Top 5 risks when sourcing human organs and tissue
for the manufacture of cell-based therapies and devices

The following risks should be considered when sourcing human organs and tissues for the commercial manufacture of cell-based therapies and devices.

1 Compliance with Federal and State Requirements

Is your sourcing partner compliant with applicable US federal and state requirements for the recovery and use of human biospecimens in the manufacture of cell-based commercial products? Whether your source direct or through a third party, it is critical that your commercial partner has the right experience and expertise in building donor eligibility programs in accordance with 21 CFR Part 1271 (HCT/P) as well as applicable state requirements.

2 Adequate Consent/Authorization Language

Do your sourcing partner's consent/authorization practices cover the intended commercial use? Consent/authorization forms and practices tend to vary across providers, so experience with obtaining the proper informed consent and/or authorization is essential to assuring donors and their families that the gifted organ or tissue is procured and used in an ethical manner.

3 Consistency

Access to reproducible, high-quality tissue is a key driver for success. What are the odds that obtaining tissue from multiple providers could result in inconsistencies? The impact could be detrimental as you scale production. Make sure your providers maintain quality programs and systems to ensure reproducible, high quality tissue acquisition.

Chances are that customized human biospecimen procurements are required to meet the specific needs of your research, product development and manufacturing requirements. Confirm with your provider that they offer/support the specific needs you may have. Employing a standardized, scientific-driven, human biospecimen collection program reduces sample-to-sample variability and leads to biospecimens you can trust and compare.

In addition, look for a provider who employs Quality by Design (QbD) best practices and as well as appropriate accreditations and licensure that further validate performance and expertise.

4 Ability to scale

In the early stages of product development, obtaining biospecimens for the derivation of clinical product can often be done with single sourcing provider. However, when scaling production, the ability to obtain higher volumes of biospecimens to meet your market demands should be, at the end of the day, one of the most important considerations. Does your sourcing partner possess the capacity to meet your bioprocessing needs as you scale commercially? Do they have experience supporting large-scale projects?

5 Project management

The successful management of large-scale projects requires adherence to well developed and standardized project management practices. From project conception through implementation, until closure, project scope and deliverables must be managed according to an established set of project management practices. The ability to keep stakeholders, the project team and operations informed on the project goals, timelines and posed risks is essential for project success.

Vet your sourcing partner to make sure they have the right experience and qualifications to handle large scale need for human tissue, and that they are qualified/licensed to obtain human biospecimens for commercial research and development. This will also serve your own compliance requirements.

This list is just a start. Within each risk factor noted, there are additional elements that entail additional complexities. Other variables not mentioned in this document need to be addressed to ensure the highest quality and consistency during development.

About NDRI

The National Disease Research Interchange (NDRI) is the nation's leading source of human tissues, cells and organs for scientific research. A not-for-profit 501 (c)(3) organization founded in 1980, NDRI is funded in part by the National Institutes of Health, public and private foundations and organizations, pharmaceutical and biotechnology corporations.

NDRI is a 24/7 operation that partners with a nationwide network of over 130 tissue source sites (TSS), including organ procurement organizations (OPO), tissue banks, eye banks, and hospitals. The TSS, are distributed throughout the USA, in 45 states, with concentrations in major metropolitan. Their wide geographic distribution allows NDRI to provide biospecimens from donor populations with diverse demographics and also facilitates the timely and efficient provision of fresh tissues directly to researchers across the U.S. and the world.

For more information and questions on how NDRI can service your tissue procurement needs, contact us at gkopen@ndriresource.org, 800-222-NDRI (6374), ext. 240 or visit our website at www.ndriresource.org.

NDRI
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