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WHITE PAPER

Build vs. Outsource

Items You Need to Consider When Deciding to Build or Outsource Biostorage Expansion

In the Life Sciences industry, research samples, human specimens, biologic and pharmaceutical materials are often the most prized intellectual assets within an organization due to their future scientific and commercial value.

Introduction

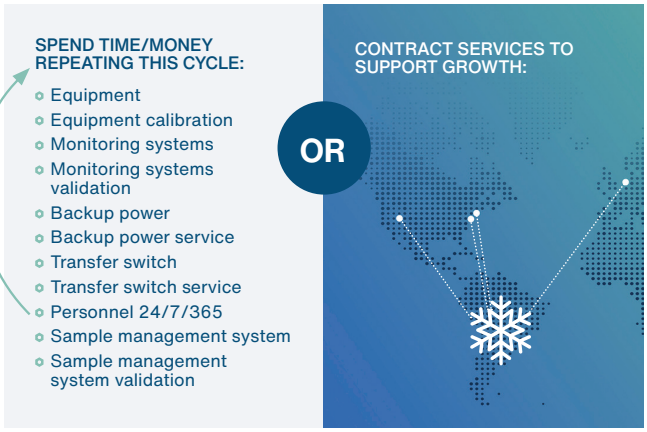
Researchers from nearly every medical discipline have begun to realize the importance of a centralized biostorage facility on campus. Some may have started investigating the technical infrastructure required to manage and categorize their work, or planned the staffing for sample monitoring, but many still face the challenge of building such a program without much guidance.

As outlined in Contract Pharma, this approach, where samples are regarded as intellectual property, requires not only a change in management methodology, but also substantial investments in:

- Building specialized, secure facilities with dedicated, scalable storage space
- Purchasing state-of-the-art equipment
- Establishing global sample management systems
- Creating a sophisticated cold chain logistics infrastructure that spans pickup and delivery, handling, processing and storage at exacting temperatures and conditions
- Hiring skilled personnel with expertise in sample storage, logistics, sample management, quality assurance, operations and clinical laboratory management
- Maintaining staff training, certifications and accreditations
- Validating equipment, technology and processes
- Developing standard operating procedures (SOPs), maintaining global compliance and business continuity plans
- Managing global logistics (import/export) associated with sample centralization

Outsourcing has always been an alternative option for facilities that lack the real estate or capital, but with the right biostorage partner, outsourcing should be considered on any new biostorage build project, regardless of size. In this white paper, we will consider the trade-offs between "outsourced" biostorage and an on-campus "build" model by breaking down the investments listed above, one-by-one.

Outsource partners allow clients to focus on core competency



Building specialized, secure facilities with dedicated, scalable storage space

In more metropolitan areas, real estate is priced at a premium. While great for investment, purchasing more space for a scalable operation on or near a research campus may be out of the question or simply unavailable.

In the past, many institutions have turned to the basement for biostorage or biorepository placement, but this comes with its drawbacks.

For example, ultra-low temperature (ULT) freezers generate heat and require a well-ventilated, air-conditioned room to maintain optimal operation. When cryogenic storage is required, a regular supply of liquid nitrogen (LN2) must be maintained. Running an LN2 supply network to the basement or delivering LN2 supply tanks to a basement can be quite challenging.

You also run into the challenge of sample access in a basement. *How does a researcher pick up a sample from the biorepository and transport it to their lab while maintaining storage temperatures?* Some use dry ice, others use portable ULT freezer models, yet suddenly onsite storage does not seem as convenient when you can work with an outsourced biostorage partner that will deliver your samples to the bench as part of your biostorage contract.

Building permits are usually required on any project that will require LN2 storage or electrical wiring for multiple ULT freezers. Depending on the local governing bodies, other permits may be required for a new building site or an extension, so it is important to understand the local permit requirements prior to breaking ground on the build, to avoid construction delays.

Facility security may be one of the easier elements to procure once a final security plan has been created. *Will a full-time security guard be necessary? Swipe access? Surveillance cameras? Freezer locks? Remote sample monitoring?* If choosing an outsource partner, all these security features are usually included.

Purchasing the latest equipment

Researching and acquiring state-of-the-art equipment is a key factor to ensure sample safety and efficacy is maintained.

However, even with the purchase of new equipment or products, the maintenance to keep that equipment operating in optimal conditions must be considered. Each device may require special hookups or maintenance regiments. They may require service plans or have variable warranty periods, and in the end, all equipment fails at some point during its lifetime and will need to be repaired or replaced.

When purchasing new equipment, please consider the environmental impact that piece of equipment may have on the campus footprint. With science and research striving to reach new sustainability levels, new equipment should be selected that helps achieve these goals, not hinder them.

For refrigerators and freezers, select models that give the most storage space in the smallest footprint. This will be critical when filling a room full of freezers while leaving space to scale. Work with a storage racking provider to customize storage racks that maximize the space within your refrigerators and freezers.

Equipment maintenance is the next item to explore. Whether hiring an internal equipment service team or partnering with a laboratory service provider, have a plan in place. As mentioned above, all equipment fails but keeping equipment running in tip-top condition may prevent sample loss at the point of the failure. *What is the plan for a power outage? Are generators and backup generators on the list of equipment for procurement?* They will also require maintenance and validation.

When working with an outsourced partner, equipment decisions no longer matter. The safety of the samples falls on the partner. They select the equipment to meet the project requirements and maintain the equipment to safeguard samples, with plans in place and staff on standby to react in the event of an equipment failure or power outage.

Establishing a global sample management system

Sample management systems can be kept simple or quickly become complicated, depending on the inputs for the project. Consider who needs access to samples, when they will need access, how to organize and categorize samples and establish the SOPs to make the sample logging clean and regimented from the very beginning.

Security may come into play here when you have multiple researchers sharing storage equipment. *Should samples be accessible 24/7? Will you need a team available to collect samples for the researchers? How will you organize samples of various sizes, materials, and types?* When working with a sample management software company, providing answers to these questions up front will really help establish the correct program.

Alternatively, sample management decisions and answers to the questions listed above, fall to the outsourced biostorage partner – if that is an option for your organization. Often, these biorepositories will give you remote sample monitoring and have systems in place to report on sample storage, request specific samples and the staff on board to complete the request. Some outsourced partners will charge for these services. Be sure to find a partner who includes this as part of their biostorage program. It should not be an additional cost on their system and the right partner will have the programs and staff available to manage these requests.

Establishing a sophisticated global cold chain logistics infrastructure and managing global logistics (import/export) associated with sample centralization

Samples must be tracked (i.e. temperature monitoring, humidity, light, etc.) and traceable (GPS location) at all times, within a GMP compliant organization.

When a research organization is first getting established, the idea of shipping samples to the ends of the earth is never really a consideration, but once the research grows and begins to scale, pre-planning for these steps could make all the difference.

Who should you partner with to execute sample movements? What tracking tools are required for your SOPs? How long will samples be in transit? Does that change what type of shipper must be used to transport the material? How much will that cost?

Outsourced storage companies should have a robust cold chain logistics infrastructure built into their storage program. Some offer refrigerated trucks or their own sample movement transport, while others charge for local, last mile movements. All outsourcing partners work with global couriers to manage the actual biomaterial movement and should include at least the shipment planning and know-how within their contracted terms.

Hiring skilled personnel with expertise in sample storage, logistics, sample management, QA, operations, and clinical laboratory management

With the help of HR, hiring the right team members is critical to the success of the operation. Skilled personnel, with experience in biostorage and a conviction for sample management best practices, will be worth their weight in gold.

Responsibilities of skilled personnel include SOP writing, freezer management and maintenance, equipment validation, sample security, data security, logistics, procurement, etc. Do not underestimate the power of hiring a qualified and dedicated team.

When partnering with an outsourced biostorage company, the overhead is included in the storage program, but the comfort of knowing your materials stored with an experienced team of sample management experts may be priceless.

Developing SOPs, maintaining global compliance and business continuity plans, maintaining staff training, certifications, and accreditations

Before discussing the maintenance of training, certifications, and accreditations, it is best to plan which certifications and accreditations are applicable for the operation, both now and in the future.

- Quality Assurance, Standard Operating Procedures and Quality Manual
  - ISO 9001 – Quality Management
  - ISO 20387 – General Requirements for Biobanking
  - Corrective and Preventative Action Plan (CAPA)
- Regulatory Compliance
  - 21 CFR Part 210 – Current Good Manufacturing Practice (cGMP) in Manufacturing, Processing, Packaging or Holding of Drugs in General
  - 21 CFR Part 211 – Current Good Manufacturing Practice (cGMP) for Finished Pharmaceuticals
  - 21 CFR Part 600 – Biological Products: General
  - 21 CFR Part 1271 – Human Cells, Tissues, and Cellular and Tissue-Based Products
- CDER – Registered to FDA's Center for Drug Evaluation and Research
- CBER – Registered to FDA's Center for Biologics Evaluation and Research
- EU GDP for APIs Registration – Good Distribution Practices for Active Pharmaceutical Ingredients
- IATA Certification – Safe Transport of Hazardous Materials by Air in accordance with the Good Distribution Regulation
- USDA Permits – United States Department of Agriculture
- CDC Permits – Centers for Disease Control and Prevention

Once selected, there will be specific steps and procedures to develop, validate, execute and audit to obtain the desired certifications and accreditations. From there, the basic Quality Assurance plan should include information on how staff will maintain training and how often. If any of the regulating bodies change procedures, specifications or requirements, internal procedures will need to be updated to comply, and new training must be completed and recorded.

Outsourced biostorage programs will offer the basic compliance (i.e., ISO 9001, GDP). Research which partners have the most accreditations and certifications, and you will realize the list of potential partners becomes much shorter. Choose one that will best meet your Quality Assurance plans, or partner with them to consult your build-out.

Validating equipment, technology, and processes

To remain compliant with the organizations' certifications and qualifications, equipment, technology and processes must be regularly validated and audited.

All equipment must be calibrated, re-calibrated and validated to confirm optimal operation. Based on your Quality Assurance plan, this could be scheduled quarterly, annually or bi-annually. There are services out there to help with equipment calibration and validation, or you can hire experienced staff to manage it for the organization. If considering an outsourced biostorage partner, be sure to question them on their equipment calibration and validation standards.

What to consider when selecting an Outsourced Biostorage Partner

If building a new biorepository or biobank is not in the plan, and expanding current storage infrastructure seems impossible, be sure to do the research required to find the right biostorage solutions partner.

Understand the service fees

Partner with a biostorage company that is determined to build a long-term relationship with your program and organization. Understand the pricing schedule, read the fine print and measure-up what services are included in the storage contract and which are not. Look for clear, predictable pricing based on sample space and inclusive of unlimited sample pulls, project setup costs, regular report publication, and any other sample management charges. This will allow you to budget correctly, without the fear of hidden fees or variable pricing.

Location

Do you want something close by? Do you need a mirror bank on the other side of the country? There are pros and cons to both models and plenty of biostorage partners available to meet those models. Do you need one biostorage partner that manages multiple sites and multiple locations to best-fit your global organization? Research the reach of different biostorage companies and select a partner that helps with cold chain logistics management.

Accreditations and certifications

As mentioned above, most biostorage companies will have GMP and meet the most common ISO standards. Look for a partner that holds the most accreditations and certifications, and be sure they have standardized all across their sites. This not only sets your organization up for scale, but ensures you stay compliant with your own Quality Assurance policy, regardless of how it might change or evolve. The partners with the longest list of accreditations and certifications have experience and that experience has been tested, validated and proven.

Added services

A biostorage partner should absolutely specialize in biostorage best practices, but also include experience and qualified services in all areas of regulatory compliance, cold chain distribution, storage protocols, equipment management, monitoring and comprehensive storage management. When a partner is selected, they must help you move your current storage to the new facility, without losing samples or equipment assets. And most importantly, these added services should be included as part of the contract. Sometimes, based on storage site proximity, these partners will even include regular, scheduled sample transport to the bench. Find a ***partner/company*** that will not nickel and dime every sample retrieval.

Proven experience and expertise

Lastly, find a partner that has established numerous cGMP biological and pharmaceutical storage facilities, and one that has experienced and planned for the unexpected. Biostorage is about planning, backup planning and building a backup plan for that. Biologic materials, samples and specimens are highly valuable assets that should be protected at all costs. Natural forces, power outages, human error — they happen and must be planned for.

About SciSafe Services, Part of BioLife Solutions

The SciSafe Services team consists of some of the leading voices in pharmaceutical and biological sample management. With over 60 years combined industry experience, SciSafe is one of the most experienced and knowledgeable teams in the field of commercial biorepositories. SciSafe has built flourishing relationships with over 300 of the world's leading and most admired organizations. Clients have repeatedly chosen to store their most valued and irreplaceable samples because they trust SciSafe to care for their samples as if they are their own.

We value and respect our long-term relationships with our clients.

SciSafe by the numbers.

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