Clinical Process Instruction Manual

Quality Control Records Maintenance Process Instruction

Policy:

The Tissue Program management team is responsible for the designation and management of quality control functions. The Quality Specialist-Tissue is responsible for the review of records related to quality control functions including the following items:

- environmental monitoring of the dedicated recovery suite;
- maintenance of records and logs of periodic equipment and facility inspections;
- equipment monitoring records for maintenance within specified tolerance limits, and reviewing records of other equipment utilized in tissue recovery that have specified tolerance limits;
- acceptability determinations of supplies and reagents;
- process validation studies; and
- equipment qualification studies

This document describes the processes for review and handling of records related to quality control functions.

Process:

General

1. Performance of the quality system sub-processes is systematically monitored and measured through the audit program, the lessons learned process, the complaint handling process, and collected quality control records. This is to ensure effectiveness and identify opportunities for improvement.

2. Ontario Health - Trillium Gift of Life Network (OH-TGLN) establishes and maintains records to provide evidence of conformity to requirements.

3. It is the responsibility of the Quality Specialist-Tissue to ensure quality control processes are carried out, documented, reviewed and/or approved and reported at required intervals.

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Quality System Records

4. Key process equipment is regularly maintained in accordance with maintenance plans specified by equipment manufacturers or departmental managers responsible for the equipment.

5. Purchased products and reusable products requiring sterilization services are verified against specified requirements prior to use.

6. Process equipment is selected for ability to consistently produce products and provide services that meet specified requirements. Selection and evaluation of process equipment are addressed in *Clinical Supplier Selection and Evaluation, QSP-6-1.*

Validation and Inspection

7. Inspection of recovered tissue shall be carried out in accordance with the specifications within the Clinical Process Instructions.

8. Inspection results for recovered tissue shall be recorded in the applicable donor record, which includes documentation of non-conforming work.

9. Inspection records for equipment, facilities, and supplies are documented in respective individual equipment, facilities and supply, inventory or other applicable quality control files.

10. All processes which cannot be subsequently measured or monitored shall be validated by the Quality Specialist - Tissue. The validation shall be conducted using the most relevant and current Clinical Process Instructions and which are in compliance with *American Association of Tissue Banks (AATB) Current Standards for Tissue Banking* and other applicable guidelines approved by the Director, Quality Assurance and Performance Improvement.

Control of Measurement Devices

11. It is the responsibility of the Quality Specialist-Tissue to identify the measurements and tests to be carried out with the accuracy required and the equipment to be used; ensure that all measuring, test and inspection equipment is identified, maintained, controlled and checked/calibrated at defined intervals and; maintain adequate records of the control of measurement devices.

12. General requirements for control of measurement devices includes:

    12.1. Measuring and testing equipment used throughout the Tissue Program will be identified and logged. No personal equipment is permitted.

    12.2. Reference only equipment will be subject to regular inspection by the user and changed

when deterioration is apparent.

12.3. All other measuring and testing equipment will have a calibration record noting acceptance criteria, identification marking, location, checking frequency, calibration dates and results.

12.4. The method of calibration will be identified (e.g. by a calibration laboratory or in house against calibrated standards).

12.5. Equipment failing to meet the required standard must be identified for repair or discarded and the record amended.

12.6. New equipment will be checked or calibrated before issue and the calibration record prepared, where necessary.

12.7. After completion of the calibration, the details will be amended on the equipment record.

12.8. All measuring and testing equipment will be stored in conditions to ensure accuracy and fitness for use.

12.9. Measuring and testing equipment are calibrated against measurement standards traceable to international or national measurement standards where available and applicable.

Verification of Purchased Product

13. All purchased products are subjected to a visual inspection by trained receiving personnel. Some designated products are also subjected to a more detailed and technical quality control inspection. Processes for performing these inspections are defined in *Tissue Recovery Supplies Inventory,* CPI-9-517 and *Tissue Critical Supply Inspection and Storage,* CPI-9-522. .

14. Results of inspections and tests are recorded. Instructions for establishing records for specific types of inspections are defined in the user manuals for each piece of equipment. Filing and maintenance of inspection records are regulated by procedures.

Records:

- *No records*

References:

- *Standards for Tissue Banking, American Association of Tissue Banks, United States, 14th edition, 2017. K1.100.*