory criteria appropriate to the cell source and donor health status.

8.7.1. Donors of Hematopoietic Progenitor Cells (HPCs), Mesenchymal Stem/Stromal Cells (MSCs), Stromal Vascular Fraction (SVF), shall meet age, medical, and genetic compatibility criteria as outlined in Appendix 5. Eligibility determinations and supporting documentation shall be completed and approved prior to collection.

8.8. For stem cell types where engraftment or immune rejection may occur, facilities shall perform donor-recipient compatibility testing, including HLA typing where indicated, to minimize graft-versus-host disease and non-engraftment risks.

8.9. Donor Follow-up

8.9.1. Facilities shall establish a documented donor follow-up program to monitor donor health after donation.

a. Adult allogeneic donors:

i. Follow-up shall be performed at least once within six (6) months post-donation to assess recovery and identify any delayed adverse events.

ii. Additional follow-up may be performed based on clinical indication or program requirements

b. Maternal donors for cord blood and perinatal tissue:

i. Postpartum follow-up shall be performed in accordance with cord-blood standards to confirm maternal health status and identify any new risk factors.

c. Autologous donors:

i. Follow-up shall be performed as clinically indicated to support donor and recipient safety.

8.10. If a donor is deemed ineligible, they shall be notified confidentially and provided with the reason for deferral, along with guidance regarding future eligibility where applicable.

8.11. The rationale for any deferral decision, as well as documentation of donor notification, shall be recorded and retained in accordance with DHA standards and confidentiality requirements.

8.11.1. Donor recruitment shall be ethical, transparent, and strictly voluntary, without coercion or undue influence.

8.11.2. Donation shall be voluntary without monetary payment or reward. The sale or purchase of human cells or tissues is strictly prohibited.

8.11.3. Reimbursement may only be provided for reasonable, documented expenses directly related to the donation process, including loss of income and costs associated with recovery, processing, preservation, and supply of HCT products. Such reimbursement shall not constitute financial inducement.

8.11.4. Donor rights, welfare, and autonomy shall be safeguarded through informed consent and independent evaluation. Oversight shall be provided by an Institutional Review Board (IRB) and Ethics Committee in accordance with DHA ethical requirements.

8.11.5. Donors shall be legally competent to provide consent. For minors or vulnerable adults, parental or legal guardian consent and Ethics Committee approval shall be obtained prior to any collection.

8.11.6. All donor recruitment and marketing materials shall be factual, evidence-based, and comply with DHA advertising and ethical regulations. Misleading or exaggerated claims regarding stem cell benefits are prohibited.

8.12. Donor Education and Counselling

8.12.1. Facilities shall provide donors with culturally appropriate and scientifically accurate educational materials that include, at minimum:

a. Purpose and scope of donation
b. Short-term and long-term health risks
c. Alternative treatment options for autologous procedures/donations
d. Potential future use of donated material, including possible use as starting material for ATMP development or commercialization pathways

8.12.2. Donor education and counselling shall be delivered by qualified healthcare professionals. Private and confidential counselling sessions shall be provided

to address donor questions, concerns, and emotional support prior to obtaining consent.

8.12.3. Documentation of donor education and counselling, including copies of educational materials provided and records of counselling sessions, shall be retained in the donor file in accordance with DHA record retention requirements.

8.13. Informed Consent Process

8.13.1. Written informed consent shall be obtained in Arabic and/or English, or in a language clearly understood by the donor, prior to any medical screening or collection activity.

8.13.2. The informed consent process shall include, at minimum:

a. Description of the collection process and procedures
b. Explanation of potential risks and benefits
c. The donor's right to withdraw consent at any time without penalty
d. Confidentiality, data protection, and privacy measures
e. Information on all intended research or therapeutic applications and any potential future uses of donated material

8.13.3. Consent forms shall be standardized, validated, and approved by the relevant Ethics Committee and shall include a documented acknowledgement from the donor confirming understanding.

8.13.4. Consent forms and associated documentation shall be securely stored and retained in accordance with DHA documentation requirements to ensure traceability and availability during audits.

9. **STANDARD SIX:** COLLECTION, PROCESSING, LABELLING, CRYOPRESERVATION, AND STORAGE

9.1. Facilities shall develop and maintain detailed, approved SOPs describing each process step for collection, processing, labelling, cryopreservation, and storage.

9.1.1. SOPs shall incorporate quality control and quality assurance measures and be reviewed at least annually or when major changes occur.

9.1.2. Detailed SOPs should define the procedures and process steps including quality control and quality assurance.

9.2. Collection of Cells and Tissues

9.2.1. Collection procedures shall be validated to minimize risks to the donor, prevent contamination, and maintain cell viability and integrity by minimizing ischemic time. All collections shall be performed aseptically using sterile, single-use equipment and techniques that preserve biological quality.

9.2.2. Collection methods shall follow Appendix 6: Stem Cell Types, and Collection Methods and shall be selected based on stem cell source, donor condition, and a documented risk assessment approved by the Medical Director.

9.2.3. Comprehensive collection documentation shall include donor identifiers, collection parameters, operator details, and laboratory testing results.

i. Collection documentation shall be retained for a minimum of twenty-five (25) years, as these records form part of the donor medical information and traceability.

9.2.4. Collected cells and tissues shall be labelled using ISBT 128 and/or GMP-compliant labelling systems to ensure chain-of-custody and traceability. Labels shall be verified for accuracy, legibility, and barcode integrity before release

9.2.5. Any adverse event during the collection process shall be documented, classified by severity, and investigated. Serious adverse events shall be reported to DHA as soon as possible and not later than seventy-two (72) hours from the time of awareness. Root-cause analysis and CAPA shall be completed and recorded.

9.2.6. Collection practices shall comply with AABB or FACT-JACIE standards, EU Directive 2004/23/EC and associated regulations, or US Good Tissue Practice (21 CFR Part 1271). Facilities shall maintain documented evidence of compliance, including certificates, SOP cross-references, and audit records.

9.3. Processing and Manufacturing

9.3.1. All processing steps for human cellular and tissue products (HCTs) shall comply with AABB or FACT–JACIE standards. Only GMP-compliant materials and reagents approved for clinical use shall be used. All processing equipment shall be qualified and validated prior to routine use. Labelling shall follow ISBT 128 requirements.

9.3.2. All manufacturing of Advanced Therapy Medicinal Products (ATMPs) shall be performed in GMP-certified facilities. Each batch shall have complete batch processing documentation, quality control results, and release authorization by a Qualified Person (QP) or equivalent authorized individual.

9.3.3. Packaging and labelling shall provide clear information to ensure safe and correct use, including product name, cell or tissue type, dosage or cell count, method of administration, expiration date, and storage conditions.

9.3.4. Each ATMP shall be accompanied by a package leaflet providing detailed user information in Arabic and English, validated for accuracy, readability, and clinical relevance.

9.3.5. Labelling shall follow ISBT 128 or the Single European Code (SEC), ensuring traceability and regulatory compliance.

9.4. Cryopreservation, storage and transportation:

9.4.1. Facilities handling HCTs shall comply with AABB or FACT–JACIE standards for cryopreservation, storage, and transportation. Cryopreservation procedures shall be validated to ensure temperature stability and product viability. Storage systems shall be temperature-mapped, continuously monitored, and equipped with alarm systems tested at defined intervals.

9.4.2. Manufacturers of ATMPs shall comply with GMP for ATMP requirements for cryopreservation and storage. Stability programs shall be established to define

storage duration, temperature ranges, and re-testing intervals where applicable.

9.4.3. Transportation of HCTs and ATMPs shall comply with PIC/S GDP Guide PE 011-1 and ATMP-specific GMP requirements. Shipping systems shall be validated, temperatures shall be monitored throughout transit, and chain-of-custody documentation shall be maintained.

9.4.4. Cord blood, peripheral blood, and mesenchymal or adipose derived stem cells shall not be mixed or co-stored within the same cryo-container or cylinder.

9.4.5. Each stem cell type shall be processed and preserved under distinct, validated procedures specific to its cryo-protectant solution, freezing rate, and storage conditions.

9.4.6. Physical and procedural segregation between different cell lines shall be maintained to ensure traceability, contamination prevention, and product integrity.

9.4.7. Storage equipment and processes must be validated and periodically calibrated according to quality management standards.

9.5. Point of care reconstitution of an ATMP includes:

9.5.1. Reconstitution is the process performed at the administration site to prepare an ATMP for immediate use and is distinct from manufacturing. Reconstitution may include:

a. Resuspension, dissolution, or dilution with approved solvents or buffers.

b. Mixing with patient-specific cells, adjuvants, or authorized substances.

c. Splitting into doses or adjusting dose (e.g., cell count).

d. Loading into infusion bags, syringes, delivery systems, or surgical devices.

9.5.2. These steps are considered reconstitution only when they cannot be performed during manufacturing without compromising product quality and are completed at the administration site immediately prior to administration.

9.5.3. Reconstitution shall be performed according to manufacturer-validated procedures under aseptic conditions.

9.5.4. The manufacturer shall provide clear written instructions, including required equipment, materials, and solvents.

9.5.5. The administration site shall document all reconstitution steps and verify adherence to manufacturer instructions.

9.5.6. While manufacturers are responsible for validating reconstitution procedures and providing requirements and materials, the administration site is responsible for compliant execution.

9.5.7. The administration site shall ensure that facilities, equipment, personnel, and procedures meet required standards, and shall maintain documentation confirming proper execution and environmental controls.

10. **STANDARD SEVEN:** PRODUCT TESTING, VALIDATION, AND QUALITY ASSURANCE

10.1. Product testing shall be conducted within a documented Quality Management System (QMS) framework to verify that all stem-cell-based products meet predefined

specifications, regulatory standards, and release criteria prior to distribution or clinical use.

10.2. Product testing for raw materials and final release shall be performed according to validated methods and limits described in the European or United States Pharmacopoeia. Alternative methods may be used only if validated in accordance with ICH Q2 (R2) and approved by DHA

10.3. All product and material testing shall be performed in ISO 17025-accredited laboratories or equivalent facilities operating under GMP. Analytical activities used for ATMP release shall comply with GMP Part IV requirements

10.4. Facilities shall perform validated analytical testing appropriate to product type to confirm identity, purity, sterility, potency, viability, and genetic stability. All test results shall be reviewed by the Quality Unit before product release, and retained in accordance with DHA record-keeping policy

10.4.1. Cell identity shall be confirmed using validated methods, including STR profiling and flow-cytometric marker analysis.

a. STR analysis shall be used to verify donor identity. Autologous products shall demonstrate a 100% STR match between donor and product; any mismatch shall classify the product as non-autologous.

b. Flow cytometry shall demonstrate expected cell-surface marker expression for the specified cell type. For MSCs, CD73, CD90, and CD105 shall be positive while CD34, CD45, and HLA-DR shall be negative. Identity test

acceptance criteria and results shall be documented in the batch record prior to product release.

10.4.2. Cell purity testing shall be performed to verify that the product meets defined purity thresholds.

a. Flow cytometry shall be used to quantify the percentage of the target cell population.

b. For mesenchymal stem cells (MSCs), purity acceptance criteria shall include:

i. >95% positive for CD73, CD90, and CD105

ii. <2% positive for CD34 and CD45

iii. <1% positive for HLA-DR

Note: Any result outside these limits shall trigger investigation prior to product release.

10.4.3. Sterility testing for bacterial, fungal, and mycoplasma contamination shall be performed after isolation, prior to cryopreservation, and before clinical use using validated culture or rapid-detection methods with appropriate incubation timeframes.

10.4.4. Endotoxins test: Endotoxin levels shall be determined using a validated LAL or equivalent assay. Endotoxin results shall not exceed 5 EU/kg body weight per hour of infusion, or a more stringent product-specific limit if established

10.4.5. Stem cell potency testing shall be performed to verify functional and phenotypic characteristics.

a. Morphological assessment shall be conducted to evaluate cell characteristics such as size, shape, colony structure, and overall cellular morphology.

b. Marker analysis (e.g., immunocytochemistry, flow cytometry, RT-PCR) shall be used to confirm expression of potency-associated markers.

c. Pluripotent stem cells shall demonstrate expression of markers such as OCT4, SOX2, NANOG, TRA-1-60, TRA-1-81, and SSEA-4.

d. Acceptance criteria for potency markers and assay performance shall be defined in product-specific SOPs, and test reproducibility shall be demonstrated during validation.

10.4.6. Cell viability testing shall be performed to confirm acceptable viability prior to product release.

a. Dye-exclusion assays (e.g., Trypan Blue, 7-AAD by flow cytometry) may be used, where viable cells remain unstained and non-viable cells take up the dye.

b. Metabolic activity assays (e.g., MTT, Alamar Blue, ATP-based methods) may be used to assess viability based on cellular metabolic function, with ATP-based assays preferred for quantitative accuracy.

c. Viability shall be at least 70% at the time of release, unless a different acceptance criterion is justified and supported by process validation.

10.4.7. Genetic stability testing shall be performed to detect chromosomal or genomic abnormalities that may impact product safety or function.

a. Cytogenetic analysis (e.g., karyotyping, FISH) shall be used to assess chromosomal integrity and ploidy.

b. Tumorigenic mutation analysis shall be performed during master cell bank establishment and as required based on risk to assess genomic stability.

c. Whole-genome or whole-exome sequencing may be performed to detect genetic mutations or variations of concern.

d. Genetic stability testing shall be performed at master-cell-bank establishment and periodically thereafter based on process risk. Any detected abnormalities shall be documented, evaluated, and reported to the Quality Unit prior to product release or continued manufacturing use.

10.4.8. Cell safety testing shall be performed prior to transplantation to confirm absence of tumour-forming potential and inappropriate differentiation risk.

a. Tumorigenicity testing shall confirm absence of residual pluripotent cells using validated methods such as PCR for pluripotency markers (e.g., OCT3/4) and/or in-vivo models when required based on product risk.

10.4.9. Abnormal differentiation risk assessment shall verify stable lineage commitment through expression of appropriate lineage-specific markers prior to clinical use.

a. Acceptance criteria shall be defined in product-specific procedures, and results shall be documented before product release

10.5. Validation and Qualification

10.5.1. All critical processes, test methods, and equipment shall be validated to demonstrate consistent performance against defined acceptance criteria.

a. Installation Qualification (IQ): Confirms proper installation of equipment and supporting utilities.
b. Operational Qualification (OQ): Verifies that equipment operates according to defined specifications and GMP requirements.
c. Performance Qualification (PQ): Confirms the process performs as intended under routine operating conditions.
d. Validation protocols and reports shall be approved by the Quality Manager and maintained within the Quality Management System (QMS).

10.5.2. Analytical assays shall be validated for specificity, accuracy, precision, linearity ($r \geq 0.95$), sensitivity, and independence as per ICH Q2 (R2). Validation summaries and acceptance criteria shall be documented and retained.

10.5.3. All processing protocols for cell collection, isolation, expansion, formulation, and cryopreservation shall be validated before routine use. Validation demonstrates consistency and reproducibility of approved processes and shall not be interpreted as authorization for clinical use of unapproved therapies.

a. Validation shall be required only for processes permitted under DHA regulations, including autologous workflows and approved allogeneic or ATMP-related procedures.
b. Each validation study shall include a minimum of ten (10) representative samples, conducted across multiple batches runs to demonstrate inter-batch reproducibility.
c. Critical steps, equipment, and operator performance shall be included.
d. Acceptance criteria shall be predefined and aligned with product specifications.
e. Any deviations observed during validation shall be documented and addressed before implementation.
f. Revalidation is required when major process changes occur.

10.6. Role of Quality Assurance (QA) The QA Unit shall establish and maintain SOPs, ensure continuous training of personnel, oversee all processing steps to prevent errors, and review all deviations, non-conformances, and CAPA prior to batch release.

10.6.1. Facilities shall maintain complete and legible Batch Manufacturing Records (BMRs) for each product lot, documenting all cell isolation, expansion, testing, cryopreservation, and storage activities.

a. BMRs shall be retained for **ten (10) years** when they are purely manufacturing/QMS documents, and **twenty-five (25) years** when linked to donor, product, or recipient traceability.

11. STANDARD EIGHT: CLINICAL APPLICATION AND ADMINISTRATION

11.1. General requirements include:

11.1.1. All clinical applications of stem cell therapy shall be conducted in accordance with DHA regulations, UAE Federal Law, and internationally recognized medical, scientific, and ethical standards. Ethical approval shall be obtained through a DHA-registered Institutional Review Board (IRB) and Ethics Committee prior to patient enrolment.

a. Applications shall be submitted through the DHA website: https://dha.gov.ae/en/MedicalEducationandResearch/MedicalResearch

11.1.2. All clinical applications of stem cell therapy shall be carried out in accordance with Dubai Health Authority (DHA) regulations, UAE Federal Law, and internationally recognized medical, scientific, and ethical standards.

11.1.3. Stem cell therapies shall be based on documented evidence of safety, efficacy, and scientific rationale supported by peer-reviewed research and recognized clinical guidelines Stem cell therapies shall be based on proven safety, therapeutic validity, and scientific rationale.

11.1.4. Facilities shall ensure that all therapies are governed by the following principles:

a. Patient safety
b. Transparency
c. Informed consent
d. Clinical appropriateness
e. Regulatory authorization
f. Professional accountability

11.1.5. The core principles guiding any therapy shall include the following:

a. Patient safety
b. Transparency
c. Informed consent
d. Clinical appropriateness

e. Regulatory approval

f. Professional accountability

11.1.6. Only autologous, minimally manipulated stem cells shall be used for routine clinical applications. Facilities shall maintain documented verification of manipulation level and donor–patient identity before administration Only ATMP with approvals from MOHAP/EDE and autologous HCTs are allowed for routine clinical use

11.1.7. Stem cell therapies involving substantial manipulation, allogeneic sources, or systemic administration shall only be performed within approved clinical trials or accredited transplant programs, with prior written authorization from DHA. All other therapies involving manipulation, allogeneic sources, or systemic use must fall under approved clinical trials or transplantation programs in accredited centres (appendix 7).

11.1.8. The use of stem cells for experimental or unproven purposes outside approved research or licensed programs is prohibited. Any observed non-compliant activity shall be reported to DHA for review and corrective action. The use of stem cells for unproven or experimental purposes without regulatory oversight is prohibited.

11.2. To ensure scientific validity, patient safety, and regulatory compliance, facilities shall classify each stem cell therapy based on:

11.2.1. Source (autologous vs. allogeneic)

11.2.2. Manipulation level (minimal vs. substantial)

11.2.3. Intended use (homologous vs. non-homologous)

11.2.4. Regulatory status (approved, investigational, or prohibited)

11.2.5. Route of administration (localized vs. systemic)

11.2.6. Sample type (e.g., bone marrow, peripheral blood, adipose tissue, cord blood, placental tissue,)

11.2.7. Classification records shall be documented and reviewed annually by the Quality Manager. To ensure scientific validity, patient safety, and regulatory compliance, all stem cell therapies shall be categorized based on:

a. Source (autologous vs. allogeneic),

b. Manipulation level (minimal vs. substantial),

c. Intended use (homologous vs. non-homologous),

d. Regulatory status (approved, investigational, or prohibited),

e. Site of administration (local vs. systemic).

11.3. Stem cell therapies shall be classified into the following five categories:

11.3.1. Category 1 – Approved Clinical Use:

a. Approved Clinical Use refers to stem cell therapies that are approved for clinical application under regulatory oversight.

b. For autologous use: cells are collected from and administered to the same patient, with minimal manipulation to preserve their original biological

characteristics and functions and applied for the same basic biological function (homologous use) within licensed healthcare facilities.

c. For allogeneic use, the only currently approved therapies are hematopoietic stem cells (HSCs) for serious, life-threatening blood and immune system disorders, and the mesenchymal stem cell (MSC) product Ryoncil (remestemcel-L-rknd), approved by the FDA for paediatric graft-versus-host disease (GVHD); all other allogeneic stem cell products remain investigational and require regulatory approval before clinical use.

11.3.2. Permitted applications:

a. Hematopoietic stem cell transplantation (HSCT) is a therapy used to treat leukaemia, lymphoma, multiple myeloma, and other approved blood and immune diseases. HSCT may be autologous, using the patient's own stem cells, or allogeneic, using stem cells from a compatible donor to reconstitute the patient's blood and immune system.

b. Intraoperative use of autologous adipose-derived stromal vascular fraction (SVF) for homologous use (e.g., wound healing or structural tissue support), where permitted by applicable regulations, may qualify as a minimally manipulated human cell and tissue-based product (HCT/P).

c. Minimal manipulation typically includes procedures such as washing, filtration, centrifugation, or mechanical separation, provided these processes do not alter the relevant biological characteristics of the cells or

tissues. Such products are used without ex vivo expansion, genetic modification, or deliberate functional alteration.

d. When the criteria for minimal manipulation, homologous use, autologous application, and same-surgical-procedure exemption are met, these therapies may be regulated under a less stringent regulatory pathway rather than as advanced therapy medicinal products (ATMPs) or biological drugs.

e. Because these therapies use the patient's own cells and are processed only to the extent necessary for their intended homologous function, they are generally associated with a lower risk of immune rejection and communicable disease transmission compared with allogeneic or extensively manipulated cell-based products.

f. Examples include minimally manipulated bone marrow–derived cellular preparations for bone or cartilage repair and adipose-derived SVF for wound healing or structural tissue support.

g. Refer to examples of Autologous, Minimally Manipulated Products (Category 1 Use) in appendix 8.

11.3.3. Criteria for inclusion

a. The cell product retains original biological structure and function

b. Intended clinical effect is homologous to the original tissue function

c. No substantial manipulation (e.g., expansion, genetic modification, enzymatic digestion beyond isolation, if any of these processes are required, it must be conducted under category 2 (investigational use with approved clinical trials protocol).

d. Performed in a DHA-licensed facility by a DHA-licensed specialist within scope of practice

e. Governance: Shall comply with applicable standards, including FACT-JACIE, NetCord, GMP, and CLSI, for processing, traceability, and clinical documentation

11.3.4. Category 2 – Investigational / Clinical Trials Only:

a. Category 2 includes stem cell therapies (autologous and allogeneic) as well as other biological products that are not approved for routine clinical use but have supporting preclinical or early-phase clinical evidence.

b. All therapies under Category 2 require DHA-approved protocols and structured clinical trial investigation depending on the product type and the level of manipulation:

i. Autologous cell-based therapies involving substantial manipulation—including ex vivo expanded mesenchymal stromal cells (MSCs), enzymatically processed stromal vascular fraction (SVF), extracellular vesicles/exosomes, cultured fibroblasts, and processed microfat or

nanofat grafts—are generally regulated as biological drugs or advanced therapy medicinal products (ATMPs).

- Prior to broader clinical use, these products typically require early-phase clinical evaluation, such as pilot or feasibility studies, conducted under appropriate regulatory authorization (e.g., IND, CTA).
- Study size and design are determined on a case-by-case basis based on product characteristics, intended indication, and risk profile, rather than a fixed minimum number of patients.

ii. Allogeneic cell-based therapies—including hematopoietic stem cells (HSCs) used for new indications, allogeneic mesenchymal stromal cells (MSCs), immune effector cells (natural killer cells), and other allogeneic biological products—are generally regulated as biological drugs or advanced therapy medicinal products (ATMPs).

- These products require regulatory oversight and authorization and are typically developed through a phased clinical trial program (e.g., Phase 1/2 and Phase 3 or equivalent), with study design and progression determined by risk profile, indication, and regulatory guidance.
- Such development must be conducted under the supervision and approval of DHA.

iii. Autologous Therapies products include:

- Ex vivo expanded mesenchymal stromal cells (MSCs) derived from bone marrow, adipose tissue, Wharton's Jelly, or other approved tissue sources.
- Autologous biological products involving more than minimal manipulation, including:
    - Stromal vascular fraction (SVF) when enzymatically processed or otherwise processed beyond minimal manipulation
    - Extracellular vesicles / exosomes
    - Cultured autologous fibroblasts
    - Platelet-rich plasma (PRP) and platelet-rich fibrin (PRF) when processed, combined, or used outside minimal-manipulation and homologous-use criteria
    - Bone marrow aspirate concentrate (BMAC) when further processed, combined, or used beyond homologous indications
    - Processed microfat or nanofat grafts when manipulation exceeds simple mechanical processing for structural tissue support.

iv. Requirements:

- Pilot Validation / Early-Phase Evaluation
- DHA requires pilot validation studies involving a minimum of 10–15 patients per indication to demonstrate initial safety, feasibility, and preliminary efficacy.
- Study design, endpoints, and patient selection must still be approved by DHA, considering the product's manipulation level and intended clinical indication.

v. Processing

- Processing must occur in DHA-approved, GMP-compliant facilities, including:
  - Defined QC procedures
  - Sterility and endotoxin testing
  - Identity and potency testing, where applicable
  - Full traceability and chain of identity from patient tissue collection through processing and re-administration to the same patient
  - Validated SOPs

vi. Regulatory Submission and Oversight

- Prior to patient enrolment and trial initiation, the following must be submitted for DHA approval:

- Clinical trial protocol
- Supporting preclinical or pilot data
- Manufacturing and processing SOPs
- Ethics Committee approval
- Investigator and facility credentials, as required
- Clinical use may proceed only after DHA authorization and remains subject to ongoing monitoring.

vii. Allogeneic Therapies

- Hematopoietic stem cells (HSCs) for new indications beyond currently approved blood or immune disorders.
- Allogeneic mesenchymal stromal cells (MSCs) from any tissue source (bone marrow, adipose, Wharton's Jelly, or other approved sources).
- Other allogeneic biological products, including:
  - Immune effector cells (e.g., T-cells, NK cells)
  - Stem cell-derived extracellular vesicles / exosomes
  - Fibroblasts
  - Any other allogeneic cell or tissue product considered by DHA.
- Requirements:

- Must follow full clinical trial phases (Phase 1, 2, and 3) with DHA-approved protocols.
- Preclinical safety and early-phase clinical data must support progression to human trials.
- Clinical trials must comply with GCP, GMP, and DHA reporting requirements.

11.3.5. Scope: Use is restricted to approved clinical trials conducted under DHA oversight.

a. Regulatory requirements

i. Trials shall be registered with the DHA Research Ethics Committee.

ii. Protocols shall follow Good Clinical Practice (GCP) requirements.

iii. Safety-monitoring provisions shall be defined in the protocol, with independent oversight implemented when required based on study risk.

b. Reporting obligations

i. Adverse events shall be reported in accordance with DHA timelines.

ii. Annual safety updates and final study results shall be submitted to DHA.

c. Funding and patient billing

i. Participants shall not be charged for investigational therapy unless specifically authorized by DHA and clearly stated in the informed-consent documentation.

ii. Any patient-funded research shall undergo independent ethical and financial review.

11.3.6. Category 3 – Compassionate / Special Access Use:

Access to stem cell therapies outside routine care or formal clinical trials, permitted only in exceptional cases where no approved alternatives exist.

a. Permitted applications

i. Autologous or allogeneic MSCs for severe or life-threatening conditions with no satisfactory alternatives

ii. Investigational iPSC-based therapies for serious genetic disorders when trial enrolment is not feasible

iii. Umbilical-cord-derived MSCs for critical, treatment-resistant conditions (e.g., severe lung disease, refractory inflammatory conditions)

b. Requirements

i. Conducted only in DHA-licensed hospitals or academic medical centres

ii. Prior DHA approval with documented medical justification

iii. Detailed informed consent addressing investigational nature, risks, and alternatives

iv. Participants shall not be charged unless explicitly authorized by DHA and disclosed in the consent form

v. Any patient-funded access shall undergo independent ethical and financial review

c. Oversight and monitoring

i. Case-by-case approval and oversight by DHA

ii. Adverse events shall be reported to DHA as per required timelines

iii. Safety and treatment outcomes shall be submitted to DHA for review

11.3.7. Category 4 – Not permitted and not supported by clinical evidence.

a. The use of stem cells (allogeneic and autologous)—regardless of source, manipulation, or administration route—for indications lacking scientific validation, or for purposes of enhancement, aesthetics, or general wellness, are not permitted. Such applications are considered unsafe and ethically inappropriate.

b. This restriction is in place to ensure patient safety, and such uses may only be considered following appropriate clinical trials and regulatory approval as a validated product.

c. For autologous stem cell applications with minimal manipulation, protocol validation involving a minimum of 10–15 patients are required to obtain approval prior to use. For allogeneic stem cell applications, full clinical trials including phases 1, 2, and 3 must be conducted to demonstrate safety and efficacy before regulatory approval by DHA.

d. Refer to appendix 10 for stem cell validation & clinical trial checklist.

11.3.8. Examples of applications Not Permitted by DHA

a. Systemic stem cell infusions for anti-aging, immune enhancement, or "detoxification"

b. Stem cell injections for autism, Alzheimer's disease, infertility, erectile dysfunction, or cerebral palsy without regulatory approval.

c. Cosmetic enhancement (e.g., breast augmentation, facial rejuvenation, hair restoration) using stem cell-enriched product.

d. "Miracle cure" claims or unproven therapies marketed directly to consumers or on social media

e. Risk justification:

i. Lack of peer-reviewed evidence supporting safety or clinical efficacy

ii. Risk of tumorigenesis, immune reactions, infection, or misuse

iii. Frequently associated with misbranding, false advertising, and exploitation of vulnerable patients

f. Compliance requirements

i. Facilities must implement internal controls to prevent unsupported applications.

ii. Suspected instances should be reported to DHA promptly.

iii. Documentation and investigation must follow the facility's Quality Management System (QMS).

g. Regulatory and Compliance Measures

i. Temporary suspension or revocation of the healthcare professional or facility license, if applicable.

ii. Notification to DHA for review and corrective measures.

iii. Internal investigation within the facility's QMS.

Note: The intent is to protect patient safety and ensure compliance with DHA standards, while providing a structured and professional process for monitoring and corrective action.

11.3.9. Category 5 – Transplant Programs Only:

Use of allogeneic (donor-derived) hematopoietic or mesenchymal stem cells exclusively within FACT-, AABB-, or JACIE-accredited transplant programs, or for approved indications (e.g., GVHD) administered under licensed hematopoietic transplant protocols or equivalent oversight.

a. Permissible applications

i. Allogeneic HSCT for malignant and non-malignant disorders (e.g., AML, aplastic anaemia, thalassemia)

ii. Cord blood transplantation through accredited international donor registries (e.g., WMDA)

iii. Use of matched unrelated or sibling donor cells for immunodeficiency and bone marrow failure syndromes

iv. FDA-approved MSC-based therapy (e.g., remestemcel-L) for acute paediatric GVHD administered within a licensed transplant program

b. Requirements:

i. Administration shall occur only within dedicated transplant units that have:

- Active accreditation under FACT, NetCord, or equivalent
- Documented SOPs for donor HLA typing, infectious-disease screening, eligibility evaluation, cryopreservation, thawing, infusion, and post-transplant management
- Validated procedures and equipment for critical steps including cryopreservation, thawing, infusion, and safety monitoring

ii. Oversight shall be provided by a licensed transplant physician and a multidisciplinary clinical team.

iii. Post-transplant follow-up shall be conducted for engraftment, complications (e.g., GVHD), and outcome reporting, with documentation maintained in the patient medical record and Quality Management System.

c. Processing and Handling:

i. GMP-grade reagents and controlled cleanroom conditions shall be used for any ex vivo manipulation.

ii. Chain-of-identity and chain-of-custody documentation shall be maintained from donor to recipient.

iii. Compliance with WHO GMP Annex 4 and FACT-JACIE cellular product handling requirements shall be ensured.

iv. Traceability records shall be verified during internal audits to confirm full documentation and continuity of custody.

12. **STANDARD NINE:** ETHICAL AND LEGAL CONSIDERATIONS

12.1. Stem cell research shall be conducted in accordance with DHA regulations, UAE Federal Law, and international ethical principles to ensure the responsible and equitable advancement of science while upholding human dignity

12.1.1. Facilities shall not engage in the collection, culture, or therapeutic use of embryonic stem cells. All research and therapy activities shall be limited to ethically permissible adult, perinatal, or induced pluripotent stem cells (iPSCs) under approved oversight.

12.1.2. Facilities shall establish ethics review mechanisms to ensure equitable access, voluntary consent, and the prevention of donor exploitation. Any potential ethical conflict shall be escalated to the Institutional Review Board (IRB).

12.2. Ethical Considerations

12.2.1. Source of Stem Cells

a. Embryonic stem cells: Donation, collection, and therapeutic use of embryonic stem cells are prohibited in Dubai.

b. Adult stem cells: Sourced from bone marrow, adipose tissue, or peripheral blood, and shall require informed consent, documented donor eligibility, and ethical oversight to prevent donor exploitation.

c. Induced pluripotent stem cells (iPSCs): Generated through cellular reprogramming and shall require informed consent with disclosure of genetic-manipulation risks and ethical review to ensure appropriate donor protection.

d. Perinatal stem cells: Derived from umbilical cord blood and placental tissue and shall require documented parental consent and ethical review where applicable to ensure transparency and donor protection.

12.3. Fair Access and Equity

12.3.1. Affordability: Facilities shall ensure that access to stem cell therapies does not unfairly disadvantage low-income or vulnerable populations, and equity safeguards shall be reviewed through institutional ethics processes.

12.3.2. Global equity: Initiatives shall promote fair participation in research and access to regenerative medicine for underserved communities, with ethical oversight to prevent exploitation and protect voluntary consent, including escalation to the Institutional Review Board (IRB) when required.

12.4. Unproven Therapies and Exploitation

12.4.1. Unregulated practices: Concerns include unlicensed or unregulated stem cell services, misleading advertising targeting vulnerable patients, lack of scientific evidence to support therapeutic claims, and absence of long-term safety data. Facilities shall not promote or perform unproven stem cell therapies.

12.4.2. Transparency and accuracy: All information and advertising related to stem cell services shall be accurate, evidence-based, and non-misleading to avoid exploitation of patients and families.

12.4.3. Internal oversight: Facilities shall maintain internal monitoring to ensure compliance with ethical and advertising standards, with potential violations escalated to the Quality Manager and reported to DHA as required.

12.5. Legal Considerations

12.5.1. Research Oversight and Governance

a. Institutional Review Board (IRB): All research involving human stem cells shall be reviewed and approved by an Institutional Review Board registered with DHA to ensure ethical and legal compliance.

b. Ethics Committees: Sensitive research involving human biological materials shall undergo ethics review to ensure scientific justification, participant protection, and compliance with UAE ethical standards.

c. Licensing requirements: Researchers and facilities handling human stem cells or human biological materials shall obtain applicable DHA research approvals and licenses prior to commencing any study, in accordance with UAE regulations and international research ethics standards.

12.5.2. Regulation of Clinical Applications

a. Approval pathways: Regulatory authorization shall be obtained for all clinical stem cell applications prior to patient use. Stem cell-based products shall be classified and regulated as drugs, biologics, or advanced therapies, with evidence of safety, quality, and efficacy submitted in accordance with DHA requirements.

b. Post-treatment oversight: Facilities shall ensure continuous post-treatment monitoring, adverse-event reporting, and long-term outcome follow-up in accordance with DHA directives to support ongoing evaluation of safety and efficacy.

c. Prevention of unproven therapies: Facilities shall not promote or administer unapproved or unproven stem cell therapies and shall cooperate with DHA in monitoring and reporting unregulated practices and supporting public education regarding associated risks.

d. Enforcement and governance: Physicians or facilities administering unauthorized stem cell therapies shall be subject to regulatory sanctions including license suspension or revocation, legal action, and placement on DHA's non-compliance registry. Facilities shall maintain internal reporting and governance mechanisms to identify and document potential non-compliant practices.

12.5.3. Intellectual Property and Commercialization

a. Patents and ownership: Stem cell-derived inventions may be patented; however, commercialization activities shall respect donor rights, human dignity, and ethical standards. Facilities shall ensure transparent ownership disclosure and equitable benefit-sharing where applicable

b. Biobanking: Public and private biobanks shall obtain and maintain DHA licensing and shall operate with documented donor consent, transparent use policies, and compliance with data-protection, biosafety, and ethical standards.

12.6. Data Protection in Stem Cell Research

12.6.1. Stem cell research facilities shall implement data protection systems ensuring confidentiality, encryption, and controlled access for all personal, genetic, and medical data Stem cell research involves collecting and analysing sensitive data, including personal, familial, and genetic information, which necessitates compliance with data protection regulations.

12.7. Compliance with Data Protection Laws

12.7.1. Organizations handling patient data in Dubai shall comply with applicable data-protection regulations, including the UAE Personal Data Protection Law (Federal Decree-Law No. 45 of 2021). Where relevant, systems and processes shall be aligned with internationally recognized frameworks such as the General Data Protection Regulation (GDPR) and the Health Insurance Portability and Accountability Act (HIPAA) for handling sensitive biological and genetic information

12.8. Patient Anonymity and Data Security

12.8.1. Anonymization: Donor and patient data shall be anonymized or de-identified in research databases. Public disclosure of identifiable information is prohibited.

12.8.2. Access control: Access to patient samples and genetic data shall be restricted to authorized personnel only, with role-based permissions documented and enforced.

12.8.3. Oversight: Compliance with data-protection controls shall be reviewed at least annually through internal audits and documented risk assessments.

12.9. Local Database Regulations

12.9.1. Facilities shall maintain local databases or collaborate with DHA-approved data centres for biological data storage. Off-site backups shall be encrypted and access controlled. Any data breach shall be reported to DHA within seventy-two (72) hours of detection

12.9.2. Facilities storing human biological materials for clinical use shall operate in GMP-qualified environments and maintain a valid DHA license. Compliance with DHA inspection requirements shall be demonstrated through annual review

12.9.3. Universities and research institutions storing cells or tissues solely for research, without clinical application, shall obtain IRB and academic authority approvals, maintain ethics oversight, and report storage activities annually to DHA for registry purposes.

13. STANDARD TEN: ACCREDITATION AND CERTIFICATION

13.1. The level of external accreditation and certification required for stem cell practices shall be determined by the risk profile of the operation, defined by type of product handled (HCT or ATMP), process complexity, and clinical application. Facilities shall maintain documentation of their risk classification and corresponding accreditation obligations.

13.1.1. Facilities performing minimal manipulation of human cells or tissues shall comply with AABB or FACT requirements, or another DHA-approved equivalent. Facilities manufacturing Advanced Therapy Medicinal Products (ATMPs) shall maintain GMP certification for ATMPs, or an equivalent authorization issued by a recognized competent authority.

13.1.2. Stem cell practices engaged in the collection of starting material, processing, or storage of Advanced Therapy Medicinal Products (ATMPs) shall hold valid GMP

certification issued by the Emirates Drug Establishment (EDE). In addition, facilities should also hold internationally recognized GMP certification that has been verified and accepted by DHA. All GMP certifications, scope statements, and renewal records shall be maintained on file and made available to DHA upon request or change in scope.

13.1.3. Any stem cells or tissues collected, processed, or stored outside the UAE shall originate from GMP-certified facilities accredited by a national competent authority or recognized accreditation body.

13.1.4. Full documentation of GMP certification, batch traceability, and quality control results shall be submitted to DHA prior to use.

13.1.5. Meet the requirements of EU Directive 2004/23/EC and its implementing directives.

a. Subject to DHA review and approval, DHA may recognize stem cell therapies that comply with WHO Good Tissue Practice guidelines or US FDA Current Good Tissue Practice (21 CFR Part 1271), provided that supporting evidence of accreditation (such as AABB certification) and product quality validation is submitted and verified.

13.2. Each facility shall establish policies and procedures ensuring integrity, competence, and traceability of all accredited processes. Accreditation performance, audit findings, and corrective actions shall be reviewed by management at least annually.

13.2.1. Accreditation, audit, and Corrective Action Prevention Action (CAPA) shall be retained for **ten (10) years**, except where records relate to specific donors, products, or patients, in which case **twenty-five (25) years** shall apply.

13.3. Facilities shall conduct internal audits and proficiency testing programs at least annually to verify ongoing compliance with accreditation and regulatory standards. Audit results and corrective actions shall be reviewed during management meetings.

13.4. Laboratories performing stem cell testing shall participate in at least one (1) recognized External Quality Assessment Scheme (EQAS) annually for each accredited testing domain. EQA results and improvement actions shall be documented and retained.

13.5. All accreditation and certification documents, including assessment reports, CAPA, and compliance certificates, shall be securely stored in both electronic and hardcopy formats with controlled access. Facilities shall ensure these records are readily available for DHA or accrediting body review at any time.

14. **STANDARD ELEVEN:** DATA MANAGEMENT AND REPORTING

14.1. Facilities handling stem cell data shall implement validated and access-controlled digital systems that ensure confidentiality, integrity, availability, and auditability of data. Systems shall include encryption, user authentication, automatic backup, and disaster recovery mechanisms to protect data against loss or unauthorized access

14.2. Record keeping and traceability requirements shall include the following:

14.2.1. All health and laboratory records, including donor, product, and recipient information, shall be maintained for a minimum of **twenty-five (25) years** in accordance with UAE ICT laws. Records shall be traceable, retrievable, and protected from alteration. Audit trails shall document all data entries, modifications, and access events.

a. Facilities shall comply with the DHA Health Information Assets Management Standard for sample and data retention.
b. Facilities shall comply with the DHA Health Information Sharing Policy for secondary use of data (including research).
c. Facilities shall comply with the DHA Health Data Quality Policy for health information component requirements.
d. Facilities shall comply with the DHA Consent and Access Control Standard for health information consent and access authorization.
e. Personnel responsible for data handling and record management shall receive documented training on the above standards

14.3. Standardized Labelling Protocols

14.3.1. All stem cell products shall be labelled in accordance with ISBT 128 standards to ensure full traceability. Labels shall include:

a. Donation Identification Number (DIN)
b. Product type (e.g., HSC, MSC)
c. Collection and processing date

d. Storage conditions (e.g., cryopreserved or fresh)

e. Expiration date

f. Handling instructions

14.3.2. Each product label shall include a machine-readable ISBT 128 barcode linked to the facility's traceability system. Barcode systems shall be verified for accuracy and validated for use across collection, processing, storage, and clinical workflows.

14.3.3. Barcodes used for cryopreserved products shall use validated cryogenic-grade labels tested for legibility, adhesion, and scanning performance at ultra-low temperatures (≤ −150°C). Periodic inspection shall confirm barcode readability throughout storage and handling.

15. STANDARD TWELVE: CLINICAL TRIAL GOVERNANCE FOR STEM CELL THERAPIES

15.1. Institutional Eligibility for Clinical Trials

15.1.1. Clinical trials involving unapproved or investigational uses of stem cell therapies shall only be conducted in:

a. DHA-licensed hospitals with established clinical research capacity, registered Institutional Review Boards (IRBs), and trained personnel; or

b. Recognized academic or research institutions authorized by the UAE Ministry of Education and the DHA with active clinical research infrastructure.

15.1.2. Standalone clinics, private medical centres, or commercial laboratories shall not conduct stem cell clinical trials independently unless:

a. A formal collaboration agreement is established with a recognized university or research institution; and

b. The collaboration is approved by the DHA through the standard Clinical Trial Application (CTA) process.

c. The agreement shall clearly define the responsibilities of the sponsor, principal investigator, and data ownership to ensure accountability and regulatory compliance.

15.2. Ethical and Regulatory Requirements

15.2.1. All stem cell clinical trials shall obtain prior approval from:

a. The DHA Research Ethics Committee (REC); and

b. A recognized Institutional Review Board (IRB), if applicable.

c. All principal investigators and sub-investigators shall have documented Good Clinical Practice (GCP) training prior to trial initiation.

d. Ethics and regulatory oversight shall be maintained throughout the conduct of the study, with reports submitted to the REC/IRB as required.

15.2.2. All stem cell clinical trials shall be registered in a recognized clinical trial registry such as:

a. clinicaltrials.gov

b. WHO ICTRP or any other registry approved by DHA and shall also be registered locally in the DHA Research Registry before trial commencement.

15.2.3. All stem cell clinical trials shall comply with ICH-GCP (E6 R2) and UAE Federal clinical research regulations. Facilities shall maintain inspection-ready documentation, including investigator files, protocol deviations, safety reports, and other essential trial records to demonstrate ongoing compliance.

15.3. Clinical Trial Authorization (CTA)

15.3.1. A Clinical Trial Application (CTA) shall be submitted to DHA prior to trial initiation, and no trial activities may commence until written DHA authorization is received. The CTA must include:

a. Preclinical safety data (minimum of 10 independent biological samples)

b. Detailed clinical protocols and investigator CVs

c. Informed consent templates

d. REC and/or IRB approvals

15.3.2. All trial personnel shall be DHA-licensed and trained in Good Clinical Practice (GCP). Investigator and staff qualifications, certifications, and GCP training records shall be retained in the Trial Master File

15.4. Permitted and Prohibited Research Indications

15.4.1. Investigational stem cell trials shall focus on conditions with scientific rationale and unmet medical need, supported by preclinical and early-phase safety data. Permissible indications include:

a. Neurological conditions (e.g., autism, Parkinson's disease, Alzheimer's disease, stroke recovery)
b. Metabolic disorders (e.g., diabetes, obesity-related complications)
c. Orthopaedic and degenerative diseases not yet approved for standard therapy
d. Rare or refractory conditions lacking effective treatments

15.4.2. The following indications are prohibited under DHA clinical trial policy, and any attempt to conduct such research shall be reported to DHA and result in immediate suspension of trial authorization:

a. Systemic rejuvenation or anti-aging interventions
b. Wellness, vitality, or immune-boosting applications
c. Cosmetic or aesthetic enhancement
d. Sexual health treatments (e.g., erectile dysfunction) unless specifically approved under an authorized trial protocol

15.4.3. Facilities shall not market or advertise investigational stem cell therapies. The Quality Manager shall ensure all promotional materials undergo review and approval prior to public dissemination.

15.5. Oversight and Enforcement

15.5.1. DHA retains the authority to audit, suspend, or terminate any clinical trial in cases where:

a. Participant safety is at risk

b. Non-compliance with regulatory or ethical standards is identified

c. Unauthorized promotion or unapproved therapy offerings are found

Facilities shall fully cooperate with DHA during audits and provide access to all requested documentation and data.

15.5.2. Serious non-compliance, including unapproved therapy use or concealment of safety incidents, may result in:

a. Suspension or revocation of investigator or facility licenses

b. Legal prosecution and financial penalties

c. Listing of the violator in DHA's non-compliance registry

15.5.3. All violations shall be documented within the facility's Quality Management System (QMS).

15.6. Post-Trial Requirements and Commercialization

15.6.1. Upon trial completion, a Market Authorization Application (MAA) shall be submitted to DHA and must include:

a. Clinical trial safety and efficacy data

b. Documentation of GMP-compliant manufacturing processes

c. Cost breakdowns and pricing proposals (inclusive of VAT)

d. Data ownership, access, and sharing rights shall be defined and approved by DHA prior to commercialization.

15.6.2. Facilities shall implement DHA-mandated post-market surveillance for long-term safety monitoring of approved stem cell therapies. Adverse events shall be reported to DHA within fifteen (15) calendar days of awareness.

15.7. Prevention of Commercial Exploitation

15.7.1. Facilities shall not use ongoing or pending clinical trials to:

a. Promote unapproved products to the public

b. Claim therapeutic benefit prior to regulatory approval

c. Charge participants or offer paid access to trials unless explicitly allowed in the approved protocol

15.7.2. Misuse of clinical research status for financial or marketing gain is a serious violation of DHA regulations and shall result in enforcement action, including publication in DHA's non-compliance registry.

16. STANDARD THIRTEEN: KEY PERFORMANCE INDICATORS (KPIs)

16.1. All DHA licensed facilities providing Stem Cell services are required to report the indicators specific to the scope of the services.

16.2. Each facility providing the services shall assign a quality representative who will be responsible for reviewing the data from departments and reporting the Key Performance Indicators (KPIs) to DHA annually.

16.3. The quality representative must consider the following in data collection:

16.3.1. Assure staff awareness of the KPIs and data collection lead(s) are adequately skilled and resourced.

16.3.2. Create a data collection plan based on strong methodology and available resources.

16.3.3. Assure adequate data collection systems and tools are in place.

16.3.4. Back up the data and assure protection of data integrity.

16.3.5. Assure continuous review of service performance and implementation of improvement plans.

16.3.6. Reporting shall be on an annual basis to (MonitoringKPIs@dha.gov.ae).

16.4. Quality representative shall report to DHA the following measures as outlined in the below KPI Cards:

16.4.1. Clinical Indicators (collection/ therapy/ transfusion facilities)

a. KPI 1: Collection Success Rate

b. KPI 2: Compliance to Outcome Follow-up

c. KPI 3: Percentage of Sentinel Events

d. KPI 4: Percentage of Unplanned Hospital Transfers

16.4.2. Laboratories/ Stem cell Banks Indicators

a. KPI 1: Average Processing Turn-around Time

b. KPI 2: Contamination Rate

16.5. To effectively monitor and enhance the performance of services, all DHA licensed facilities providing stem cell services shall have additional internal quality monitoring and improvement measures that cover quality, clinical outcomes, operational efficiency, and

patient satisfaction serving as measurable benchmarks for success and progress. Additional measures are included in Appendix 9.

16.6. KPIs related to safety, traceability, and product integrity naturally require closer attention, and facilities are expected to apply appropriate limits to maintain compliance with international best practices.

KPI: Collection Success Rate	
Main Domain:	Process
Subdomain:	Effectiveness
Applicability:	Stem cell collection facilities
Indicator Definition:	The total successful stem cell collection procedures per 100 conducted collections. The indicator supports effectiveness in service provision and promotes excellence in care
Calculation:	Numerator: number of successful stem cell collections Denominator: Total number of performed stem cell collections
Target:	NA
Methodology:	Numerator/Denominator x 100
Measuring Unit:	Percentage
Collection Frequency:	Annual
Desired Direction:	Higher is better
Rationale:	Ensures effectiveness of the collection technique and clinical team's readiness.
KPI Source:	DHA
KPI: Compliance to Outcome Follow-up	
Main Domain:	Process
Subdomain:	Effectiveness
Applicability:	Stem cell therapy facilities

Indicator Definition:	Percentage of stem cell therapy/ administration procedures where a follow up was conducted with patients' post-therapy. The indicator aims to support follow up and documentation of treatment effectiveness and any complications.
Calculation:	Numerator: number of stem cell therapies where at least one follows up was conducted with patients Denominator: Total number of performed stem cell therapies
Target:	>80%
Methodology:	Numerator/Denominator x 100
Measuring Unit:	Percentage
Collection Frequency:	Annual
Desired Direction:	Higher is better
Rationale:	Monitor post-therapy results to assess effectiveness and delayed complications.
KPI Source:	DHA
KPI: Percentage of Sentinel Events	
Main Domain:	Quality
Subdomain:	Patient Safety
Applicability:	Stem cell collection facilities, stem cell therapy facilities
Indicator Definition:	The total number of sentinel events occurring per 100 stem cell procedure. The indicator applies to health facilities involved in stem cell collection and (or) stem cell administration/ transfusion. Reporting of sentinel events shall be within DHA specified timeframe and through the approved channels.

Calculation:	Numerator: number of sentinel events related to stem cell collection/ transfusion Denominator: Total number of performed stem cell collections/ transfusions
Target:	NA
Methodology:	Numerator/Denominator x 100
Measuring Unit:	Percentage
Collection Frequency:	Annual
Desired Direction:	Lower is better
Rationale:	Encourage safe practice and corrective actions in health facilities
KPI Source:	DHA
KPI: Percentage of Unplanned Hospital Transfers	
Main Domain:	Quality
Subdomain:	Patient Safety
Applicability:	Stem cell collection facilities, stem cell therapy facilities
Indicator Definition:	The total number of stem cell procedures where an unplanned transfer to higher level of care occurred (hospital, ICU, etc.) per 100 stem cell procedure. The indicator applies to health facilities involved in stem cell collection and (or) stem cell administration/ transfusion.
Calculation:	Numerator: number of stem cell collections/ transfusions where an unplanned hospital/ higher care transfer occurred Denominator: Total number of performed stem cell collections/ transfusions
Target:	NA
Methodology:	Numerator/Denominator x 100
Measuring Unit:	Percentage
Collection Frequency:	Annual

Desired Direction:	Lower is better
Rationale:	Encourage safe practice and corrective actions in health facilities
KPI Source:	DHA
KPI: Average Processing Turn-around Time	
Main Domain:	Process
Subdomain:	Waiting time and Efficiency
Applicability:	Stem cell processing laboratories/ Banks
Indicator Definition:	Average time required to process stem cell samples as per internal policies and international best practice
Calculation:	Average number of days for processing stem cell samples per type during the reporting period.
Target:	NA
Methodology:	Average
Measuring Unit:	Days
Collection Frequency:	Annual
Desired Direction:	Lower is better
Rationale:	Measures workflow efficiency to ensure samples are handled within validated time windows
KPI Source:	DHA
KPI: Contamination Rate	
Main Domain:	Quality
Subdomain:	Effectiveness
Applicability:	Stem cell processing laboratories/ Banks
Indicator Definition:	Number of stem cell batches where contamination was detected during the processing phases per 100 stem cell processed batches
Calculation:	Numerator: number of stem cell batches where contamination was detected Denominator: Total number of processed stem cell batches/ samples

Target:	NA
Methodology:	Numerator/Denominator x 100
Measuring Unit:	Percentage
Collection Frequency:	Annual
Desired Direction:	Lower is better
Rationale:	Identifies sterility failures that may impact quality control.
KPI Source:	DHA

REFERENCES

1. AABB. (2021). Standards for cellular therapy services, 10th edition. AABB. Retrieved from https://www.aabb.org/ (Accessed February 24, 2025).
2. Clinical and Laboratory Standards Institute (CLSI). (2019). A quality management system model for laboratory services, 5th edition. CLSI. Retrieved from https://clsi.org/ (Accessed February 24, 2025).
3. Dominici, M., Le Blanc, K., Mueller, I., Slaper-Cortenbach, I., Marini, F. C., Krause, D. S., & Horwitz, E. (2006). Minimal criteria for defining multipotent mesenchymal stromal cells. Cytotherapy, 8(4), 315–317. https://doi.org/10.1080/14653240600855905
4. Dubai Civil Defence. (2023). Fire safety guidelines. Retrieved from https://www.dcd.gov.ae/ (Accessed February 24, 2025).
5. Dubai Health Authority (DHA). (2023). Digital health regulations. Retrieved from https://www.dha.gov.ae/ (Accessed February 24, 2025).
6. Dubai Municipality. (2023). Hazardous waste regulations. Retrieved from https://www.dm.gov.ae/ (Accessed February 24, 2025).
7. European Directorate for the Quality of Medicines & HealthCare (EDQM). European Pharmacopoeia. 11th ed. Strasbourg, France: Council of Europe; 2023.
8. European Medicines Agency (EMA). (2024). Guidelines relevant for advanced therapy *medicinal products*. Retrieved from https://www.ema.europa.eu/en/homepage (Accessed February 24, 2025).

9. European Medicines Agency (EMA). (2023). *GMP guidelines for ATMPs*. Retrieved from https://www.ema.europa.eu/ (Accessed February 24, 2025).
10. Foundation for the Accreditation of Cellular Therapy (FACT) & JACIE. (2021). *FACT-JACIE Accreditation Manual, 8th edition*. Retrieved from https://www.factwebsite.org/ (Accessed February 24, 2025).
11. General Data Protection Regulation (GDPR). (2018). *Regulation (EU) 2016/679 of the European Parliament and of the Council*. Retrieved from https://gdpr.eu/ (Accessed February 24, 2025).
12. Health Insurance Portability and Accountability Act (HIPAA). (1996). *Public Law 104-191*. Retrieved from https://www.hhs.gov/hipaa/ (Accessed February 24, 2025).
13. International Council for Commonality in Blood Banking Automation (ICCBBA). (2023). *ISBT 128 for cellular therapy, 15th edition*. Retrieved from https://www.iccbba.org/ (Accessed February 24, 2025).
14. International Organization for Standardization (ISO). (2015). *ISO 14644-1: Cleanroom and associated controlled environments*. Retrieved from https://www.iso.org/ (Accessed February 24, 2025).
15. International Organization for Standardization (ISO). (2015). *ISO 14644-2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration*. Retrieved from https://www.iso.org/ (Accessed February 24, 2025).

16. International Organization for Standardization (ISO). (2022). *ISO 14644-4: Design, construction, and start-up*. Retrieved from https://www.iso.org/ (Accessed February 24, 2025).
17. International Society for Blood Transfusion (ISBT). (2023). *ISBT 128 standard for blood and cell therapy labelling*. Retrieved from https://www.isbtweb.org/ (Accessed February 24, 2025).
18. International Society for Stem Cell Research (ISSCR). (2021). *ISSCR guidelines for stem cell research and clinical translation*. Retrieved from https://www.isscr.org/guidelines (Accessed February 24, 2025).
19. National Institutes of Health (NIH). (2009). *NIH guidelines for human stem cell research*. Retrieved from https://osp.od.nih.gov/ (Accessed February 24, 2025).
20. Nuffield Council on Bioethics. (2023). *Bioethics guidelines*. Retrieved from https://www.nuffieldbioethics.org/ (Accessed February 24, 2025).
21. Snowden JA, McGrath E, Duarte RF, Saccardi R, Orchard K, Worel N, et al. JACIE accreditation for blood and marrow transplantation: past, present and future directions of an international model for healthcare quality improvement. Bone Marrow Transplant. 2017; 52: 1367-71
22. European Directorate for the Quality of Medicines & HealthCare (EDQM). *European Pharmacopoeia*. 11th ed. Strasbourg, France: Council of Europe; 2023.

23. U.S. Food and Drug Administration (FDA). (2024). *Developing potential cellular and gene therapy products*. Retrieved from https://www.fda.gov/ (Accessed February 24, 2025).
24. U.S. Food and Drug Administration (FDA). (2023). *Guidance on human cell, tissue, and cellular and tissue-based products (HCT/Ps)*. Retrieved from https://www.fda.gov/ (Accessed February 24, 2025).
25. U.S. Food and Drug Administration (FDA). (2023). *Guidelines on electronic records & data integrity*. Retrieved from https://www.fda.gov/ (Accessed February 24, 2025).
26. World Health Organization (WHO). (2010) *WHO guiding principles on human cell, tissue and organ transplantation*. (WHO/HTP/EHT/CPR/2010.01) Retrieved from https://www.who.int/ (Accessed March 8, 2025)
27. World Health Organization (WHO). (2023) *Considerations in developing a regulatory framework for human cells and tissues and for advanced therapy medicinal products. Annex 3, TRS 1048.* Retrieved from https://www.who.int/ (Accessed March 8, 2025)
28. World Health Organization (WHO). (2022). *WHO approach towards the development of a global regulatory framework for cell and gene therapy products*. Retrieved from https://www.who.int/ (Accessed February 24, 2025).
29. World Health Organization (WHO). (2023). *Guidelines on digital health and data security*. Retrieved from https://www.who.int/ (Accessed February 24, 2025).
30. World Marrow Donor Association (WMDA). (2023). *Standards for stem cell donor registries*. Retrieved from https://www.wmda.info/ (Accessed February 24, 2025).

APPENDICES

APPENDIX 1: CLEANROOM CLASSIFICATIONS

Cleanroom Classifications:

When considering a certain ISO classification of cleanroom, it is critically important to ensure that your operation's needs align with the scope of the ISO level you select. For example, choosing a modular cleanroom that is more robust than the needs of your operation may make it difficult to meet the ROI of the cleanroom. Additionally, selecting a cleanroom that does not meet the needs of your operations can lead to the contamination of your products or services, which will incur further costs and may affect future customer relations. Facilities must adhere to the following mandatory requirements for the design, construction, and operational safety of stem cell laboratories in Dubai, United Arab Emirates:

1. Grade A cleanrooms (equivalent to ISO Class 5) are designated for high-risk operations requiring stringent contamination control.
    - The maximum allowable airborne particle concentration is 3,520 particles ≥ 0.5 µm per cubic meter, and unidirectional airflow is required to minimize contamination.
    - These cleanrooms are essential for the open processing of cellular products under aseptic conditions.
2. Grade B Cleanroom is suitable for aseptic preparation, filling, and compounding, Grade B cleanrooms maintain ISO Class 5 at rest and ISO Class 7 during operation. Airborne particle limits include:
    - **At rest**: 3,520 particles ≥ 0.5 µm per cubic meter

- In operation: 352,000 particles ≥ 0.5 µm per cubic meter

  These cleanrooms serve as the buffer zones for Grade A areas to prevent contamination during manufacturing.

3. **Grade C** Cleanroom: Equivalent to ISO Class 7 at rest and ISO Class 8 in operation, Grade C cleanrooms are used for intermediate manufacturing steps. The maximum allowable particle concentration is 352,000 particles ≥ 0.5 µm per cubic meter, ensuring controlled cleanliness during processing.
4. **Grade D** Cleanroom: Grade D cleanrooms are designated for non-aseptic processes and general manufacturing. These spaces are equivalent to ISO Class 8 and allow up to 3,520,000 particles ≥ 0.5 µm per cubic meter. These areas are used for gowning, early-stage manufacturing, and material handling before entering higher-grade cleanrooms.

APPENDIX 2: CRYOPRESERVATION AND STORAGE STANDARDS

1. **LN2 Cryogenic Storage**:
    - Cryogenic storage vessels shall maintain temperatures below −150°C to preserve the viability of cryopreserved cells.
2. **Safe Operating Levels**:
    - **Vapor-phase LN2 storage**: LN2 levels should remain above the minimum fill line, typically ensuring at least 5–10 cm (2–4 inches) of LN2 at the bottom of the vessel.
    - **Liquid-phase LN2 freezers**: LN2 levels should remain above 50% of vessel capacity, with refilling schedules to avoid levels dropping below 30%.
3. **Safety Systems**: Liquid nitrogen storage shall utilize vacuum-insulated tanks with dual temperature probes and continuous data logging for auditing.
4. Automated alarms shall notify staff automatically if:
    - **Temperature fluctuations exceed defined limits.**
    - **LN2 lev**els fall below critical thresholds.
5. **Fire Suppression**: Dubai Civil Defence-approved fire suppression systems shall be installed in all LN2 storage areas.
6. Regular liquid nitrogen replenishment schedules shall be implemented to avoid system failure.
7. Staff handling LN2 shall undergo specialized safety training, including emergency response protocols.
8. **Oxygen Level Monitoring**: Sensors shall be installed in LN2 storage rooms to prevent asphyxiation hazards, and temperature mapping should verify that all areas stay below −150°C.

APPENDIX 3: FACILITY REQUIREMENTS

1. **Structural Design and Materials - Walls and Flooring**:
    - Use non-porous, chemical-resistant materials (e.g., epoxy resin flooring, stainless steel, reinforced fiberglass wall cladding) to ensure easy cleaning and prevent contamination.
    - Walls shall be seamless and designed for easy disinfection to prevent microbial growth.
    - Anti-static flooring shall be installed in all sensitive areas to prevent electrostatic discharge.
    - Slip-resistant surfaces should be provided in wet zones to ensure personnel safety.
2. **HVAC System and Pressure Mapping**:
    - Pressure **Differentials**: Clean zones shall maintain positive pressure differentials of +15 Pa, while hazardous waste areas shall have negative pressure of -10 Pa.
    - HVAC Redundancy: N+1 redundancy should be implemented in HVAC systems to maintain airflow during equipment failures.
    - Humidity Control: HVAC systems shall incorporate humidity control to prevent excessive moisture accumulation.
    - Routine maintenance and filter replacements for HVAC systems should follow manufacturer recommendations.
3. **Biosafety Protocols - Biosafety Cabinets (BSCs)**:
    - Class II BSCs located in the appropriate surrounding environment shall be used for handling stem cell cultures and processing biological samples.
    - BSCs shall be placed away from doorways and high-traffic zones.
    - Annual certification of BSCs shall comply with NSF/ANSI 49 standards.
4. • **Oxygen Monitoring for LN2 Areas**:
    - O2 sensors shall trigger alarms if oxygen levels drop below 18%.
    - Sensors should be calibrated monthly using gas mixtures.

APPENDIX 4: PERMITTED SPECIALTIES AND APPROVED INDICATIONS

Authorized Specialty	**Approved Indication**
Haematology / Oncology	Hematologic malignancies (AML, ALL, lymphoma, myeloma) via HSCT (autologous/allogeneic)
Paediatric Haematology / Oncology	Paediatric HSCT for thalassemia, SCID, leukaemia
Immunology / Infectious Diseases	Immune reconstitution via HSCT (e.g., SCID, aplastic anaemia)
Plastic and Reconstructive Surgery	Autologous fat graft enrichment, wound reconstruction, post-surgical soft tissue repair
Orthopaedic Surgery	Localized osteoarthritis, cartilage injury (autologous SVF, same-day procedure)
Pain Medicine / Anaesthesiology	Musculoskeletal pain management (e.g., joint/spinal injections of SVF)
Physical Medicine & Rehabilitation	Tendon, ligament repair and musculoskeletal soft tissue support
Neurology	Peripheral nerve injuries (localized, homologous use); investigational for CNS only

APPENDIX 5: DONOR ELIGIBILITY BY TYPE OF STEM CELLS AND TISSUE

1. **Hematopoietic progenitor cells (hpcs) eligibility**
    - **Sources**: Bone marrow, peripheral blood (PBSCs), umbilical cord blood (UCB).
    - **Donor Eligibility Criteria**:
        - **Age**:
            - Bone Marrow & PBSC Donors: 18-60 years
            - Umbilical Cord Blood (UCB): Neonatal donors only
        - **Health Screening**:
            - No history of cancer, blood disorders, or autoimmune diseases
            - No chronic infections (HIV, HBV, HCV, syphilis, CMV-active)
            - No high-risk behaviours (IV drug use, travel to malaria-endemic regions)
        - **Genetic & HLA Matching**:
            - Allogeneic donors require HLA compatibility
            - Autologous donors need sufficient stem cell mobilization
        - **Blood Tests**:
            - Haemoglobin ≥ 12.5 g/dL
            - PBSC donors shall respond to G-CSF mobilization
2. **Mesenchymal Stem/Stromal Cells (MSCs) Eligibility**
    - **Sources**: Bone marrow, adipose tissue, umbilical cord tissue, amniotic fluid, placenta
    - **Donor Eligibility Criteria**:
        - **Age**:
            - Bone marrow and adipose derived MSCs: 18-50 years
            - Umbilical Cord MSCs: Neonatal donors only
            - Amniotic Fluid MSCs: Collected from consenting mothers
        - **Health Screening**:
            - No history of cancer, chronic infections, or auto-immune diseases

- No recent use of immunosuppressive drugs
- Adipose: No diabetes, severe obesity (BMI >35), or metabolic syndrome

- **Tissue Considerations**:
  - Bone marrow MSCs decrease with age; younger donors preferred
  - Adipose MSCs yield higher but can be affected by obesity (BMI >30)

    Abdominal fat provides higher stem cell yield than thigh/gluteal areas
  - Umbilical cord MSCs have high proliferative potential

3. **Stromal Vascular Fraction (SVF) Eligibility**

- **Source**: Adipose tissue, enzymatically or mechanically dissociated
- **Donor Eligibility Criteria**:
  - Same health criteria as adipose derived MSCs plus:
  - **Infection Risk Assessment**:
    - Screen for contaminants and residual enzymes
    - Ensure sterility for immediate use
  - **Blood Tests**:
    - Normal WBC count (infection-free status)
    - No coagulation disorders to prevent bleeding
  - **Processing Considerations**:
    - Avoid donors with excessive scarring

4. **Induced Pluripotent Stem Cells (iPSCs) Eligibility**

- **Source**: Somatic cells (skin fibroblasts, peripheral blood mononuclear cells)
- **Donor Eligibility Criteria**:
  - **Age**: 18-55 years (younger cells reprogram better)
  - **Health Screening**:
    - No history of cancer, neurodegenerative diseases, or genetic disorders
    - No chronic viral infections (HIV, HBV, HCV)

- **Genetic & Epigenetic Factors**:
  - DNA shall be mutation-free for proper reprogramming
  - Avoid donors with high exposure to smoking, radiation, or chronic stress
- **Storage Considerations**:
  - Requires genetic validation before use
  - Long-term cryopreservation in liquid nitrogen

APPENDIX 6: STEM CELL TYPES AND COLLECTION METHODS

Hematopoietic Stem Cells (HSC) – refer to DHA standard for Clinical Hematopoietic Stem Cells Transplant Services

- **Bone Marrow Aspiration:** The procedure shall be conducted under sterile conditions by qualified healthcare professionals, following DHA standard for donor safety and pain management.
- **Peripheral Blood Stem Cells:** Leukapheresis, using G-CSF mobilization, shall follow DHA-approved protocols, ensuring donor safety and optimized stem cell yield.
- **Umbilical Cord Blood:** Collection shall occur under aseptic conditions immediately after delivery, following DHA's stringent timing and procedural standard to ensure cell yield and safety.

Mesenchymal Stem Cells (MSC):

- **Umbilical Cord/Placenta:** MSC collection from Wharton's jelly or placental tissue shall follow DHA's sterile procedures to maximize yield and viability.
- **Adipose Tissue:** Liposuction techniques for MSC collection shall meet DHA's safety standards to ensure minimal risk to the donor and optimal cell viability.
- **Dental Pulp:** Protocols shall be followed to preserve cell integrity during collection from extracted teeth.
- **Amniotic Fluid and Membrane:** Collection during caesarean or amniocentesis shall adhere to DHA's aseptic protocols.
- **Exosome Harvesting:** Exosome harvesting from MSC culture shall be validated under DHA-approved conditions to maintain integrity.

Autologous Stem Cell Sources

- **Autologous** stem cells are derived from the same patient who will receive the treatment.
- As these stem cells are from the patient's own body, they avoid complications like immune rejection or graft-versus-host disease (GVHD), making them an attractive option for various therapies.

Advantages of autologous stem cells

- **No Immune Rejection:** Since the stem cells are from the patient's own body, there is no risk of immune rejection.
- **Lower Risk of GVHD:** Autologous stem cells eliminate the risk of GVHD.
- **Ethical Considerations:** There are no ethical concerns related to donor consent or the use of embryonic stem cells, as the patient's own cells are used.

APPENDIX 7: CLINICAL APPLICATIONS AND USE OF STEM CELLS

Category	Regulatory Classification	Permitted Scope of Activity	Authorized Settings	Mandatory Regulatory Conditions / Restrictions
1	**Approved Clinical Use**	• Autologous stem cells • Minimally manipulated only • Homologous use only • Allogeneic hematopoietic stem cells (HSCs) for approved blood and immune disorders	DHA-licensed healthcare facilities	• Autologous use only • No substantial manipulation permitted • No non-homologous indication allowed • Any process change requires prior DHA approval • Full traceability and informed consent mandatory
2	**Investigational Use (Clinical Research)**	• Early-phase research • Translational validation • Clinical trials (Phase I–III)	DHA-approved research sites and licensed healthcare facilities	• DHA (Ethics Committee) approval required • GCP compliance required • No patient charging unless explicitly approved by DHA
3	**Compassionate / Expanded Access**	• Use in severe or life-threatening conditions • No suitable alternative therapy available	DHA-licensed hospitals only	• Case-by-case DHA approval • Strict informed consent • Time-limited and monitored use • Not permitted as routine clinical service
4	**Applications Not Supported by Scientific Evidence**	• Wellness, enhancement, cosmetic, longevity, anti-aging, or unvalidated uses	Not permitted for routine clinical practice	• Prohibited outside DHA-approved clinical trials • Marketing or service delivery not allowed • Violations subject to enforcement action, including license suspension

5	**Transplant Programs Only**	• Allogeneic HSCT and MSC therapies as part of recognized transplant programs	FACT / AABB / JACIE-accredited transplant centres	• Accreditation mandatory • GMP-compliant processing required • Validated SOPs and systems • End-to-end traceability (donor to recipient)

APPENDIX 8: EXAMPLES OF AUTOLOGOUS, MINIMALLY MANIPULATED PRODUCTS

(CATEGORY 1 USE)

Product	Minimal Manipulation Allowed	Typical Use
Bone marrow aspirate (BMA)	Collected and concentrated (BMAC) without expansion	Bone, cartilage, tendon repair
Bone marrow MSCs	Washed, filtered, concentrated (no ex vivo expansion)	Bone or cartilage repair
Adipose tissue	Mechanical processing to obtain SVF; washing, filtration, centrifugation	Cartilage support, soft tissue repair, wound healing
Fibroblasts	Isolated and washed, no expansion	Tissue repair or wound healing
Exosomes / conditioned media	Derived directly from autologous cells, no modification	Tissue regeneration (experimental, may require Category 2 if manipulated beyond collection)
Platelet-rich plasma (PRP)	Blood centrifuged and concentrated, no additives that alter function	Wound healing, cartilage repair
Platelet-rich fibrin (PRF)	Blood centrifuged to form fibrin matrix	Soft tissue repair, dental, orthopaedic repair
Microfat / nanofat grafts	Mechanical processing of fat, no expansion	Tissue repair (cosmetic use requires Category 2)

APPENDIX 9: ADDITIONAL INTERNAL KPI MEASURES

1. LABS / STEM CELL BANKING

KPI	Purpose	Measurement / Formula	Acceptance	Reporting
Labelling & Traceability Accuracy	Ensures every stem cell product is correctly linked to the donor and recipient at every stage to prevent mix-ups and ensure product integrity.	Correct labels ÷ total labels × 100	100%	Monthly
Infectious Disease Testing Compliance	Ensures complete and timely screening of donors to protect recipients, staff, and downstream processing.	Completed tests ÷ required tests × 100	100%	Monthly
Cryogenic Storage Stability	Ensures continuous preservation of cellular viability by maintaining validated LN_2 temperature conditions.	% of time within validated temperature	100% in range	Monthly
Equipment Calibration & Certification	Ensures accuracy of equipment used in processing to avoid deviations that affect quality or safety.	Certified equipment ÷ total critical equipment	100%	Quarterly
Serious Adverse Event Reporting	Ensures quick escalation of significant events that may impact safety or regulatory compliance.	Time from event awareness → reporting	Within 72 hours	Monthly
Chain of Custody Compliance	Ensures complete traceability during every product handover from collection to storage.	Completed chain-of-custody forms ÷ total	100%	Monthly

KPI	Purpose	Measurement / Formula	Acceptance	Reporting
Contamination Rate	Identifies sterility failures that may impact product suitability and quality control.	Contaminated batches ÷ total batches × 100	Facility-defined target	Monthly
Processing Turnaround Time	Measures workflow efficiency to ensure samples are handled within validated time windows.	Batches within TAT ÷ total batches × 100	Facility-defined target	Monthly
Environmental Monitoring Excursions	Detects deviations in temperature, humidity, particulate count, or pressure differentials.	Number of excursions	Facility-defined target	Monthly
Deviation Rate	Tracks how often processes drift from approved SOPs, indicating potential training or process gaps.	Deviations ÷ total procedures × 100	Facility-defined target	Monthly
CAPA Closure Rate	Measures the effectiveness and timeliness of corrective and preventive actions.	Closed CAPA ÷ total CAPA × 100	Facility-defined target	Monthly
Staff Competency Compliance	Ensures personnel are trained and qualified to perform assigned duties safely.	Competent staff ÷ total staff × 100	Facility-defined target	Quarterly

2. CLINICS / HOSPITALS – COLLECTION

KPI	Purpose	Measurement / Formula	Acceptance	Reporting
Donor/Maternal Infectious Disease Testing	Ensures donor and maternal safety and protects downstream clinical applications.	Completed ÷ required × 100	100%	Monthly
Collection Labelling Accuracy	Ensures the collected sample is identified correctly at the very first step.	Correct labels ÷ total	100%	Monthly
Consent Compliance	Ensures donors provide informed, voluntary, and properly documented consent.	Completed consents ÷ total cases	100%	Monthly
Transport Condition Compliance	Ensures that samples arrive at the laboratory under validated conditions.	In-range shipments ÷ total shipments	No deviations without CAPA	Monthly
Chain of Custody Compliance	Ensures traceability from point of collection to arrival at the laboratory.	Completed documents ÷ total	100%	Monthly
Serious Adverse Event Reporting	Ensures timely escalation of donor-related serious events.	Time to report	Within 72 hours	Monthly
Donor Eligibility Turnaround Time	Measures responsiveness and operational efficiency in screening donors.	Avg number of days	Facility-defined target	Monthly

KPI	Purpose	Measurement / Formula	Acceptance	Reporting
Collection Adverse Event Rate	Identifies risks or complications arising during collection procedures.	AEs ÷ total collections × 100	Facility-defined target	Monthly
Collection Success Rate	Measures effectiveness of the collection technique and readiness of the team.	Successful collections ÷ total collections × 100	Facility-defined target	Monthly
Service Availability	Measures how consistently the site can support scheduled collections.	Operational days ÷ total days	Facility-defined target	Monthly
Staff Competency Compliance	Ensures collectors are trained and assessed for competency.	Competent staff ÷ total staff	Facility-defined target	Quarterly

3. CLINICS / HOSPITALS – THERAPY / TRANSFUSION

KPI	Purpose	Measurement / Formula	Acceptance	Reporting
Product Identity Verification	Prevents wrong-patient/wrong-product events by confirming product identity before infusion.	Verified matches ÷ total cases	100%	Monthly
Therapy Consent Compliance	Ensures patients are fully informed and consent is documented before therapy.	Completed consents ÷ total	100%	Monthly
Storage & Handling Pre-Infusion	Ensures viability and safety of the product immediately before administration.	In-range ÷ total	100% in range	Monthly

KPI	Purpose	Measurement / Formula	Acceptance	Reporting
License Scope Compliance	Ensures therapy is performed only within the approved DHA scope of service.	Count of violations	Zero	Quarterly
Serious Adverse Event Reporting	Ensures timely reporting of clinically significant outcomes post-therapy.	Time from event → report	Within 72 hours	Monthly
Infusion Reaction Rate	Tracks safety issues during administration to identify training gaps or product issues.	Infusion reactions ÷ total infusions × 100	Facility-defined target	Monthly
Outcome Follow-up Completion	Monitors post-therapy results to assess effectiveness and delayed complications.	Completed follow-up ÷ required	Facility-defined target	Monthly
Procedure Delay Rate	Identifies operational inefficiencies affecting patient service delivery.	Delayed procedures ÷ total procedures × 100	Facility-defined target	Monthly
Emergency Readiness (Mock Drills)	Confirms that staff can effectively manage infusion-related emergencies.	Pass / Fail	Facility-defined target	Quarterly
Administration Adverse Event Rate	Tracks non-serious AEs to support continuous improvement.	AEs ÷ total infusions × 100	Facility-defined target	Monthly

APPENDIX 10: STEM CELL VALIDATION AND CLINICAL TRIAL CHECKLIST

Step	Task	Autologous (Pilot Validation)	Allogeneic (Full Clinical Trial)	Notes / DHA Requirements
1	Define indication & objectives	Clearly specify disease/condition, expected outcomes	Clearly specify disease/condition, expected outcomes	Must align with scientific rationale and DHA guidelines
2	Develop study protocol	Design study, define inclusion/exclusion, outcomes, sample size (10–15 patients)	Full protocol covering Phase 1, 2, 3 trials; endpoints, inclusion/exclusion, randomization, controls	Protocol must follow GCP principles
3	Stem cell source & characterization	Source, manipulation, route of administration, QC tests	Source, manipulation, route of administration, QC tests, donor eligibility, immunogenicity tests	DHA requires detailed documentation for traceability
4	SOP development	Collection, processing, storage, labelling, administration	Collection, processing, storage, transport, labelling, administration, quality control	SOPs must be approved by DHA Ethics Committee
5	Preclinical/pilot data	Optional pilot/preliminary data on safety	Required preclinical data to support safety and rationale	Preclinical studies must comply with GCP/GMP standards
6	Prepare regulatory submission	Submit protocol, SOPs, informed consent forms	Submit protocol, SOPs, informed consent forms, preclinical data	Documents must be complete for DHA Ethics Committee review
7	Ethics Committee review	Submit to DHA Ethics Committee	Submit to DHA Ethics Committee	Approval is mandatory **before any study/trial initiation**

Step	Task	Autologous (Pilot Validation)	Allogeneic (Full Clinical Trial)	Notes / DHA Requirements
8	Obtain ethics approval	Required before starting pilot validation	Required before Phase 1 trial initiation	Must be documented and on file
9	Conduct study/trial	Pilot validation study with 10–15 patients	Phase 1 (safety/tolerability), Phase 2 (preliminary efficacy), Phase 3 (confirmatory efficacy & safety)	Adherence to protocol is mandatory
10	Safety monitoring	Record adverse events, ensure patient follow-up	Record adverse events, serious adverse events, and long-term safety	DHA requires GCP-compliant safety reporting
11	Data analysis	Analyse safety and preliminary efficacy	Analyse each trial phase and overall outcomes	Statistical methods must be predefined in protocol
12	Prepare report	Validation report summarizing results	Interim reports for Phase 1 & 2, final report after Phase 3	Report must include safety, efficacy, and QC data
13	Submit report to DHA	Submit pilot validation report for review	Submit interim & final reports to DHA for review	Submission required before wider clinical use
14	DHA approval for clinical use	Required after validation approval	Required after completion of Phase 3 trial and regulatory review	Only after DHA approval can product be used clinically