Quality approaches to allow multi-site equivalence in pluripotent stem cell based product manufacturing

[Abstract]

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Designing manufacturing processes to consistently produce process sensitive pluripotent stem cells (PSC) and cells derived from PSC of sufficient quantity and quality for clinical application is challenging and complex. The manual production of cell therapies in flask based processes is controlled primarily through adherence to SOPs which can allow variations in process by individual operators. This can lead to clinical production processes with little direct control of critical quality attributes, significant reliance on endpoint quality testing and subsequent high wastage costs, and overly large banking requirements. Demonstrating equivalence when manufacturing across multiple sites is required to ensure comparability and is considered “difficult for cell-based medicinal products”.

Researchers from the UK RMP PSC Platform (Cambridge, Sheffield and Loughborough Universities and NIBSC) are working with product and process developers including Lund University, I-Stem and Fraunhofer-IBMT to conduct scaled up experiments to:

a. Understand the stability and variation of pluripotent stem cell cultures where different PSC lines are expanded and differentiated over multiple passages starting from independent vials.

b. Demonstrate product equivalence when performing end-to-end production of a therapeutic from PSC where the production is done at the developer site, a second biological variation demonstrator site and the manufacturing protocol optimisation site.

c. Automated expansion of PSC at three international sites emulating manufacture of cell therapies for global markets using the National Institute of Health “standard ruler cell line”.

The paper will report initial results of the application of a novel quality framework to permit manufacturing at multiple sites.