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

Donor Tissue Bank of Victoria submission Feb 2010

Clause Ref.	Page Ref.	Comment	Rationale
General		Some terms may require further definition and framing as to how this can be achieved or deemed necessary e.g. 'where required' – who deems where required – the bank or the auditor? Clause 300. e.g. 'where appropriate' on clause 328 – is it appropriate to not monitor transport conditions if the method is validated? Clause 314 – will need a definition of 'dry'. e.g. 'where…is important' in clause 333 (e.g. cleaning of the room floor close, but within a critical area), e.g. suitable for intended us in 511 – who defines whether it is suitable e.g. DMSO is not defined by the manufacturer for being suitable for tissue graft processing, e.g. 'authorised person' – is this someone the tissue bank authorises or is registered in some way to perform the task (clause 806 and 809) and are different tasks authorised by different people, 'controlled condition' clause 818 – what is controlled? – does this mean particles/access control/humidity (observing that these conditions are unlikely to be controllable by the tissue bank in mortuaries and theatres)	Ambiguus terminology results in misinterpretation of the clause and the significance of the term (i.e. the degree of assurance required to meet the requirement (e.g. dry could be interpreted by the audited as 'not wet', but by an auditor as requiring a humidity below a certain level that is continually assured.
103	5	We strongly suggest reconsideration the use of the term 'efficacy' in human banked tissues	Unless clear guidance is provided in how this can be ascertained, considering the highly variable sourcing (each donor is unique), utilisation, and biological response of the recipient, it is a requirement that may deter further progress in this field.
104	5	Bullet point 8 – change 'subsequently handled' to 'Subsequent handling instructions ensure quality is maintained throughout shelf life'	The licensed tissue bank cannot 'control' how the tissues are handled in the hospitals between delivery and actual use.
318	14	Equipment does not need to be designed for tissue banking purposes, rather suit it's intended purpose	This is a very niche industry where equipment may be suitable for application for tissue banking but not designed for the purpose e.g. a scalpel handle/sagittal saws are designed for surgery, not tissue banking but are essential for practice
328	15	Recording device or alarms may be inappropriate for certain scenarios	Tissue in transit may be controlled in a validated system, and the download of data may not be possible prior to use of the tissue.
403	17	Documents should be written as instructions rather than statements should be changed to 'to provide clear and unambiguous direction'	Within a procedure there may be alternate pathways or paths that are defined by the outcome of the previous step, hence defined instructions make the procedure cumbersome

			or unusable or would have to be so vague they would not provide direction. Instructions should be a preference where appropriate.
509	20	'any defect' is too prescriptive.	There may be instances where a proportion of defect is acceptable or expected (e.g. 1 pipette tip in 5000) where notification would not be appropriate/relevant
512	20	'without doubt' should be 'within return acceptance criteria'	100% assurance can never be guaranteed. The process should be risk based.
805	23	'prior to donation' should be changed to 'prior to release' with regard to medical history.	There may be instances where such/partial information may be gathered after donation, or cannot be obtained prior to donation e.g. results of autopsy.
819	25	Physical examination should only be a requirement for deceased donors	Requirement for full physical examination for live donors is not pragmatic (not appropriate to undertake a full examination on a blood donor or by hospital staff for tissue). For living donors risk can be minimised by the interview with the donor.
829	26	Change load configuration to dose mapping.	The dose that is delivered is the key parameter, not how the box is loaded.
907	29	Remove appropriately	It is either validated or not validated
913	29	Remove 'corrective' from last sentence.	There may be contamination inherent in the nature of collecting tissues (e.g. an expected contamination rate), hence corrective action of all/any contamination is not appropriate.
916	30	The prevention of the donor from making another donation is problematic in the tissue arena. Please define 'if appropriate'.	Not feasible to preclude further donation for living donors unless there is central registries of deferred donors and these are checked prior to patients going to theatre in hospitals.
917	30	Should include autologous tissue (not just autologous blood).	Equally applicable to both