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Biopreservation considerations for GMP cell and tissue bioprocessing, clinical development, and delivery

Cellular therapies, regenerative medicine, and biobanking utilize cell and tissue products sourced from blood, bone marrow, and various tissues. The clinical and commercial utility of these products is potentially impacted by stability limitations, which include transport of the source material and biopreservation of the final cell or tissue product (either frozen or non-frozen). Often in cell and tissue processing, there may exist a gap between biopreservation method optimization from a cryobiology perspective and the process development that results in the cryopreserved or non-frozen cell/tissue product. Traditional home-brew reagent cocktails (including serum) utilized for biopreservation are a point of risk within a GMP clinical manufacturing process and may be suboptimal options in comparison to pre-formulated GMP intracellular-like formulations. This discussion will offer best practices recommendations for integrating biopreservation methods within Good Manufacturing Practices (GMP), share lessons learned from cell therapy manufacturing and biobanking, and offer suggestions for integration of biopreservation methods within biobanking and regenerative medicine with consideration to the quality and regulatory footprint. Topics include best practices in optimizing biopreservation workflow, including transportation and storage of source material and final dose, post-preservation assessment variability, and evaluation, selection, and validation of ancillary and excipient reagents.

Biography

Aby J Mathew was part of the founding team of BioLife Solutions, Inc., and is a co-developer of BioLife's biopreservation media solutions. He has been researching low-temperature biopreservation since 1994, and his studies contributed to the development of BioLife's current commercial HypoThermosol® and CryoStor® product platforms and intellectual property foundation. He was BioLife's first Director of Manufacturing, established BioLife's initial quality system, and is currently Senior Vice President & Chief Technology Officer. He is a member of AABB, BEST Collaborative, ISCT, ARM, TERMIS, and the Society for Cryobiology. He is a member of the Board of Directors and the Advisory Panel of the Parent's Guide to Cord Blood Foundation, the Scientific Advisory Board of HemaCare Corporation, the founding Board of Directors of the Cord Blood Association, the NIST-AMTech National Cell Manufacturing Consortium, and the California Institute for Regenerative Medicine (CIRM) Clinical Advisory Panel.

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