[Biobanking for Biologics and Cell Therapies: All Biobanks Are Not the Same](http://blog.fisherbioservices.com/biobanking-for-biologics-and-cell-therapies-all-biobanks-are-not-the-same)

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Until recently, most biorepositories were primarily used for archival sample storage. Researchers would generate large [sample collections](http://blog.fisherbioservices.com/top-considerations-when-establishing-a-biospecimen-collection-part-i) for research with a broad idea of how they would or could be used.  Although this required expert temperature monitoring while in storage at biorepositories, it did not demand a lot of transactional activity, debits and credits from the inventory, as there was no defined use for the sample.

However, in the last ten years the industry landscape has evolved. With the introduction of advanced biotherapeutics and personalized medicine, biorepositories have transformed from archival storage facilities into true biobanks where the overall workflow now includes numerous complex transactions. Many of these transactions are associated with adding value through an integrated workflow that seamlessly connects the sponsor, bio-manufacturer, clinical center, and patient into a tandem, well-coordinated process chain. Additionally, in some instances sample collections are developed with a more targeted end-use in mind, resulting in smaller inventories.

Let’s explore the expanded focus across our industry from biorepositories for traditional research (biospecimens) to biobanking for therapeutic components (biologics and cell therapies).



**Shift in Research Focus**

For traditional research biorepositories, the business model was crafted to accommodate broad spectrum studies. Researchers gathered large biospecimen collections and this high quantity allowed them the flexibility of utilizing their sample collection for a variety of research.

Researchers now weigh their options differently than in the past; do they want to allocate funding to the storage of massive legacy collections? Or do they want to focus on smaller, more targeted collections that correlate to therapeutics? While many legacy collections still exist in biobanks today, research also now focuses on more targeted collections.

**Biobanking for Biologics and Cell Therapies**

The development, administration, and storage of a cellular therapy or biologic involves many moving parts. This is not due to regulatory demands being intensified, but rather as we have gained more experience, we have discovered additional challenges that must be overcome to ensure success. Autologous cell-based therapies use a patient's own cells for the manufacture of a treatment that is then administered only to that patient. While the sample size for this process is very small (only one patient) the process is very complex.  Allogeneic cell-based therapies are derived from an unrelated donor or donors and administered to the relevant population of patients. Allogeneic cell-based therapies are similar to biologics in the sense that if they are commercialized they can be manufactured on a large scale and administered to a larger sample size. Since these are biologically derived substances that are administered to the patient from an external environment there are many variables that can impact the safety and integrity of the biologics. Therefore, they require greater care in the custody of a biobank.

Due to the complexity associated with the administration of biologics and cell therapies to the patient, they experience many transactions in the chain of custody. This high volume of transactions increases the need for standardized processes to ensure the therapy remains efficacious. Based on the number of steps in the supply chain, it’s increasingly important to have safeguards in place that minimize risk and ensure the material is at the correct temperature and hasn’t experienced any excursions.

**Minimizing Risk**

While temperature maintenance remains a critical aspect of sample integrity, researchers are now looking beyond temperature and focusing on the impact of long-term storage on sample integrity. In addition, there is increased attention to the data associated with the sample’s molecular viability, well beyond just the temperature data. These include freeze-thaw cycles, time out of temperature, sample handling and manipulation, and [time in transit](http://blog.fisherbioservices.com/transporting-critical-bio-material-how-do-you-safely-move-an-irreplaceable-biospecimen-collection)—all have become integral data points associated with measuring sample integrity.

One way to [minimize risk](http://blog.fisherbioservices.com/video-understanding-risk-how-to-manage-high-value-biologics-part-1) is to proactively improve operations through [internal process improvement initiatives](http://blog.fisherbioservices.com/introducing-insideaccess-an-insiders-look-at-making-the-most-of-near-misses). It’s also important to involve resources such as quality assurance, process managers, software compliance, and validations. Improvements in process and increased transparency among key organizational roles will enable a smooth transition throughout the chain of custody.

The evolution of biorepositories to biobanks has helped identify some of the necessary data points that should be analyzed when measuring sample integrity. By adhering to SOPs for biologics and cell therapies, you not only put in place procedures that ensure excellent management of biological material, but these SOPs trickle down and apply to biospecimen management as well. Whether managing high value material or a high volume of biospecimens, sample integrity is at the core of our industry. However, it is the valuable partnerships and proprietary biobanking processes, workflow, and risk mitigation tactics that truly set some biobanks’ expertise above the rest.