ERA Comment to TGA consultation on

"Draft Australian code of good manufacturing practice human blood and blood components, human tissues and human cellular therapies"

ERA Consulting (ERA) has a number of comments on the aforementioned code as follows:

A. #314, page 14

ERA suggests the following revision, to change:

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, humidity)*** (Bold added)

to the following:

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

Reason: The current wording can be taken to imply that light and humidity are conditions that must be monitored. This may not always be possible, and if not necessary in a particular case, may become a burden and impediment to use of facilities that are otherwise suitable.

B. #828, page 26

ERA suggests the following revision, to change:

828. There should be procedures in place for all specific processing steps such as: antibiotic treatment, enzymatic digestion, the use of cell selection devices, addition of additives or growth factors.

to the following:

828. There should be documented procedures in place for all specific processing steps such as: antibiotic treatment, enzymatic digestion, the use of cell selection devices, addition of additives or growth factors.

Reason: Clarity

C. #837, Page 27

837. The VMP should be performed when there are significant changes to the manufacturing process, including any change in equipment or materials which may affect product quality and/or reproducibility of the process.

Comment: The intent behind this statement could be clarified. Consider replacing "The VMP" with "re-validation".

D. # 915, Page 30

ERA suggests the following revision, to change:

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.

to the following:

915. The manufacturer should ensure that where **a Tissue and Cellular Therapy** 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.

Reason: Clarity

E. #917, Page 30

917. Where applicable, autologous Blood or Blood Components and Cellular Therapies from donors with repeatedly reactive mandatory screening tests, intended to be reintroduced into that donor, records should be available to demonstrate the rationale for this use. Where applicable, product should be appropriately labelled. Authority for the release of this product should be documented.

Comment: ERA suggests that the word "reactive" could be qualified, as "reactive (confirmed previously positive)".