CONSULTATION SUBMISSION· TGA

Draft Australian Code of Good Manufacturing Practice
Human Blood and Blood Components, Human Tissues and Human Cellular Therapies

australian biotechnologies

HUMAN TISSUE PROCESSING FACILITY, FRENCHS FOREST, NSW

CONSULTATION SUBMISSION· TGA

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1. Clause 109

A program for self inspection should be established, documented and implemented to periodically assess the effectiveness of the quality system.

Recommend:

Repeated in Clause 104, recommend deleting second to last bullet point from Clause 104.
Re-word Clause 109 to read:
"A program for self inspection should be established, documented and implemented to periodically assess the effectiveness and applicability of the quality system."

2. Clause 113

Comment:

We support the addition of periodic reviews to this Code as it has become standard throughout the Therapeutic Industry. Specifically, the requirements in the draft Code are similar to the FDA Annual Product review, ISO 13485 Product Review and TGA Pharma and OCT Product review requirements.

3. Clause 307

Donor interview facilities should enable interviews to be conducted in private.

Recommend:

Re-word Clause 307 to read:
"If applicable, Donor interview facilities should enable interviews to be conducted in private."

4. Clause 314

Storage areas should provide adequate space, suitable lighting, and be arranged and equipped to allow dry, clean and orderly placement of stored material under monitored environmental conditions (eg temperature, light and humidity.

The above clause implies that all storage areas now require temperature, light and humidity monitoring. The cost of implementation and maintenance would greatly exceed the benefit.

Recommend:

- Re-word Clause 314 to read:
  "Storage areas should provide adequate space, suitable lighting, and be arranged and equipped to allow dry, clean and orderly placement of stored material under monitored environmental conditions."

5. Clause 328

Where controlled temperature conditions (including transport, where appropriate) are required, the environment should be monitored as follows:

- There should be temperature recording devices, and records kept and reviewed;
- There should be an alarm to indicate that a temperature control system has failed. The system should permit resetting only by authorised personnel, and should be checked at regular defined intervals.

Comment:
Please confirm that the distribution of human tissue transported in an esky containing dry/wet ice or other coolant system does not require constant monitoring when the esky and quantity of ice have been validated to maintain a temperature over a fixed period of time.

6. Clause 806

For tissue collections, there should be a documented procedure for defining the medical assessment, if not able to be done on the day of donation. For a live donor, the donor selection records, including consent and medical history, signed by the donor would be witnessed and signed by an authorised person.

Comment:
Please define "Authorised Person",

7. Clause 818

Collection of cells and tissues should be performed aseptically and carried out under controlled conditions. Equipment used should be sterile. Retrieved tissue and cellular therapies should be packaged using sterile containers and in a manner which will minimise contamination.

Detailed over leaf is an excerpt from Submission regarding TGO Order XXX Standards for banked musculoskeletal tissue:

Clean Collection Environment: The definition as given states the following:
Clean Collection Environment means an area or facility, such as a mortuary or equivalent facility with the following conditions:

(a) Air-conditioning to regulate temperature, humidity and particulates required for maintenance of tissue quality; and……

Retrieving tissue banks won't be able to comply, mortuary facilities in Australia have, as their core business the practice of performing autopsies on deceased, be they Coroner's cases or routine hospital post-mortems. No mortuaries maintain records detailing daily readings of temperature, humidity and particulates.

In the recently published 12th Edition of Standards for Tissue Banking the American Association of Tissue Banks[1] states the following:

> *"All tissue shall be recovered in an aseptic* or *clean fashion using standard surgical preparation with sterile packs, instrumentation, and technique. Prior to recovery, the Recovery Site must be evaluated for suitability using pre-established criteria designed to control contamination and cross-contamination (see AATB Guidance Document N.* 2). *The Recovery Site evaluation must be documented."*

The 2nd Edition of the Council of Europe Guide to Safety and Quality Assurance for Organs, Tissue and Cells[2] states:

> *"The ideal procurement environment should be an operating room,* or *another suitably validated location, depending on specific requirements for the tissue procured.*
>
> *The following points should be considered for the tissue retrieval procedure:*
>
> *Every effort should be made to minimise contamination during procurement;*
>
> *Tissues may be removed using aseptic technique The general site of retrieval should be documented and area access should be restricted. All working surfaces used during retrieval should be disinfected."*

Recommend:

Re-word the definition to read:

"Clean collection environment means an *area* or *facility, such* as a *mortuary* or *equivalent facility with the following conditions:*

(a) control measures to limit access to qualified and operational persons;
(b) sufficient space to perform the tissue recovery and avoid cross contamination;
(c) work surfaces able to be adequately cleaned prior to commencing retrieval.

Prior to commencing the retrieval the facility must be evaluated for suitability using pre-established criteria designed to ensure the control of contamination and cross-infection. Findings must be documented.

Comment:

Please define "Controlled Conditions" with direct reference to proposed Clause 818.

8. Clause 819

Collection documentation records should include:

- The donor identity
- The date, time and place of the procedure
- The identity of the person(s) performing the procurement
- For cellular therapies; the Cells retrieved, Donor and Cell selection information;
- For Tissues; the Tissues retrieved, Donor and Tissue selection information, details of the Physical Examination of the donor prior to collection

Detailed below is an excerpt from Submission regarding TGO Order XXX Standards for minimising infectious disease transmission via therapeutic goods that are human blood and blood components, human tissues and human cellular therapies.

Physical Examination:

The definition as given includes the need for a Physical Examination of Living Donors. Given that these donors are (in the main) patients undergoing total hip arthroplasty the possibility of the examination being completed are minimal at best. Patients are assessed as suitable for surgery by the treating Orthopaedic Surgeon; acceptance into the donor program is dependant on completion of Medical/Social Questionnaire rather than a physical examination.

Recommend:

Re-word Clause 819 as follows:

Collection documentation records should include:

- *The donor identity*
- *The date, time and place of the procedure*
- *The identity of the person(s) performing the procurement*
- *For cellular therapies; the Cells retrieved, Donor and Cell selection information;*
- *For Tissues; the Tissues retrieved, Donor and Tissue selection information*
- *For tissue retrieved from deceased donors details of the Physical Examination of the donor prior to collection*

9. Clause 910

Test records should include at least the following:

- Reference to the donation;
- Details of equipment and materials used;
- References to the relevant specifications and testing procedures;
- Test results, including observations and calculations;
- Date(s) of testing;
- Identification of the person(s) who performed the testing;
- Identification of the person(s) who reviewed the results, including a check of calculations, where applicable

Comment:

Suggest a separate clause be developed for Sterility testing. For sterility testing remove equipment, the list of incubators and biological safety cabinets could be immense for one sample alone.

10. Clause 1004

The development, implementation and operation of a computer system should be carefully documented at all stages and each step proven to achieve its written objective.

Comment:

Please delete - clause superfluous due to Clause 1006 which lists the expected documentation required to support a computer system.