TGA consultation on draft Australian code of Good Manufacturing Practice for Human blood and blood Components, Human Tissues and Human Cellular Therapies (Dec 2009)

Section 1 QUALITY MANAGEMENT

As a general comment we find this document deficient in addressing labelling issues –this pivotal aspect of quality management receives minor attention herein.

Section 2 PERSONNEL AND TRAINING

205 The quality and production nominees should have a relevant tertiary level qualification, (eg. in medicine, science, medical laboratory science, nursing), and have had practical experience, at management level, in the manufacture of therapeutic products.

We suggest the addition of "quality" to the list of examples of relevant tertiary education. Similarly practical experience should be replaced by "in depth knowledge" as the nominees by nature of their position would find it difficult to maintain competence.

Section 3 PREMISES AND EQUIPMENT

319 There should be protocols which address installation (IQ) and operational (OQ) qualification of equipment. These protocols should be approved and include the predefined acceptance criteria and the development of procedures for operation, calibration, maintenance, and cleaning. Qualification should be recorded, reviewed and approved prior to use of the equipment.

This section fails to address equipment re-entry.

Section 8 COLLECTION AND PROCESSING

810 Where State/Federal requirements require consent for the collection, tissue or cells, the consent should be obtained. In exceptional circumstances where consent cannot be obtained at collection, the consent should be obtained before tissue or cellular therapies can be released.

May be an issue for burns patients as they are often still intubated at the time of release – these products are normally released under exception

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 tissue(s) retrieved, Donor and Tissue selection information,
Details of the physical examination of the donor prior to collection

Confidentiality of the donor should be maintained.

In the allogeneic setting should the recipient identity also be recorded.

Submitted by XXXXXX XXXXXX & XXXXXX on behalf of XXXXXX, XXXXXX XXXXXX

Date: 12/02/2010

Section 9 QUALITY CONTROL

905. Screening tests for donor suitability should be carried out by a competent laboratory. Where required by legislation the laboratory should be licensed by the regulatory authority for therapeutic products.

Does this infer that the laboratory doing the testing should be TGA licensed, as the TGA are the regulatory authority for therapeutic products? The meaning of "competent" is not defined. Currently many organisations are using NATA-accredited laboratories.

915. The manufacturer should ensure that where Tissue and Cellular Therapies does not meet the product specifications a review of the product should be undertaken. Only when a risk based approach and/or regulatory requirements have been met can such products are released.

Procedures for the management of products where all requirements have not been fulfilled should be established and maintained. Records including actions taken should be documented and maintained.

(a) We noted a typographical/grammatical error at end of the second sentence of 1st paragraph ie. "can such products <u>are</u> released". Should probably read ie. "can such products <u>be</u> released".

(b) Is this referring to the system for "exceptional release" where it is a requirement for TGA notification and/or authority to release? If so can TGA clarify how this mechanism is expected to function and what timeframe for response is expected if release is urgent due to medical need for a unique patient?

916. Products not released should be identifiable from those which conform to specification and have received their final inspection. Appropriate records should be maintained. In the event that the final product fails release, and where applicable, a check should be made to ensure that other products from the same donation and products prepared from previous donations (where applicable) given by such donors have been identified. There should be an immediate update of the donor record to ensure that the donor cannot make a further donation, if appropriate.

HPC products are usually cryopreserved post collection. Those with non conforming donors are identifiable. Products are not actually released for supply until a transplant is required, however products are cleared as suitable for release upon receipt of satisfactory testing results – there is no change in identification at this point for cryopreserved products in our current system.