T-Cell Therapy Development Studies Rely on HemaCare Leukopaks to Facilitate Donor Sourcing

Introduction

The development of cell and gene based therapies in the United Kingdom is currently getting a well-deserved boost. The U.K. government has invested heavily in the sector, to the extent of funding an impressive new research facility for a non-profit cell therapy organization, which hosts clients from both the U.K. and other European nations who are developing novel cell and gene based therapies. Clients are provided with the infrastructure to enable promising new therapies to be translated more smoothly and rapidly into commercially viable treatments. Because the European based cell therapy company sponsors many different clients in both the academic and pharmaceutical fields, they are keen to keep abreast of the latest innovations and technologies, in particular those having to do with process development and manufacturing.

In the U.K., there are still many logistical challenges involved in obtaining precursor material for T-cell therapy studies. Image credit: Pixabay.com

One particular investigator has been working with the cell therapy company for several years as a Lead Technical Scientist. As part of this role, he's been responsible for research relating to the development of T-cell based therapies; therapies that have gained notoriety of late due to their very promising success against certain types of cancer. The lead scientist explains that the downstream success of such therapies starts with obtaining high quality precursor material, in the form of leukophoresis products from human donors. Getting high quality leukopaks can be a challenge, however, especially in the U.K., where compensated donations for human blood-related products aren't permitted.

"Human apheresis products are not readily available here [in the United Kingdom]; there are one or two people who are expanding their apheresis labs, but this process takes time. The main issue is that you can't compensate donors, as you can in the U.S., so availability is seriously limited." - Lead Technical Scientist, European-based cell therapy company

In light of the fact that the cell therapy industry is now positioned to offer many new medical breakthroughs, there are signs that such regulations could be relaxed in the future. For now, however, human leukopaks are largely unobtainable in the U.K., and scientists must work around these regulations by ordering from the United States, where compensation for donors has already been approved.

Sourcing Precursor Material for Cellular Therapies

The logistics of shipping a live cellular product from Los Angeles in the U.S., all the way to London in the U.K., are complicated. Products must be shipped without losing the functionality that makes these immune cells so valuable in the first place. It generally takes 48 hours or more for human blood products not only to be shipped well over 5,000 miles, but also to clear customs in London-no mean feat. And as with many things, the process isn't always perfect. Flights can be delayed, shipments can be bumped to a later flight, or customs officials may not realize the urgency of putting the necessary paperwork through for a live product. Occasionally, individual leukopaks are delayed in transit such that they are no longer usable when they arrive. But these occasions, while frustrating, are fairly infrequent.

"HemaCare does everything they can from their end of things to make sure the transition goes smoothly. In general, they do excellent work in supporting us, and making sure shipments get on the right plane and get sent out on time." - Lead Technical Scientist, European-based cell therapy company

Sourcing apheresis material, like the leukopaks the cell therapy company receives from HemaCare, involves more than just shipping. Each order needs to closely match the patients who will ultimately benefit from the therapeutic in development or commercial production, so donor requirements are an important part of the process. Many of the

diseases for which the European-based company's clients are trying to find a cure disproportionately affect the elderly population. Therefore, leukopaks are regularly ordered from healthy donors over the age of 50, in order to get better insight into what goes wrong when disease does strike. HemaCare's long history of rapport with their donors, and its large donor database, allow them to offer specific options like this, that just aren't available in the U.K.

The U.K. government-sponsored company has also made good use of HemaCare's donor network by requesting "recall" donors, or even excluding specific donors when necessary to get either wider donor representation, or a better matched profile. Although there are some alternate leukopak providers in the United States with similar products, the company's lead technical scientist expresses his trust in HemaCare:

"We preferentially choose HemaCare because we have a good relationship with them. They have good pricing, a high-quality product, and customer service is excellent."

Cryopreservation Offers a Potential Solution

One prospect that could really help mitigate leukopak availability in the near future would be to utilize cryopreserved products. Assuming cryopreserved leukopaks retain high viability and functionality [1], the potential impact on cell therapy logistics is huge. Quality control tests run on apheresis material both before and after shipping show that there can be losses in cellular viability during transit. Though this situation is a concern, at present European-based cell therapy companies have no real alternative. Shipping the material frozen, therefore, could mitigate viability losses, and have a huge positive impact on the burgeoning industry.

Researchers at the non-profit cell therapy company have already done some investigation into optimizing cryopreservation and thawing conditions for the various T-cell therapies they are helping develop. Their studies show that freezing and thawing processes are intimately related, and that understanding optimal conditions for these methodologies is key to guaranteeing high quality clinical material. Research done on site at HemaCare shows that T-cells isolated from their cryopreserved leukopaks have viability and functionality profiles similar to that of cells isolated from fresh leukopaks (see Fig.1).

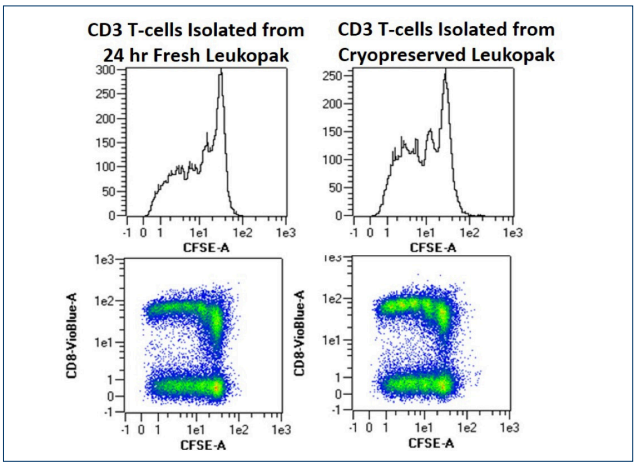

Fig. 1. CD3+ T cells isolated from both Day 1 fresh leukopaks, and post-thaw cryopreserved leukopaks showed similar high proliferative function.

The cell therapy company's lead technical scientist has already been using cryopreserved CD3+ T-cells (sourced from HemaCare) for a bio-bank he is building. However, because dealing with cryopreserved leukopaks involves extra processing at the clinical site, the situation is somewhat more complicated than for in-house materials. While he is enthusiastic about the prospect of cryopreserved leukopaks, the company's lead technical scientist realizes he would need the cooperation of his clients to ensure that the necessary studies are carried out to assess the impact of cryopreservation on the downstream functionality of a given therapeutic. Such studies will largely depend on the client's decision for what form their final product will take. Clients who intend to market a cryopreserved final product are much more likely to be interested in using cryopreserved precursor material. The company is hopeful that they will get the approval to go the cryopreserved route, since having "off-the-shelf" availability of stem or immune cell precursor material would greatly simplify the logistics of cell and gene therapy research. This presents a scalable option for emerging autologous and allogeneic cell therapies for the global research community that requires sustainable apheresis shipments from a global provider of primary human peripheral blood and hematopoietic cells.

References:

[1] Eastwood G., et al. Cryopreserved leukopaks maintain cell viability and functionality: a solution for cell therapy logistics. Journal for ImmunoTherapy of Cancer. 3(Suppl 2):P383. 2015.

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