ACCEGEN
BIOTECHNOLOGY

Cell Products Storage SOP

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AcceGen offers a large product portfolio covering tissue samples, tissue arrays, cells, as well as other biological materials. For our business practices, we strictly comply with the following policies:

Storage must be arranged for the following categories of materials.

- Packaging materials (including label stock)
- Raw materials
- Intermediates
- Retained samples
- Finished product

Sufficient capacity should be allowed and in the case of cell-based therapeutics (CBTs) it is prudent to provide back-up capacity in case of equipment failure for materials that require low temperature storage. Depending on the value and status of the inventory it is good practice to establish an alarm system with warning levels within the range of critical temperatures. A call-out Rota of qualified members of staff is an essential part of this provision. CBT manufacture generally requires a perishable raw materials inventory and low temperature finished goods store and so it is important to provide a back-up power supply, preferably with an uninterruptible power supply to bridge the momentary pause between power failure and start of back-up generator to ensure continuity of digital monitoring and control. Storage areas should be subject to regular performance review and inspection, including assessment of potential ingress of weather or pests.

The status of the goods in inventory should be clearly signed e.g. products in quarantine, released goods, rejected goods and returned or recalled product. Defective goods must be stored away from those that may qualify for use. Goods in quarantine, e.g. goods inwards awaiting clearance for use or product awaiting instruction to release, should be protected from unauthorized access by measures such as locking cabinets or cages.

Records must be kept of the performance of environmental controls for the storage areas of sensitive stock, typically this comprises temperature and humidity controls. Repeated exposure of cells to ambient temperature, even without thawing, can affect cell health over time. An organization will do well to

arrange liquid nitrogen storage vessels in such a way that straws of cells are withdrawn in the order that they are expected to be used. This avoids repeated withdrawal and replacement of unused cells.

- Development of standard protocols which are applied consistently;
- Maintenance of biospecimens in a stabilized state as much as possible. Try to avoid frequent freeze/thaw cycles which can damage sensitive biomaterials and limit their viability and longevity;
- Frequent validation of storage equipment such as low-temperature freezers;
- Availability of back-up equipment and knowledge of emergency processes when equipment malfunctions do occur.

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