FACTORS TO CONSIDER WHEN OUTSOURCING BIOREPOSITORY SERVICES
EXECUTIVE SUMMARY

Many pharmaceutical/biotechnology companies, government agencies and academic institutions concerned with human health are turning to partners with biorepository expertise to store and manage their specimen collections. Careful selection of a biorepository partner is critical to preserving the value of the specimens, as lack of compliance with standardized storage and handling procedures may invalidate the results of future research and, where applicable, impact regulatory filings.

The ideal biorepository outsourcing partner is meticulous about quality assurance and quality control of all aspects of the sample life cycle. Such biorepositories develop and consistently adhere to comprehensive standard operating procedures (SOPs) based on published best practices and relevant standards, as applicable for each sample type, intended use and global location.
EXECUTIVE SUMMARY (CONT’D)

Optimal storage conditions depend on the specimen type, the analyte under observation, the intended future usage of the specimen, its anticipated duration of storage and whether the business requires dynamic (undergoing active testing) or static (archived) storage. The ideal biorepository supports a range of storage conditions (e.g., temperature, humidity, light) and has the staff and equipment to perform any necessary sample processing procedures.

The variability in optimal sample handling and storage procedures, coupled with the need for strict adherence to SOPs, makes the experience and training of a biorepository's employees an important consideration for outsourcing decisions. Managerial staff should possess expertise in specimen science to ensure sample integrity and appropriately customize handling and storage processes to accommodate current and future advances in medical research techniques. An ideal biorepository partner also emphasizes the safety and security of the specimens and their associated data, its employees and its facilities.

INTRODUCTION

Scientists have been preserving biological specimens for further study for several generations, but the rapid development of molecular analysis techniques in the late 20th century caused exponential growth in the field of biospecimen science. Many pharmaceutical/biotechnology companies, government agencies and academic institutions concerned with human health have adopted biorepositories—collections of biological specimens—as a cost-effective approach to archiving samples from clinical trials for further research. As each specimen is linked to a de-identified individual for whom demographic, treatment and/or outcome information is available, use of samples from the biorepository may allow researchers to answer future questions without the time or expense of another clinical trial.1,2

At present, there are hundreds of biorepositories with large collections and thousands of additional repositories that hold specimens from a single researcher or facility. As a result, there are countless variations in specimen lifecycle management practices that can—and do—influence the outcomes of research performed using the samples.3 Standardization and quality assurance are of the utmost importance, and keeping abreast of current trends, emerging technology and regulatory requirements around the globe can be costly in terms of both personnel time and monetary resources. Increasingly, sponsors are turning to partners with biorepository expertise to store and manage their specimen collections. This approach has several benefits:

• Frees the company or agency to concentrate on its core business or mission;
• Enables compliance with regulatory requirements for sample retention without continual capital investment;
• Reduces costs associated with sample storage, handling and retrieval, particularly when outsourcing is an opportunity to centralize multiple specimen inventories from different locations;
• Avoids costs associated with continuous staffing when the workload in biorepositories is inherently variable.

Careful selection of a biorepository partner is critical to preserving the value of the specimens, as lack of compliance with standardized storage and handling procedures may invalidate the results of future research and, where applicable, impact regulatory filings. This paper reviews several key factors to consider when choosing an outsourcing partner for biorepository services.
QUALITY AND COMPLIANCE

Any collection of storage units can be called a repository. However, the value of that repository is determined by the quality of the sample storage and handling procedures practiced by the facility. Substandard or inconsistent procedures limit the long-term value of samples and call into question the accuracy of any findings based on the samples. Both the International Society for Biological and Environmental Repositories (ISBER) and the National Cancer Institute (NCI), part of the U.S. Department of Health and Human Services, have issued best practice documents for biorepositories. These voluntary guidelines emphasize standardized methods for collection, long-term storage, retrieval and distribution of samples. Consistent adherence to these best practices helps ensure a level of consistency that limits erroneous research findings due to differences in sample handling procedures.

Within these best practices, there are legitimate and scientifically valid differences in specimen collection, handling and storage procedures depending on the intended use of the samples, e.g. basic research, assay development, clinical trials, or epidemiologic studies. Biospecimen Reporting for Improved Study Quality (BRISQ), a recent initiative from NCI, emphasizes the need for thorough, accurate and standardized reporting of collection, handling and storage procedures for any biorepository samples used in research. The goal is to enable others to “better evaluate, interpret, compare and reproduce the experimental results.” This information will also be valuable when evaluating specimens for future studies, as advances in science and technology may require the use of samples collected or stored under specific conditions. Without detailed records, there will be no way to know whether samples banked today will be suitable for study via the scientific methods of tomorrow.

The ideal biorepository outsourcing partner is meticulous about quality assurance and quality control of all aspects of the sample life cycle (e.g. bar coding, storage conditions, handling methods, documentation). These biorepositories also develop and consistently adhere to comprehensive standard operating procedures (SOPs) based on published best practices and relevant standards, as applicable for each sample type, intended use and global location. These best practices and standards include:

- International Society for Biological and Environmental Repositories (ISBER);
- National Cancer Institute (NCI);
- Biospecimen Reporting for Improved Study Quality (BRISQ);
- Current Good Manufacturing Practice (cGMP);
- World Health Organization Good Clinical Laboratory Practice (WHO GCLP);
- College of American Pathologists/Clinical Laboratory Improvement Act (CAP/CLIA) guidelines;
- College of American Pathologists biorepository accreditation program, launched in 2011;
- Requirements for the competence of testing and calibration laboratories from the International Organization for Standardization/International Electrotechnical Commission (ISO/IEC 17025).
VERSATILITY

Within the realm of human medicine, there are numerous types of specimens that may be stored in a biorepository, such as:

- Body fluids (serum, plasma, urine, stool, semen, breast milk, etc.);
- Solid tissues from diagnostic tests, biopsies, surgeries and autopsies;
- Samples for genetic testing (saliva, buccal cells, nail clippings, etc.);
- Isolated DNA and RNA;
- Cell lines;
- Critical reagents (manufacturers’ products, antibodies, buffers, antigens, controls, etc.)

Optimal storage conditions depend on the specimen type, the analyte under observation, the intended future usage of the specimen, its anticipated duration of storage and whether the business requires dynamic (undergoing active testing) or static (archived) storage. Temperature is the most important variable, and optimal storage conditions may require cryogenic preservation with liquid nitrogen, freezing at temperatures between -20°C and -80°C, refrigeration at temperatures between 2°C and 8°C or maintenance at ambient temperature. Humidity and light exposure also may need to be regulated.

In many cases, samples must be processed upon arrival at the biorepository or as they are shipped to laboratories for further testing. Integrating processing procedures, such as aliquotting, blinding/de-identifying, heat inactivation or DNA/RNA extraction, with the bar coding and inventory procedures at the biorepository increases efficiency and decreases the risk of lost or mislabeled samples. These procedures do require additional time, so it is important to understand if both the storage and throughput capacity of a biorepository is sufficient to meet a client’s needs.

EXPERIENCE

With the variability in required storage conditions and the need for strict adherence to SOPs to maintain the integrity of the specimens in a biorepository, the experience and training of a facility’s staff is an important consideration for outsourcing decisions. Managerial positions should be filled by scientists with specimen science expertise, extensive experience with clinical trials and an up-to-date knowledge of biorepository best practices. Staff with these credentials are essential when optimizing handling procedures and storage conditions for a particular specimen type based on its intended use and on criteria from downstream analytic procedures. Ideally, these professionals should be members of the International Society for Biological and Environmental Repositories (ISBER) and have an active involvement in establishing quality practices regarding sample management and processing.

Staff involved in day-to-day sampling handling should be experienced in a variety of sample management and sample processing methodologies. Logistics staff should have evidence of appropriate training, e.g., International Air Transport Association (IATA) and U.S. Department of Transportation (DOT) certifications for the proper handling of blood-borne pathogens and working knowledge of the Occupational Safety and Health Administration (OSHA) laboratory standards.

An ideal biorepository partner emphasizes the safety and security of the specimens and their associated data, the biorepository’s employees and its facilities. In addition to
a comprehensive safety infrastructure and detailed SOPs, biorepositories should have:

- A facility with 24-hour security and limited staff access;
- Inventory control systems with role-based access so only authorized personnel can enter, view, edit, annotate, review and manage data;
- Continuous automated monitoring of storage conditions with prompt notification of designated personnel in the event of unit failures or temperature excursions;
- Detailed Business Continuity Plans (BCPs) in case of power loss, equipment failure, natural disaster or other emergency.

SUMMARY

The value of any biorepository is determined by the quality of the sample storage and handling procedures practiced by the facility. An ideal biorepository outsourcing partner is obsessed with quality assurance and quality control in all aspects of the sample life cycle. SOPs, based on best practices and relevant standards, should be comprehensive, detailed and up-to-date with advancing technology. The facility should support a wide variety of biological specimens and have the staff and equipment to perform needed sample processing procedures. A range of storage conditions (e.g., temperature, humidity, light) also must be available, as optimal conditions vary based on specimen type, its intended usage, its anticipated duration of storage and its designation as dynamic (undergoing active testing) or static (archived). Staff should possess expertise in specimen science to ensure sample integrity and appropriately customize handling and storage processes to accommodate current and future advances in medical research techniques.

REFERENCES


For more information about the PPD Vaccines & Biologics Center of Excellence or PPD’s labs services, please visit us at www.ppdi.com, contact labs@ppdi.com or call us at +1 877 643 8773.

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