THE NEED FOR GOOD STORAGE PRACTICE — BIOPRESERVATION AND BIOBANKING

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Introduction
The advent of molecular and other analytical technologies has resulted in a dramatic increase in the need for biological sample storage. As science and medical fiction become fact, specimens such as blood, serum, and tissue may hold the key to understanding disease processes or outcomes and represent invaluable intellectual property.

As such, the services that support this progress need to be developed in parallel and held to the same standards of excellence and accountability to ensure the highest level of quality, visibility, and compliance. Unfortunately, samples are often stored in an ad hoc manner without standardized processes and lack the robust and scalable information systems necessary to delineate collections and maximize their use in research. Because of the intrinsic value of these samples, poor sample management represents a significant missed opportunity for pharmaceutical and biotech companies to exploit the value of archived samples.

Accordingly, preserving samples to the highest standards has become clearly critical, not only for prospective studies, but also for retrospective analyses. Because of the inherent value of each sample, it is imperative to design sample storage processes that will ensure future scientific discovery is not put at risk by compromised sample integrity. Yet, despite its inherent value, the management of sample storage has received scant attention when the need to set standards for Good Storage Practice (GSP) is most urgent.

Good Storage Practice: Standardization and Compliance
When the FDA introduced Good Tissue Practice (GTP) in 2004 to ensure tissues used for transplantation are properly stored and do not put recipients at risk of infection, a precedent was set.1 A draft of further guidelines is currently under discussion by the FDA.2 Many of the components of GTP, such as the need for a quality system, standards for equipment maintenance, and auditing, have relevance and directly apply to GSP.

GSP should require the standardization of sample handling and management processes so that samples are prepared and stored in consistent conditions. Currently, samples are frequently stored at multiple sites, varying from an investigator center with a centrifuge and freezer to a Good Laboratory Practice (GLP) standard or College of American Pathologists (CAP) accredited laboratory. Standardization may therefore require considerations of centralization to ensure the use of a quality, validated system with appropriate and comprehensive standard operating procedures (SOPs). Centralization of sample collection, management, and storage can create economies of scale as well as efficiencies in the ability to compare data across multiple studies.3

GTP requires manufacturers to establish and maintain a quality program, emphasized and described by the International Society for Biological and Environmental Repositories (ISBER) in its 2008 guidelines.4 This includes quality assurance (QA) and risk management tools responsible for maintaining compliance with SOPs that should be reviewed and revised on a regular basis. The ISBER guidelines also describe the scope of these SOPs and recommend conducting regular audits to make certain storage providers document appropriate corrective actions relating to core GSP requirements, including re-audits of deficiencies as necessary. Internal audits should include a random check on a defined percentage of specimens to ensure that they are located correctly.

One outstanding issue for specimen storage is that little research has been done on the long-term stability of analytes in plasma or the preservation of tissue samples. While it is long believed that biological samples should be kept at low temperatures to ensure long-term viability, remarkably little evidence exists on which to base a case for a particular storage temperature. Research suggests that there is a minimal effect on protein in plasma stored at −70°C for 4 years compared to samples that were thawed and refrozen.5 Traditionally, the standard storage temperature for plasma samples has usually been either at −70°C or −80°C on the assumption that this should inhibit enzymatic processes and preserve the analytes to be measured. The choice of temperature has been dictated by common practice rather than scientific investigation. There is clearly a need for further research to investigate the long-term effects of storing sample or tissue specimens at various temperatures.

Good Storage Practice: Information Management and Audit Trails
As in GTP environments, implicit in GSP is the need for clear documentation of the performance of significant steps in the handling of specimens. This documentation should include an auditable historical record of who performed the

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work at what time and on what date. Fortunately, this formidable task can be achieved by using validated computer software designed specifically for inventory maintenance.

Many current systems are not able to comprehensively record the process of handling of samples and provide a complete historical record of the temperature at which the sample has been stored, emphasizing any deviation in temperature, particularly freeze–thaw cycles. A key element of GSP is that the temperature monitoring system and software be integrated into the inventory management system to provide complete chain-of-custody data. Comprehensive management systems are also able to identify aliquots of the parent sample and their exact location in inventory. With an increasing volume of samples in storage along with each sample's associated data, such systems must be scalable and robust to quickly locate and retrieve the physical sample and its relevant data. Due to their extreme value, companies that acquire sample collections should use appropriate scrutiny to confirm that they were stored correctly. Companies should also make sure that they can download history and associated data into their repository's database.

Good Storage Practice: Cold Chain Logistics and Management

As with GTP, GSP compliance requires correctly calibrated, routinely maintained, and regularly recalibrated equipment and supporting documentation. Similar standards of record keeping and guardianship apply to the transportation of samples, which must remain within a specific temperature range in order to maintain their integrity.

As samples are now being acquired from around the world, cold chain logistics is becoming an important component of GSP. Due to the complexities of shipping temperature-sensitive biospecimens throughout foreign countries, maintaining the global cold chain requires expertise in logistics management to guarantee samples are correctly monitored and packaged during shipping. It should also be remembered that since the terrorist attacks on September 11, 2001, global air security regulations have been tightened and, in particular, the documentation associated with biological shipments has increased, significantly altering shipping procedures. Detailed examination of documentation is a frequent occurrence and may result in the interruption of shipments in the event of a logistics error.6 In addition, air transit remains very dynamic, with regulations being reviewed annually, at a minimum. This is an area where serious penalties such as fines exist for breach of the regulations and facilities may be subject to compliance audits by the Department of Transportation.

Good Storage Practice: Business Continuity

Developing SOPs and business continuity plans is a fundamental requirement of GSP and necessitates careful preparation and anticipation of multiple scenarios—ranging from power failure to "acts of God."

Implementing redundant measures like a backup power source with regular load tests of equipment is essential to ensure the integrity of samples. Further redundancies such as duplication of IT systems with offsite placement of servers and data storage, also with appropriate uninterrupted power supply, have to be designed into long-term plans. This reduces the risk that samples and the corresponding data will not be compromised due to onsite power or server failure. Many commercial biorepositories can accommodate hundreds of freezers, and therefore, adequate and redundant HVAC is necessary due to the heat generated by electrical equipment. Furthermore, staff should be cross-trained as part of planning for unexpected events.

In any laboratory-like environment, potential hazards will always exist. Consequently, a biorepository must provide appropriate containment of organisms and protection for staff according to the biosafety level of the organism7 according to the CDC, NIH, and the DOH. The health and safety of staff should always be a top priority of management. Common issues may include protection against electric shock as well as the potential for physical danger from factors such as thermal burns from liquid nitrogen. The storage facility may need oxygen sensors installed if liquid nitrogen is used, but carbon dioxide buildup from dry ice may also be "oxygen depriving" and require such monitoring. Furthermore, the facility must also be secure and protected from intrusion at all times.

Conclusion

The ISBER guidelines represent a major step forward in developing GSP. The materials being stored are often expensive for organizations to collect and represent significant intellectual property due to ongoing analysis that can be conducted. Correct diagnosis and treatment is dependent on accurate measurement of analytes and poor sample management may put lives at risk. Therefore, it is an ethical responsibility to store correctly.

The limitless value of each stored sample is inherent by nature and warrants proper care through GSP and GTP, among other considerations. The question is: should these standardizations be left to individual researchers to decide how to store samples, or should these standards be applied by a more regulatory body, such as the FDA? This is a question to be debated, and correspondence to this journal would be an excellent starting point.

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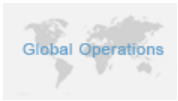

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