

As an aspect of their daily lives, research scientists are used to weighing up the pros and cons of temperature-controlled climates. But there's an extra climate they have to take into consideration these days - the financial one. Could the outsourcing of stability storage solutions be their salvation?

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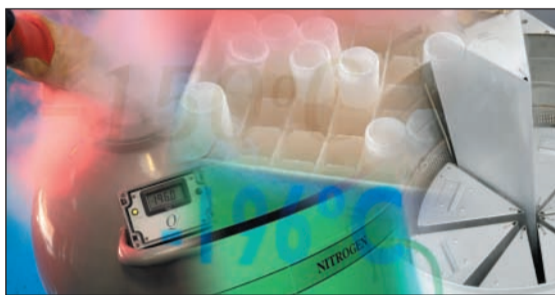


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Coming in From the Cold for Reliable Stability Storage

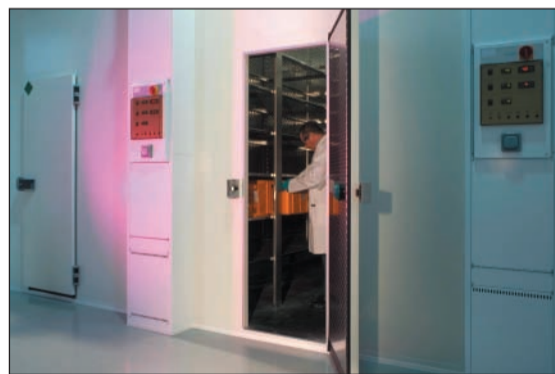
The frosty state of the current economic situation is causing many a purchasing manager to scrutinise his capital expenditure budget with a particularly wary eye. Credit crunch. Cash flow. Energy costs. Recession. All this over-hyped terminology is striking terror into the hearts of the most optimistic businessmen, business women and entrepreneurs. And as we're experiencing a chillier winter than we've had for some time, they're no doubt getting cold feet at the prospect of raising funds for expensive in-house installations. Perhaps it's time to investigate more cost-effective options?



Cryogenic Storage

An efficient, state-of-the-art suite of storage facilities covers diverse requirements - controlled environment rooms, blood banks, pharmaceutical refrigerators, ultra-low and low temperature freezers, biological cabinets and plant growth chambers for storing materials under controlled ICH and non-ICH conditions. All this calls for considerable investment, so inevitably many scientific companies are reluctant to commit to such costly in-house ventures, particularly during an economic downturn.

It's appreciated that some companies will always prefer total control of their own storage, but an experienced contract organisation can provide significant peace of mind with security for their products, as well as bringing vital cost benefits to their beleaguered bottom lines. Having outsourced their storage needs, it leaves them to do what they're best at - concentrating their internal resources on drug development and production.



Putting pharmaceutical product on store

So, what should you be looking for with the concept of out-sourced storage? No two pharmaceutical companies are the same. Every one has its own unique needs whereby different conditions are required, but your outsourcing partner should be able to observe these. Here are the 'top ten' prerequisites that you may need to consider:

UNIFORM CONDITIONS

For products that are all exposed to the same conditions, chambers should have pre-conditioned air flow circulation to ensure uniformity for all test samples, and on every shelf. Individual chambers need to be temperature- and humidity-controlled and monitored by a computer-controlled logging system. This should be linked to the company's intranet, so that alarms are recorded immediately.

CONTROLLED ENVIRONMENTS

Every storage room must be strictly monitored. Temperature and humidity control is crucial because changes can put adverse stress on storage samples, potentially resulting in inaccurate or unsuccessful results. Your outsourcing partner must also be able to provide conditions unique to your product needs. There are some instances for example, where drugs and drug-related products need to be stressed or tested at conditions outside current ICH guidelines.

REGULAR CALIBRATION

Validation must be carried out regularly to ensure that an environmental room or cabinet is capable of accurate and repeatable performance. Ideally a combination of UKAS (United Kingdom Accreditation Service) calibration probes and state-of-the-art data acquisition systems should be used to ensure that temperature and humidity levels are monitored at all times. A typical system is the Eurotherm 6000 Series data logger, designed to prevent data being tampered with, by leaving an identifiable audit trail.



Inside Stability Storage Room

Performance mapping tests should also be undertaken annually for temperature and humidity. It's crucial that rooms and systems are operating correctly and that probes have not 'drifted' from their set points. All documentation should be designed to be compliant with relevant guidelines to meet all necessary requirements.

SAMPLE TRACKING

Stability sample tracking is essential when thousands of products are being managed for different companies, all with different protocols. They must be handled properly; they must be identified correctly; they must be clearly labelled, ideally with product name and code, quantity, storage conditions, lot number and date of manufacture. This is all essential to prevent any confusion when samples are retrieved from the stability chambers.

BULK PHARMACEUTICALS

Drug products are produced using bulk pharmaceutical chemicals. The stability storage of these calls for special conditions. Manufacturers of their inactive ingredients have to comply with GMP regulations, which become relevant where a substance enters a biological or chemical synthesis or a series of processing steps.

The regulations require that all drugs be manufactured, processed, packed and held in accordance with current good manufacturing practice. During the development phase of a medicinal product, stability of the chemical constituents has to be analysed because undetected changes in raw materials specifications may affect their stability.

Stability samples need to be stored in containers that approximate to the market container. As recommended by the FDA, additional samples should also be stored under stressful conditions such as high temperature, light, humidity or freezing. In the arena of costly pharmaceuticals, nothing should be left to chance.



Vindon's Stability Storage Suite

FLEXIBLE RESOURCES

You may require your storage partner to be able to accommodate the needs of overseas markets. Emerging nations in Asia and the Middle East for instance would require different conditions from those in the UK. It could well be worth considering such an arrangement for handling retained samples, secondary storage, storage of quarantine samples, freeze/thaw testing and aerosol testing. Any storage facility should also have sufficient spare room in its premises to accept more storage space when necessary.

SECONDARY STORAGE

As we're all being told in the world of computers, back-up files are essential and we're constantly urged to keep them 'off site'. The same applies to valuable stored samples. Even if you do have your own storage facilities, it's worth considering putting a duplicate set into the tried and tested hands of an outsourced company, in a second geographical location. This could in turn minimise potential economic loss and inevitable disruption of your production schedules.

DEDICATED MAINTENANCE

Engineers should be constantly available on-site for scheduled and non-scheduled maintenance. In the event of

an alarm sounding within a room or cabinet, technicians need to deal with the problem quickly in order to avoid the loss of valuable samples or costly delays to customers' important projects.

DISASTER RECOVERY

In order to provide businesses with a secure system, it's essential to have an established disaster management capability in place for stored products. The safety of frozen sperm, eggs, embryos, biological cells and stem cells must be protected at all times. Failure to do so, for instance with inadequate temperature levels in storage vessels, could lead to the irretrievable loss of stored materials.

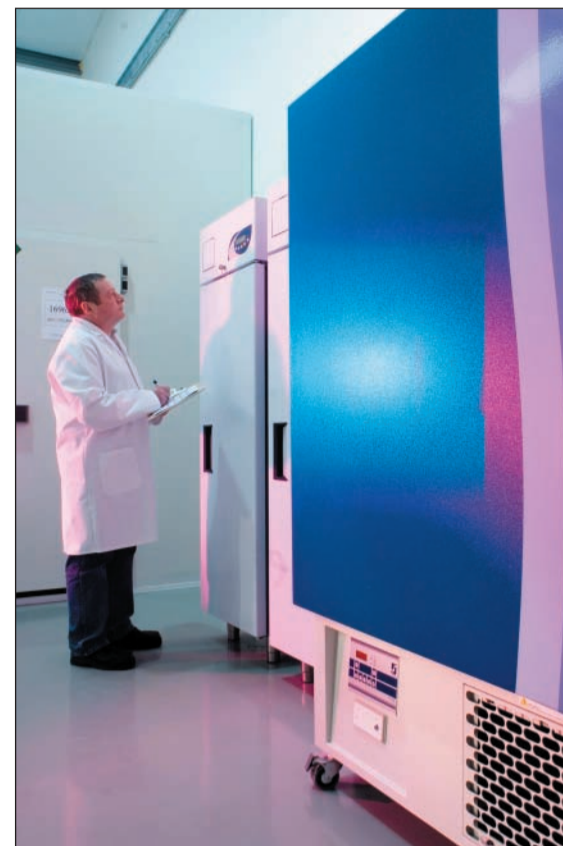
CRYOGENIC EXPERTISE

There is one final outsourcing area that you may require which, because of its relative infancy, can be quite a challenge - the world of cryogenics. Outsourcing companies such as Vindon are actively involved in developing facilities to assist in the study of the behaviour of materials at ultra-low temperatures down to -197°C . For applications in cryobiology, ultra-low temperature storage facilities are required for samples, organisms and laboratory research materials. This service necessitates the provision for a single box of samples, right up to large volumes, for retrieval at any stage prior to the completion of a research project. You would also expect constant monitoring with a paperless data logging system that should, ideally, be compliant with the requirements of the US Code of Federal Regulations.

So, all you need to do now, is find a company that can offer you some, or all, of the above. The benefits are clear. There's no need for large capital outlay on stability chambers or rooms, it reduces the need for costly laboratory space and eliminates the need to regularly service and calibrate your equipment.

In addition to the 'top ten' list above, perhaps the only other checks you need to make are the length of time the company has been undertaking stability storage and, of course, check out the stability of its finances as well. It's a costly business in which to make mistakes. Make sure also that their Quality Management system is registered to ISO 9001:2000. Companies like Vindon are regularly audited, and subsequently approved by many major pharmaceutical organisations. Vindon has many years of predicting market needs and pre-empting customer requirements and can satisfy all of these criteria.

Experience counts. Choosing a partner that understands specific market sectors will ensure a more efficient process, helping to drive your own business forward.



Ultra-Low temperature storage refrigerator for biologicals

Geographical location can have a bearing on your decision too. Vindon's new purpose-built premises in Rochdale are centrally located at the heart of the motorway network. These state-of-the-art facilities now provide much more capacity - currently over 20,000 cu metres.

Additional premises at Tramore in Ireland are helping to act as a magnet to attract high profile national and international businesses to this seaside town, in close proximity to its regional airport. This is enhancing Vindon's reputation as a best-in-class storage and disaster recovery facility for the UK and European pharmaceutical and biotechnology industries.

There's never been a better time to choose a reliable, proven stability storage service, rather than risking the cost of creating your own storage facilities. The best way of weathering the storm is undoubtedly to find some fair-weather friends to whom you can turn - at least until business confidence is with us once again. But by then your outsourcing partners may well have convinced you that this is the way forward, whatever the climate.



Easier, Safer Large-Scale Laboratory Synthesis

Asynt's new ReactoMate Super laboratory reactor system offers an elegant, safe and convenient way of handling larger-scale laboratory reactions. Asynt MD Martyn Fordham, said: "ReactoMate Super combines all the technical features of the successful ReactoMate CLR (Controlled Lab Reactor) system with a new and very stylish support system for handling larger glass vessels and reaction volumes up to 30 litres. It will appeal particularly to process development chemists working in the area between research synthesis and pilot plant scale."

The ReactoMate Super support system offers clear open access to the reactor whilst remaining completely stable even with the heaviest of vessels. It also takes all the effort out of manipulating large reaction vessels. A built-in jacking system raises and lowers the vessel and all attached ancillaries easily and safely as required for ease of access: this is especially useful when needing to charge or empty the vessel at a safe working height during operation. Interchangeable support rings and quick-release clamps allow easy exchange of reaction vessels from 1litre to 30litres, and the compact dimensions permit installation in many standard fume cupboards.

ReactoMate systems display all the desirable key features of a laboratory reactor - features and options include precise control of reaction variables, a powerful direct drive stirrer, excellent visibility and the ability to operate under vacuum or inert atmospheres. Comprehensive data logging and control systems are also available to customer requirements.

Asynt's new PTFE reaction vessel lids, with several advantages over glass, are also available for ReactoMate. Screw-in PTFE taper joints allow chemists to still use their standard jointed glassware but with the additional benefit of the ability to interchange the sizes used. PTFE lids are made with a lower profile than glass, which combined with a built-in stirrer guide significantly reduces the height of the reaction station, giving better accessibility and safety. PTFE also has better thermal insulation properties than glass, reducing condensation and making processes like distillation more efficient.

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