Dear Sir or Madam

This is a collective response from the staff of the XXXXXX (XXXXXX) and as such represents a submission from XXXXXX. Individual staff members are free to submit individual responses. However this submission reflects the view of all XXXXXX staff.

The Eye Banking Association of Australia and New Zealand (of which, XXXXXX is one of six members) formed a committee to respond collectively to the invitation. To this end, XXXXXX endorses the EBAANZ submission and offers, in addition the following comments:

Item 204. The nominees should be different persons, neither responsible to the other. They should have the authority to ensure that quality measures are employed in the manufacture (including testing) of product.

The clause “neither responsible to the other” is ambiguous. It needs to reworded and reworked.

Item 328. Where controlled temperature conditions (including during 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.

This would be impossible to implement. XXXXXX send shipments all over Australia, up to 15 per week. XXXXXX asks that packaging be returned to XXXXXX but there is only 70% compliance. Inclusion of temperature recording devices in every package would be prohibitive. A more practical alternative is that temperature monitoring of packing and transport conditions under adverse conditions be validated by manufacturers.

SECTION 10 COMPUTERS
PRINCIPLE
1000.
The introduction of computerised systems does not alter the need to observe the relevant principles given elsewhere in the Code. Where a computerised system is implemented, there should be no adverse affect on product quality and safety, or security and integrity of data.

GENERAL
1001.
Where a computer is used in connection with a step in the manufacture of the product, this should meet the same quality systems requirements for those manual functions which it replaces.

Items 1002-1017 must be observed only if a computer system replaces a manual function as described in section 1001. As such items 1002-1017 must refer to Item 1001. Additionally, when a computer system replaces a manual system, this should be defined as a critical step in manufacture.

eg Item 1012
1012. Critical data entered manually into a computer system should be checked for accuracy by a second person. The persons carrying out the data entry and verification should be identifiable.

Emphasis is on "Critical": as defined by author above. This item amongst others in the 1002-1017 is redundant when there is a corresponding manual record.

General Comment

While the following comment will feature in the EBAANZ Submission, this manufacturer would like to emphasise one point in particular: Work done by the TGA BT-TERG group was working towards separate cGMP documents for the blood sectors as distinct from the "tissues sector" XXXXXX are disappointed that there has been a reversal of that position to produce a single document. XXXXXX strongly advises that there must be a separate code for each sector to reflect the differences in activities of the two Sectors.

Thank you for inviting the XXXXXX to make a submission on this draft document.