Clinical Process Instruction Manual

Tissue Labelling and Re-labelling – General Process Instruction

Policy:

Labels shall be designed and qualified to be legible, indelible, and affixed firmly to the container under all anticipated storage conditions for the shelf life of the tissue. Tissue labels and associated labelling materials shall not be removed, altered, or obscured except to correct labelling errors.

All labelling claims shall be clear, accurate, substantiated, and not misleading.

Process:

General

1. This document describes the practices put into place to ensure that correct labels, labelling, and packaging material are used for tissue. Each labelling phase for all tissue and associated samples for testing (e.g., quarantine) shall be documented.

2. Labels shall meet appropriate written specifications and be approved by quality assurance staff prior to release for use by a designated person. Labels not meeting such specifications shall be discarded. Date of receipt, date of inspection, and the names of the staff involved in receipt and inspection shall be documented.

3. The storage area for labels and labelling materials shall be clearly identified. Access should be restricted to authorized personnel only.

4. To minimize the risk of error, tissue labelling will be done on a clear surface and any packaging and labelling materials from previous donors must be removed/discarded.

5. As each type of label is removed from inventory, one label shall be retained for the archives and the surplus labels shall be discarded. The master label list and the Clinical Process Instruction (CPI) Manual shall be updated accordingly.

6. Prior to labelling a tissue package, the container shall be inspected for evidence of impurities, defects, broken seals, or contamination that could compromise the quality, integrity, or safety of the tissue. A sufficient area of the container shall remain uncovered to permit inspection of the contents whenever possible. Any tissue or container suspected to be of questionable quality shall be quarantined immediately pending further investigation and resolution following established procedures in the CPI Manual. This review shall be documented.

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Re-labelling

8. Re-labelling may occur if an error has been discovered and only when it is 100% certain the tissue may be relabeled correctly. In this event, authorization shall be obtained from the Manager, Tissue Program – Recovery, Clinical Specialist or other pre-approved designate.

9. If the tissue cannot be verified with 100% certainty, the tissue shall be discarded.

10. The incident causing the re-labelling shall be reported and documented on the donor chart. Documentation shall include the reasons for, and events surrounding, the re-labelling.

Records:

- *No records*

References:

- *Standards for Tissue Banking, American Association of Tissue Banks, United States, 14th edition, 2017. G1.300, G3.110, G1.400, G2.100, G2.200, G2.310, G2.320, G2.340, G3.000, G3.100*