**TGA DRAFT AUSTRALIAN cGMP**
**HUMAN BLOOD AND BLOOD COMPONENTS, HUMAN TISSUES AND HUMAN CELLULAR THERAPIES**
**New Zealand Blood Service comments – February 2010**

| Clause | Comment |
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| 102. The organisations quality policy should be defined and management should take measures to ensure that the quality policy is understood, implemented and maintained at all levels of the organisation. | Add apostrophe to second word, i.e. “organisation’s” |
| 206. The Production nominee generally has the following responsibilities:<br>• to ensure that products are produced and stored according to the appropriate documentation in order to obtain the required quality;<br>• to approve the procedures relating to production operations and to ensure their strict implementation;<br>• to ensure that facilities and equipment are maintained;<br>• to ensure that the appropriate validations are done;<br>• to ensure that the required initial and continuing training of production personnel is carried out. | This clause needs to allow for delegation. In a large Blood Service the Production nominee does not normally hold direct responsibility for all of these activities. They are delegated to other appropriate positions within the organisation. |
| 207. The Quality nominee generally has the following responsibilities:<br>• to approve or reject, as appropriate, materials and therapeutic products;<br>• to evaluate process records;<br>• to ensure that all necessary testing is carried out;<br>• to approve specifications, sampling instructions, test methods and other quality procedures;<br>• to approve and monitor any subcontractors and suppliers;<br>• to ensure the maintenance of the quality department premises and equipment;<br>• to ensure that the appropriate validations are done;<br>• to ensure that the required initial and continuing training of the quality personnel is carried out. | This clause needs to allow for delegation. In a large Blood Service the Quality nominee does not normally hold direct responsibility for all of these activities. They are delegated to other appropriate positions within the organisation. |

| **Clause** | **Comment** |
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| 209. Beside the basic training on the theory and practice of Good Manufacturing Practice, newly recruited personnel should receive training appropriate to the duties assigned to them. Continuing training should also be given, and its practical effectiveness should be periodically assessed. Training programmes should be available, approved by either the head of Production or the head of Quality Control, as appropriate. Training records should be kept. | Clause should allow for delegation of approval of training programmes to other suitably qualified individuals within the relevant functional area. It would be unusual in a large Blood Service for one or two senior individuals to have the required detailed knowledge to approve the training programmes for all the functional areas in the organisation.<br><br>The term "head of Quality Control" should not be used in this context as it normally refers to the head of the laboratory conducting quality control testing on product. This individual would not be qualified to approve training programmes for the rest of the organisation. |
| 213. Personnel should not be permitted to sign or initial a document unless they have been trained and assessed as competent in the work practices associated with the signature, and in the significance of the signature. | This clause should clarify that personnel under training may sign documents provided that they are countersigned by a competent person. |
| 415. Records should be completed at the time each action is taken and in such a way that all significant activities concerning the manufacture and disposition of products are traceable. | See also clause 824.<br>Add the words "where practicable" into this clause.<br>There are certain critical processing steps in the manufacture of blood where it is not practicable to record the person who performed the step or the equipment that was used without laborious handwritten, error-prone records. Filtering of blood is a manual process step that is an example of this. There is no automated piece of equipment involved that could be used to capture data and keeping handwritten records would be tedious and fraught with error for little added value. |

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| 703. The national therapeutic goods regulatory authority should be informed promptly if products are intended to be recalled because they are, or are suspected of being defective.<br><br>704. The recall of a product should be followed immediately by an investigation of the reasons for the recall. The record of the recall should include all action taken from initial advice to final close-out. | Is there still a requirement to follow the requirements of the Uniform Recall Procedure for Therapeutic Goods (URPTG)? If so, this should be stated.<br><br>These clauses appear to reflect the main requirements of the URPTG. Like the URPTG, it does not acknowledge that there are a number of different types of recalls in the blood sector and compliance with the URPTG requirements is not possible with all of them.<br><br>NZBS understands that the TGA has allowed the Blood Service in Australia to deviate from the URPTG requirements for certain recalls related to post donation information and positive microbial cultures. NZBS would like to see this formalised in more detail in the cGMP. |
| 812. For Blood donations, the procedures should include requirements that donor selection interview and donor assessment should take place immediately before each donation and donor identification be confirmed before venepuncture. | Donor selection interview and donor assessment are the same thing. Delete one. |
| 819. Collection documentation records should include:<br>• The donor identity<br>• The date, time and place of the procedure<br>• The identity of the person(s) performing the procurement<br>• For Cellular Therapies; the Cells retrieved, Donor and cell selection information<br>• For Tissues; The tissue(s) retrieved, Donor and Tissue selection information, Details of the physical examination of the donor prior to collection<br><br>Confidentiality of the donor should be maintained. | Last bullet point: Physical examination should only apply to deceased donors. Living donors are interviewed but not physically assessed. |

| **Clause** | **Comment** |
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| 824. Records of processing should provide traceability and, as applicable, include:<br>• the date, time, venue, unique identifying donation number(s),<br>• the identity of the person(s) performing and authorising critical steps;<br>• the in-process quality control tests performed;<br>• the equipment used;<br>• all products prepared from each donation. | See clause 415.<br>Add the words "where practicable" to the 2nd and 3rd bullets.<br>There are certain critical processing steps in the manufacture of blood where it is not practicable to record the person who performed the step or the equipment that was used without laborious handwritten, error-prone records. Filtering of blood is a manual process step that is an example of this. There is no automated piece of equipment involved that could be used to capture data and keeping handwritten records would be tedious and fraught with error for little added value. |
| 830. Materials handling procedures should prevent mix-up between irradiated and non-irradiated materials. Radiation-sensitive colour indicators should also be used to differentiate between products which have been subjected to irradiation and those which have not. | Delete the word "colour". "Indicators" is sufficient. |
| 832. Cryopreservation records should be maintained including time and temperature. | The wording of this clause is too vague. What time and temperature are being referred to? |
| 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. | Replace "The VMP" with "Revalidation". |
| 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. | Replace "does" with "do". |