



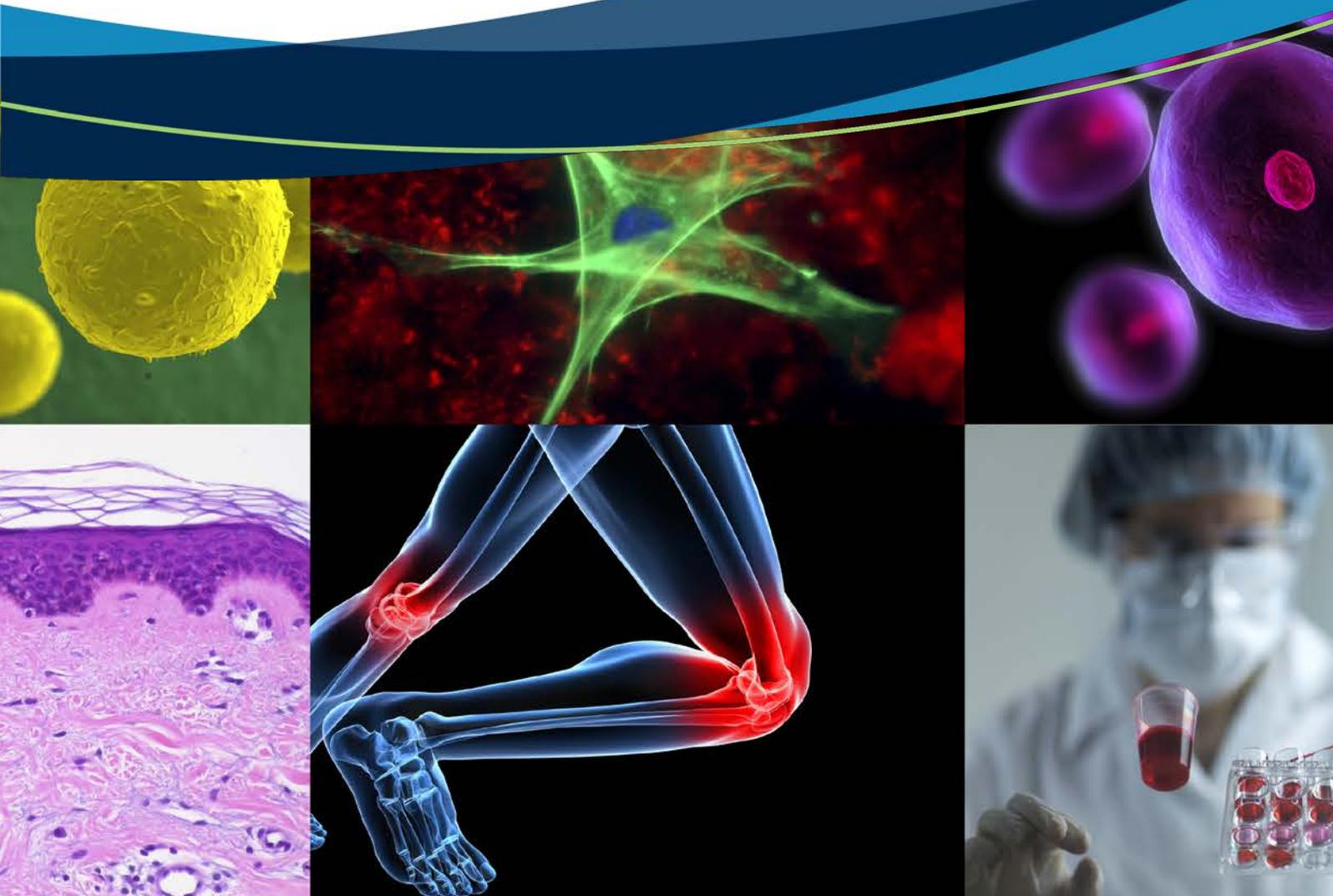
Australian Government
Department of Health
Therapeutic Goods Administration

Australian Regulatory Guidelines for Biologicals

Appendix 14 - Glossary

Version 1.1, June 2017

TGA Health Safety
Regulation



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Glossary

Term	Definition
Allogeneic use	<p>The use of blood, blood components, tissues and cellular therapy products that are removed from one person and applied to another person</p> <p>OR</p> <p>The use of a biological that is removed from one person and applied to another.</p>
Allograft	Living tissue transplanted from another individual of the same species.
Antimicrobial	A substance that can kill or inhibit growth of microorganisms. Antimicrobials include antibiotics (specific for bacteria), antiviral and antifungal agents.
Anti-HBc	Hepatitis B core antibody
Anti-HBs	Hepatitis B surface antibody
Aseptic technique	A technique that consists of measures used to prevent contamination by microorganisms.
Assisted reproductive technology	Application of laboratory or clinical technology to gametes or embryos for the purpose of achieving human reproduction.
Asystole	means the reference time for cardiac death. A documented pronounced time of death is used as asystole when life-saving procedures have been attempted and there were signs of, or documentation of, recent life (e.g. agonal respirations, pulse-less electrical activity). If death was not witnessed, 'asystole' must be determined by reference to the last time that the person was known to be alive. Asystole will be 'cross clamp time' if the tissue donor was also a solid organ donor.
Autologous use	<p>The use of blood, blood components, tissues and cellular therapy products that are removed from and applied to the same person</p> <p>OR</p> <p>The use of biologicals that are removed from and applied to the same person.</p>

Term	Definition
Autograft	Living tissue transferred from one part of a patient's body to another.
Batch number	A number (or a combination of numerals, symbols or letters) that a manufacturer gives to a batch of goods, to uniquely identify that batch. The batch number allows the batch to be traced through all stages of manufacture and distribution.
Batch number prefix	The prefix that precedes the batch number and clearly indicates that the number is the batch number. Examples of acceptable batch number prefixes include 'Batch Number', 'BATCH NUMBER', 'Batch No.', 'BATCH NO.', 'Batch', 'BATCH', 'B 'B', '(B)', 'B/N', 'Lot Number', 'LOT NUMBER', 'Lot No.', 'LOT NO.', 'Lot' or 'LOT'; or words or symbols to this effect.
Bioburden	Has the same meaning as in the Act.
Biological(s)	Has the same meaning as in the Act.
Blood	Whole blood collected from a single human donor and processed either for transfusion or further manufacturing.
Blood Components	Components of blood (red cells, white cells, platelets, plasma for infusion and plasma for fractionation) that can be prepared by centrifugation, filtration and freezing, but not including haematopoietic progenitor cells.
Cell(s)	Individual cells or a collection of cells when not bound by any form of connective tissue.
Cell culture	A method for growing cells outside of the body. For example, to sustain a population, to increase the number of cells ('expanding') or promote the production of new cell types.
Collection (Blood/blood components)	The process of removing human blood, blood components, cells or tissue from a donor.
Collection (Biological)	The process of removing a biological or a source of a biological from a donor.
Competent valve	A dissected valve that is capable of functioning in a defined effective manner.

Term	Definition
Complex methods of manipulation	Processes that are not listed under 'minimal manipulation', including such processes as demineralisation or enzymatic dissociation.
Container	Has the same meaning as in the Act.
Cord blood	Blood which contains many different types of cells, including stem cells, taken from the umbilical cord.
Critical material	Means all materials or supplies used in the manufacture of therapeutic goods which could have a direct impact on the quality, safety or function of the final goods.
Cryopreserved	Means suspended in a medium containing a suitable cryoprotectant and cooled according to a method which has been validated to allow maintenance for long periods.
Date of manufacture	For a biological, the date (day, month and year) on which the processing of the product, including the packaging, is completed.
Domino donor	A person who, by receiving an organ or tissue transplant, donates the removed organ or tissue to another recipient.
Donor	Any source, whether living or deceased, of blood, blood components, cells or tissues.
Dossier	The documentation that applicants are required to provide to the TGA in support of an application for approval of a Class 2, 3 or 4 biological. The dossier will include all scientific and technical information to support the design and production of the Class 2, 3 or 4 biological. Where there are applicable standards, the dossier will also incorporate information regarding compliance with relevant standards.
Demineralisation	The process of removing minerals (eg calcium salts from bone) from tissue.
Expiry date	The date (month and year) after which the goods should not be used.

Term	Definition
Freeze-drying	To dry (food, blood, serum, etc.) while frozen and under high vacuum, as for prolonged storage.
Genetically modified cells	A cell having had its genetic material altered by technological means, usually with the intention of changing certain characteristics and thereby altering the organism to fulfil a specific purpose.
Good laboratory practice (GLP)	A quality system concerned with the organisational process and the conditions under which nonclinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported.
Haematopoietic progenitor cells	Cells that are primitive multipotent cells capable of self-renewal as well as differentiation and maturation into all haematopoietic lineages.
HBsAg	Hepatitis B surface antigen
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HIV	Human Immunodeficiency Virus
HPC	Haematopoietic progenitor cells
HPC-A	Haematopoietic progenitor cells-apheresis
HPC-C	Haematopoietic progenitor cells-cord
HPC-M	Haematopoietic progenitor cells-marrow
HTLV-1	Human T-lymphotropic viruses type 1
HTLV-2	Human T-lymphotropic viruses type 2

Term	Definition
Homologous use	The repair, reconstruction, replacement or supplementation of a recipient's cells or tissues with a biological that performs the same basic function in the recipient as in the donor. This definition is internationally consistent and relates to the use of the product independent of whether the recipient is the same as the donor (autologous) or different from the donor (allogeneic).
In vitro diagnostic device (IVD)	Has the same meaning as in the Act.
Kit	Has the same meaning as in the Act.
Knowledgeable historian	A person knowledgeable about the donor's medical and social history, if the donor is deceased or unable to participate in an interview. A knowledgeable historian may be a person, or persons, able to provide relevant information and may be the donor's next of kin; the nearest available relative; a member of the donor's household; a person with a relationship to the donor (e.g. carer, friend, partner); or the donor's primary treating physician.
Manufacture	Has the same meaning as in the Act.
Microbial	Microorganisms including, but not limited to, bacteria, fungi, <i>Mycoplasma</i> and <i>Rickettsia</i> , but not including viruses or prions.
Microbial contamination, extrinsic	Contamination of the product caused by compromised processing.
Microbial contamination, intrinsic	Contamination of the product already present in the starting material.
Minimal manipulation	Has the same meaning as in the Act.
Monoclonal antibody	An antibody produced by a cell cloned in a laboratory, which produces antibodies more abundantly and uniformly than a natural cell, the antibody being able to bind specifically to a single site on almost any chosen antigen or reveal previously unknown antigen sites; used in medical research as a diagnostic tool or in the treatment of some diseases such as cancer.

Term	Definition
Name and address	Means the name of the sponsor and sufficient information to allow the sponsor to be uniquely identified so as to facilitate public contact and direct communication. The address must include information such as the city or suburb of the sponsor's principal place of business (not being a post office, cable, telegraphic or code address). The Australian telephone number must also be included.
NAT	Nucleic acid amplification test
Physical assessment	Means a clinical inspection of a living or deceased potential donor to determine suitability of the person to be a donor and may include, but is not limited to, assessing the relevance of any abrasion/laceration, bruise/haematoma, fracture, tattoo, piercing, scar, skin lesion, surgical incision or other distinguishing external feature that may be indicative of a behaviour or lifestyle or suggestive of any risk factor in relation to a relevant communicable disease.
Plasma	The liquid part of blood or lymph, as distinguished from the corpuscles.
Primary pack	Has the same meaning as in the Act.
Principal manufacturer	The person who carries out the total manufacture of a product or, if more than one manufacturer is involved, the person who takes overall responsibility for the manufacture of the product, including releasing the product for supply.

Term	Definition
Prion disease, risk of	<p>Having been exposed to the putative causative agent(s) of any one of the family of pathogenic transmissible spongiform encephalopathies through one of the following:</p> <p>genetic (familial) causes</p> <p>environmental factors, which includes donors who have lived in, or visited, England, Scotland, Wales, Northern Ireland or the Isle of Man for a cumulative period of six months or more, between 1 January 1980 and 31 December 1996 inclusive</p> <p>iatrogenic causes, which includes donors who have received a transfusion or injection of blood or blood components while in England, Scotland, Wales, Northern Ireland or the Isle of Man from 1 January 1980 onwards.</p>
Procedure pack	Has the same meaning as in the Act.
Processing	Means any activity involved in the preparation, manipulation, preservation for storage and packaging of a biological.
Procurement	<i>See</i> Collection
Quarantine	The isolation, physically or by other effective means, of starting or packaging materials, intermediate, bulk or finished products while awaiting a decision on their release or refusal.
Register	Has the same meaning as in the Act
Regulations	The Therapeutic Goods Regulations 1990.
Reproductive tissue	Tissue concerned with or relating to reproduction.
Retrieval	<i>See</i> Collection
Skin	The outer integument, or covering, of the body — consisting of the dermis and the epidermis and resting upon the subcutaneous tissues.
Specified microorganism	A microorganism that, if isolated from the tissue, requires the tissue to be discarded.

Term	Definition
Storage	Maintaining a substance, material or product under appropriate controlled conditions.
System	Has the same meaning as in the TG Act, as amended from time to time.
Tissue	Any constituent part of the body formed by cells.
Trained interviewer	A person who is trained in interviewing skills and is an employee of, or has a contractual arrangement with, a manufacturer.
Transport	The transfer within or between premises of a substance, material or product, under appropriate controlled conditions.
TSE	Transmissible spongiform encephalopathy
Virological	Pertaining to viruses.
Warning statements	<p>Any warning statements specified in the standard that applies to the goods.</p> <p>A warning statement where incorrect route or method of administration may be hazardous.</p> <p>Any warnings required by the Secretary, Department of Health and Ageing as a condition for inclusion in the ARTG in relation to the goods.</p> <p>Any warning statement specified in the Regulations that applies to the goods.</p>
Xenotransplantation	<p>Xenotransplantation refers to any procedure involving the delivery into a human patient of:</p> <p>live animal cells, tissues or organs: or</p> <p>human body fluids, cells, tissues or organs that have had contact with live animal cells or tissues outside the patient's body</p>

References

Resource	URL
TGA website	https://www.tga.gov.au

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	BSS	30/06/2011
V1.1	Added a definition for xenotransplantation	BSS	30/06/2017

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Reference/Publication #