Outsourcing stem cell storage

Stem cells — often referred to as 'the miracle cell' — have already taught the scientific community a great deal and it is accepted that future advances in research will offer the potential for therapeutic treatments of many medical conditions; from Parkinson's disease to spinal cord injuries. The efficient storage of these unique building blocks of life must, however, be carefully considered.

Patrick Jackson
Business Development Director, Vindon Scientific (UK)

Why is the correct storage of stem cells so important for the future of medical innovation?

Medical researchers believe that stem cell therapy has the potential to dramatically change the treatment of human disease. There are two broad categories of stem cells: adult stem cells (also known as somatic stem cells) and embryonic stem cells. Adult stem cells are already routinely used to treat life threatening conditions and are also contributing to new regenerative therapies that can be used in drug R&D.

Stem cells can be sourced from the bone marrow itself, peripheral blood and, more recently, umbilical cord blood. Stem cells from umbilical cord blood (haematopoietic stem cells) have to date been used to repair bone marrow in more than 2000 patients. In the US, cord blood has become the most frequent source of stem cells for transplantation in children. Along with ongoing research to improve the use of cord blood in stem cell transplants, a significant amount of research is being conducted to explore the application of cord blood in the field of regenerative medicine. Currently, there are ongoing clinical studies investigating the value of cord blood in the treatment of brain injury, cerebral palsy, Type 1 diabetes, heart disease and critical limb ischaemic.

The market for stem cells is very much in its infancy, but there is little doubt that stem cell storage will be the norm in years to come, not just in the private sector, but also for public health services and other public arenas. Stem cells from umbilical cord blood are one of the most commonly banked types of human tissue. They can be stored in bags or vials, or the whole blood sample can be stored. Quality assurance standards are also crucial, which is particularly relevant given that cord blood stem cells are likely to play such an important part in cellular therapies in the future. In fact, it is estimated that by 2015, there will be up to 10 000 cord blood transplants worldwide per year using banked cord blood, which is why it is important to build repositories for the storage of cells to guarantee continued successes.

New sources of stem cells from adipose tissue (fat), children's milk teeth and even hair, are regularly being identified and stored under cryogenic conditions that preserve materials unaltered; this usually involves temperatures from -160 ºC to -190 ºC. Liquid nitrogen is the most logical choice for storage at temperatures below -130 ºC, but there are risks associated with its use. The extremely low temperature of the liquid can cause severe burn-like damage to the skin either by contact with the fluid or evolving gases. Large volumes of nitrogen gas are evolved from small volumes of liquid nitrogen. This can easily replace normal air in poorly ventilated areas leading to the danger of asphyxiation. The risk of injury is moderate, with cryogenic burns the most likely injury; however in exceptional circumstances when large amounts of material are spilled in an enclosed space, asphyxiation may be fatal.

The author says...

- Stem cell storage will become routine in the public and private healthcare sectors in the future.
- The storage of stem cells generally involves temperatures from -160ºC to -190ºC, using special tanks containing liquid nitrogen.
- In particular, cord blood stem cells are likely to play an important part in cellular therapies in the future.
- Outsourcing cryogenic storage can be challenging because of the relative infancy of the market; however, it offers many advantages compared with in-house facilities that consume space and costs.

To ensure there is no cross-contamination between stored samples, it is generally recommended that materials are accommodated in the vapour phase above the actual nitrogen, where temperatures are in the region of -150 ºC to -197 ºC.

Industry experts believe that the use of dry-store freezers, specifically designed as vapour phase storage systems, offer exceptional sample security; a slight positive pressure in the sample chamber will circulate out any pathogens; and operator safety is ensured as the storage area is completely free of liquid nitrogen, which is housed in a jacket surrounding the chamber. Temperature performance to -190 °C can be achieved well below the level required to keep materials in first-class condition.

By storing stem cells taken from a baby's umbilical cord, it is now possible for parents to insure their child's future health against diseases such as cancer, diabetes, cardiovascular problems and blood disorders.

What are the benefits of outsourcing stem cell storage?

Because of its relative infancy, outsourcing cryogenics can be challenging. The current economic climate has caused many managers to closely examine the feasibility of developing in-house cryogenic facilities; however, costs can be prohibitive as capital expenditure budgets become more difficult to generate, cash flow gets tighter and energy costs escalate.

Finding the right storage partner means there's no need for large capital outlay on cryogenic freezers, liquid nitrogen vessels, control systems and laboratory space. It also eliminates the need to regularly service and calibrate equipment, as well as having staff on constant call-out duties. Additionally, it's important to strike a balance. Scientists, researchers and medical professionals need to concentrate on what they do best — the science. They don't want the mundane responsibilities associated with storage, which is why effective outsourcing can make such a difference to the efficiency of procedures.

Many businesses still do not appreciate the value of outsourcing. As reported in Pharmaceutical Technology Europe, only 43% of European chief financial officers and chief information officers have tried to calculate the impact of outsourcing on their company.1 Of those interviewed, more than a third (37%) have not even attempted to measure the possible returns on investment. This research shows just how many organizations are missing out on the potential benefits of outsourcing.

What criteria should be considered when choosing an outsourcing partner?

The right storage partner should allow a company to feel confident in the efficiency and quality of service that they offer. State-of-the-art cryogenic storage facilities should have:

- A high-security environment, including access control systems, motion detectors, smoke detectors and continual CCTV surveillance.
- Computer-controlled guarantees of temperature integrity, with constant monitoring.
- Full emergency backup including spare freezers.
- Dedicated service teams on call 24/7 to ensure immediate response and remediation in the event of emergency breakdowns.
- Proactive technicians to monitor equipment and provide preventive maintenance and repairs.

A comprehensive cryobank should be capable of providing a 'hub' for the preservation of biological samples, bone marrow, culture collections, DNA, microbial and viral seed stocks, as well as the all-important stem cells and cord stem cells. All safety issues must be in strict accordance with the latest regulations, with staff and systems in place to offer first class biological storage conditions. Ideally, the facility will provide a storage solution for short-, medium- and long-term temperature-controlled management, and incorporate secure storage and real-time tracking of the stored samples.

...an experienced contract organization can provide signigicant peace of mind with product security...

Some companies will still favour total control of their own storage, but an experienced contract organization can provide signigicant peace of mind with product security, as well as bring vital cost benefits to beleaguered bottom lines. You should not, however, be paying charges for set up, transactions or removing samples. Instead, expect a standard monthly or annual fee.
Most companies will find that outsourcing stem cell storage is a simple, cost-effective arrangement for a very precise and intricately managed service.

Reference

1. Pharmacutical Technology Europe, "European businesses neglect to measure value of outscourcing" (August, 2009). www.pharmatech.com

Patrick Jackson
Business Development Director at Vindon Scientific (UK).
Tel. +44 (0)1706 716710
patrick@vindon.co.uk