FURTHER EVALUATION OF A NOVEL COP CONTAINER SYSTEM FOR THE CRYOPRESERVATION OF ADHERENT AND SUSPENSION HUMAN CELL TYPES

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The commercialization of cell and gene-based therapies is driving a critical need for the refinement of handling, storage and transportation procedures to ensure the integrity of the product is maintained throughout its life cycle.

One such area for refinement is in the preservation of cells that is routinely performed at cryogenic temperatures. Cells are typically stored in the vapor phase of Liquid Nitrogen (LN) at approx. -180^{o}C to eliminate the risk of any degradation. For cryogenic storage, there are various container systems that are available for research and commercial use. These include traditional polypropylene (PP) screw-cap cryovials, and container systems with glass or polymer vials that are closed with a rubber stopper and aluminum seal.

Glass/rubber vial systems, although common elsewhere in the pharmaceutical industry for drug containment, are not well suited to the challenges of cryopreservation. Even beyond risk of fracture, the differences in coefficients of thermal expansion of glass and rubber can put these systems at risk of losing container closure integrity (CCI) when stored at cryogenic temperatures. Containment systems that rely on screw-caps are also at risk, as the screw thread can create a pathway that can lead to an ingress of contaminants. In contrast, a polymer/rubber vial system, comprised of materials with more comparable coefficients of thermal expansion, closed with an aluminum seal would be a better suited alternative that could better ensure that CCI is maintained throughout a product life cycle.

This research presented here is a scientific evaluation of a novel cyclic olefin polymer (COP) container system. The performance at cryogenic temperatures has been demonstrated in two separate studies. An investigation conducted without cells but measuring CCI via Oxygen Headspace of vials stored at -180°C over a 90-day period has been combined with a follow up study that compared performance between COP and PP-based container systems when cryopreserving two different cell types: adherent type human mesenchymal stem cells (MSCs) and suspension type umbilical cord hematopoietic (CD34+) stem cells.

The results showed that the polymer/rubber-based container closure system maintains CCI at -180°C, and that the cells were preserved well, as demonstrated by their viability, morphology and biomarker expression post-thaw. These findings, when combined with previously reported advantages of the novel COP container system [1], show that it is a highly suitable alternative to traditional packaging systems for cryopreservation in the field of cell and gene-based therapies.

[1] E.J. Woods, A. Bagchi, R. Nase and V. Vilivalam, Container System for Enabling Commercial Production of Cryopreserved Cell Therapy Products, Regenerative Medicine, 5(4) (2010), 659-667