ARTICLE

To build or buy? Examining the pros of building vs. buying a biorepository facility

A biorepository, also known as a biobank or biostorage facility, is a specialized facility that collects, stores, and manages biological samples or specimens, such as tissues, blood, DNA, RNA, cells, and other biological materials, for research and clinical purposes. Biorepositories play a crucial role in advancing scientific knowledge and medical research, but biopharma companies are often faced with the question of whether it's best to build an in-house biorepository facility from scratch or work with an outsourced CDMO partner who can provide immediate access to a range of ready-made biorepository solutions.

Among the advantages, working with an established biorepository partner like a CDMO provides access to state-of-the-art facilities and specialized expertise at a lower cost than building a biorepository in-house.

Additionally, it offers industry expertise from seasoned professionals who can ensure samples are handled and stored correctly — whether at a single location or multiple sites to help facilitate research needs in different locations. Some of the challenges associated with outsourcing are the loss of control and customization over the biorepository's operations and the lack of immediate access to samples.

This article examines the pros of building a biorepository in-house compared to the pros of buying a biorepository through an outsourced partner and outlines the advantages and disadvantages biopharma companies are likely to experience with either option. It's important to remember there's no one-size-fits-all approach, and that every research project has its own unique goals to consider.

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Pros of building a biorepository in-house

- **Control:** Building a biorepository from the ground up grants a biopharma company full control over biosample collection, handling, and storage. This control extends to proprietary information, problem-solving capabilities, organizational costs, and compliance with federal, state, and local regulations. It's crucial to note that biorepositories must adhere to various regulatory guidelines from different levels of government. While outsourcing biorepository needs can allow biopharma companies to focus more on their core competencies while benefiting from the expertise and specialized infrastructure of their chosen partner, it can also be difficult to hand over control of precious samples.
- **Accessibility:** An on-site biorepository ensures both quick and easy access to biosamples and their constant availability, thus eliminating the need for time-consuming and expensive sample transportation. When outsourcing biorepository needs, the logistics of accessing off-site samples may be more complicated and somewhat time-consuming. Transporting to and from a facility can result in longer turnaround times for sample access and retrieval, which has the potential to impact research timelines and project efficiencies.
- **Customization:** Biorepositories can be tailored to meet precise research requirements. Therefore, biopharma companies must consider factors such as mechanical freezers, liquid nitrogen storage, laboratory information management systems (LIMS), duration of storage, and even temperature-controlled sample processing laboratories. While outsourced biorepositories offer immediate solutions, they may not provide the optimal environment for long-term success and growth.
- **Adaptability:** When biopharma companies run their own biorepository, they can adjust collection, handling, and storage conditions as their needs evolve.

Pros of buying a biorepository by outsourcing

- **Time:** Establishing a biorepository takes time. Renovation of warehouse space, depending on the size of the facility, can take six to 18 months for design and approval, permits, construction, equipment, validations, and start-up activities. Construction from the ground up requires an additional nine to 18 months. The delays associated with building a biorepository may impact research or clinical trial objectives. Finding the right biorepository to outsource ultra-cold storage needs is significantly less time-consuming than building, and then running, a biorepository from scratch.
- **Expense:** Biorepositories provide more than "just" storage. The full scope of what they require for operation, including support systems and personnel, should be factored into the cost/value equation. For instance, a reasonable budget for basic construction is $200 to $250 per sq. ft., but additional costs include electrical switchgear which can be hundreds of thousands of dollars (backup generators cost an estimated $500,000), temperature monitoring systems (approximately another $100,000), and additional costs for redundant storage units and emergency services. Further, annual operating costs can run between $18 to $34 per sq. ft.
- **Personnel:** Hiring, training, and maintaining specialized staff requires significant resource allocation. This includes the need for continuous investment in personnel development, which could divert resources from core research activities.

Additionally, if the in-house team lacks expertise or experiences turnover, it may lead to delays, errors, or compromised data integrity, jeopardizing the overall efficiency and reliability of the biorepository.

- **Locations:** Utilizing a partner with a large global network of facilities allows for efficient storage and distribution close to a specific location and can enable seamless international collaboration when working across regions.
- **Flexible capacity:** Outsourcing biorepository services offers a remarkable degree of flexibility. While managing "half a million samples" may sound daunting, a simple calculation provides context. For instance, a standard upright freezer with 32 sq. ft. of storage space can accommodate 56,700 samples in 2ml vials. Biopharma companies can tap into this adaptable capacity, tailoring their storage needs to match their requirements. Whether their sample needs are smaller or larger, outsourcing ensures that they have the flexibility to satisfy their demands effectively.
- **Short-term storage:** Outsourcing biorepository services is particularly advantageous for short-term storage requirements. If biosamples only need to be stored for a few months, it becomes evident that constructing an entire facility for such a limited duration may not be a cost-effective or practical choice. Outsourcing allows biopharma companies to efficiently manage short-term storage needs without the long-term commitment and expenses associated with building an in-house facility.
- **Risk mitigation:** Outsourcing is a reliable solution for mitigating risks associated with biorepositories. Biorepository facilities require backup generators, a fuel supply, uninterruptible power supply (UPS) to protect electronics from power surges, temperature monitoring systems, redundant HVAC capacity (mechanical freezers generate a lot of excess heat), a disaster response plan, and on-call staff to respond to alarms after hours. Experienced biorepository partners already have robust risk mitigation strategies in place to protect critical material. By outsourcing, biopharma companies can leverage these existing safeguards, reducing the complexity and uncertainty of managing risks in-house.

Ultimately, the decision to build or buy a biorepository should be based on a careful assessment of the biopharma company's current resources, research goals, budget constraints, project timelines, and risk tolerance. While building provides customization and control, it comes with higher upfront costs and time commitments. Conversely, buying a biorepository offers convenience and potential cost savings but may limit customization and control. That's why many organizations choose a hybrid approach, where they build some infrastructure but also partner with CDMOs to leverage their third-party expertise and capabilities.

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Technical considerations for clinical trial biorepositories

Effective management of biorepositories is critical for the success of clinical trials. Following are key technical considerations that ensure the integrity and reliability of stored biological materials. Adherence to these practices is essential for maintaining sample quality, supporting accurate research outcomes, and advancing patient care.

1. **Sample collection and processing:**
   - Standardized protocols for collection, labeling, and processing to minimize pre-analytical variations
   - Time and conditions of collection, processing, and transport must be carefully controlled and recorded
   - Use of appropriate anticoagulants, preservatives, and containers specific to the sample type
2. **Quality control:**
   - Regular audits to ensure that standard operating procedures (SOPs) are followed
   - Implementation of quality management systems (QMS) such as ISO 9001 or ISO 20387 for biobanking
   - Proficiency testing and external quality assessment schemes
3. **Storage conditions:**
   - Use of proper storage conditions (temperature, humidity) for different types of samples
   - Backup power systems and alarms for freezers and liquid nitrogen tanks
   - Proper labeling and inventory systems to track specimen location and history
4. **Data management:**
   - Secure and compliant data management systems to track the chain of custody and ensure the confidentiality of patient information
   - Interoperable data systems that can communicate with other databases and electronic health records (EHR)
   - Use of barcoding or RFID systems for sample tracking
5. **Consest and ethical considarations:**
   - Ensuring informed consent is obtained and that it covers the future use of samples
   - Compliance with ethical guidelines and legal requirements, such as HIPAA in the U.S., GDPR in Europe, and other national/international regulations
6. **Biosafety:**
   - Proper handling and disposal of biohazardous materials
   - Containment strategies for handling high-risk samples
   - Regular staff training on biosafety procedures
7. **Sustainability:**
   - Long-term financial planning to ensure that the biobank can operate effectively over the lifespan of the clinical trial and beyond
   - Environmental controls to monitor and minimize energy use in storage facilities
8. **Material transfer agreements (MTAs):**
   - Legal agreements that govern the transfer of samples between institutions, protecting intellectual property rights and defining the terms of use
9. **Chain of custody:**
   - Documentation that records the ‘life history’ of a sample from collection to disposal, including all handling, transport, and analysis

10. Disaster recovery plan:

- Procedures to protect samples in the event of natural disasters, equipment failure, or other unforeseen incidents
- Regularly tested backup plans and drills to ensure the recovery of operations

11. Harmonization and standardization:

- Efforts to harmonize SOPs and practices with other biorepositories to facilitate multicenter trials and collaborative research
- Participation in networks and consortia to stay updated with best practices and emerging standards

12. Technology and automation:

- Investment in automation to increase efficiency and reduce the potential for human error
- Consideration of new technologies for long-term sample viability, such as vitrification for certain tissue types

13. Staff training and competency:

- Continuous education and training programs for staff to ensure high-quality specimen handling and compliance with evolving regulations