Draft AUSTRALIAN CODE OF GOOD MANUFACTURING PRACTICE HUMAN BLOOD AND BLOOD COMPONENTS, HUMAN TISSUES AND HUMAN CELLULAR THERAPIES

Clause 103.
XXXXXX Comment: Having to demonstrate efficacy is a concern for bone banks – the term suggests banks have conducted randomised clinical trials.

Clauses 206 & 207
XXXXXX Comment: This clause is not clear regarding whether these responsibilities (or some of the responsibilities) can be delegated.

Clause 306
XXXXXX Comment: The term 'premises' should be replaced with 'facilities'. 'Premises' is an inappropriate term and should not be used in this Code – Facility (ies) should be used throughout. Old facilities were not specifically designed for the manufacture of products and this should not be a requirement if the facility is able to meet GMP requirements. In addition, "premises" may refer to the entire building of which the Facility is a part and definitely wouldn't have been "specifically designed" for product manufacture.
Is the term "mix-ups" appropriate in a code such as this?

Clause 317
XXXXXX Comment: In this clause, is 'storage facilities' synonymous with storage equipment? If it is not and means the room or building then the last sentence should be deleted.
Suggested instead: "Storage areas/facilities should provide for suitable and effective segregation of quarantined, rejected and released material, and should be secured to ensure that quarantined or released product cannot be tampered with or removed by unauthorised persons.

Clause 318
XXXXXX Comment: The word "designed" is not appropriate. Tissue banks are not in the business of equipment design. Prefer **"suitable for its intended purpose"** as stated in the current code.

Clause 319
XXXXXX Comment: Would like to see this clause restricted to equipment **"which is critical to the control of manufacture"** as in the current code.

Clause 325
XXXXXX Comment: Would suggest rephrasing this clause eg "Defective equipment should be labelled as defective and removed from the processing area, if possible".

Clause 328
XXXXXX Comment: This clause needs be reworded to specifically exclude transport of tissue released for transplant. Requiring alarmed temperature recording devices for monitoring transport of tissue released for transplant is not helpful - by the time data is downloaded and authorised, the tissue is likely to have already been transplanted.
Hence most tissue transit is via validated systems rather than monitored/recorded/alarmed device systems.

Section 6 Subcontracting

XXXXXX Comment: The definition of a subcontractor should be very clearly defined in the glossary.

Clause 806
XXXXXX Comment: This should be reworded as follows; *For a live donor, the donor consent and medical and social history **documentation** that has been collected from the donor, should be signed by the donor and witnessed and signed by an authorised person*

Clause 807
XXXXXX Comment: This needs re-wording as follows; 'For a deceased tissue donor, there should be a statement signifying that medical records have been assessed and the donor has been found acceptable, by a nominated authorised person.'

Clauses 814 & 816
XXXXXX Comment: These clauses should be combined and should read:
"The donor identification and any critical materials used should be traceable to the donation and associated records. Donation numbers or a unique identifier to the donor should be on all product and sample containers and on donor records. This should be checked and the check recorded. Donor identification numbers should not be repeated, unless after a reasonable timeframe".

Clause 819
XXXXXX Comment: This clause should differentiate between cadaveric and living donors (eg femoral head donors) The requirement for full physical examination for live donors is neither pragmatic or relevant.
The last dot point in this clause should read: For Tissues; The tissue(s) retrieved and Donor selection information. For cadaveric donors, details of the physical examination of the donor prior to collection should also be recorded.

Clause 821
XXXXXX Comment: The word "Unintended" should be inserted into this clause (i.e. "which will prevent unintended contact"). There are some instances where contact is actually intended eg pooling milled bone.

Clauses 906, 907,909 and 910
XXXXXX Comment: These clauses require further clarification

Clause 913
XXXXXX Comment: This clause is not required in the code as it is covered in both the Infectious diseases TGO and the Tissue specific standards.

Clause 917
XXXXXX Comment: This clause only refers to autologous blood. The clause should include autologous tissue.

Clause 1000
XXXXXX Comment: The scope of this section should be clarified.

Additional comments:
The XXXXXX (XXXXXX) participated in the Australian Tissue Biotherapeutics Forum (ATBF) workshop to discuss the ATBF response to the draft code and standards. The XXXXXX supports the ATBF submission to the TGA.