



Biopharma is Moving!

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We have been 10 years in our current premises which we have now outgrown. We need more space for all our different activities and BTL needs a new laboratory with better facilities. We expect to complete a deal very shortly which will provide us with a much bigger facility. If all things go well, we shall move in February. We then have an exciting programme of improvements to carry out which will take another six months. This investment will cost us £200,000, quite a sum for a small business.

We have had a very good year indeed in 2007 and this investment shows our confidence for the future. Our business has been built on an important principle of valu-

ing our customers and giving them the best possible service. Everyone at Biopharma takes pride in that objective. There are times when we fall short and there are times when our principals don't provide what we expect. However we are all committed to improvement and work extremely hard to ensure the quality of service and product we provide is first class. Biopharma has a superb team of hard working, well qualified and dedicated people. In my business it's people that matter most. So I thank for your past and future business. I wish everyone an exciting and prosperous New Year.

Tony Gaster
Managing Director

Wizard 2 Upgrade for VirTis Freeze Dryers

2007 has seen a marked increase in awareness and interest in VirTis control system upgrades. With the earlier Mentor and Wizard 1 systems no longer supported now is the ideal time to contact Biopharma Process Systems regarding your control system upgrade questions and requirements.

Wizard 1 and Mentor are replaced by Wizard 2, a powerful yet cost effective stand alone user interface with many new and exiting features. Microprocessor-controlled, it allows storage of up to 16 different multi-step freeze drying recipes while its graphic LCD screen displays shelf temperature profiles along with continuous shelf temperature, condenser temperature and vacuum indication.

When you choose to go ahead with an upgrade your freeze dryer will be given a thorough once-over by our factory-trained engineers. You will also receive full training so that you can make the most of Wizard 2's many features, and our engineers will be happy to answer any questions that may arise.

If your VirTis freeze dryer is still in good condition but the control system is now out of date, an upgrade is an ideal and cost effective way to extend its life.

The Wizard 2 upgrade is available for VirTis AdvAntage, Genesis and Ultra freeze dryers.

Earlier this year Biopharma's Rob Sharp was at Wockhardt in Wales to upgrade the control system on their Genesis EL.

Wockhardt is a global pharmaceutical and biotech company whose numerous research initiatives cover formulations, vaccines, APIs and more. Their Genesis freeze dryer is over 5 years old but due to receiving regular



Above: Ruth Dunne with her Genesis EL; Right: the Wizard 2 computer workstation software.

maintenance is still in good working order.

Along with the control system upgrade, the customer also purchased the accompanying workstation software. Features of the software include the ability to create and upload recipes from a computer, and logging of cycle data for review and analysis.

Ruth Dunne, pictured above, reported that she was very happy with the new Wizard 2.0 control system.

For more information on control system upgrades or planned maintenance, please contact us directly and ask to speak to a member of the service department.



Update on Refrigeration Regulations

The latest regulation covering refrigerants is covered in EC Regulation number 842/2006. This was published in June of 2006 and commonly known as the **F Gases Regulation**. Supplementary guidance has been published by DEFRA in February 2007. The regulations cover certain Fluorinated (F) gases and covers HFCs – hydrofluorocarbons – used in refrigeration, fire protection, foam blowing etc; PFCs – perfluorocarbons – used in the manufacture of semi conductors and SF₆ – sulphur hexafluoride – used in high voltage switchgear. They do not cover CFCs and HCFCs which are either banned from use or being phased out under the 1986 Montreal Protocol or subsequent EC regulations. This article will look only at refrigeration applications.

The **F Gases Regulations** apply to any piece of static refrigeration equipment containing an F gas (HFC) refrigerant. These refrigerants have zero ozone depletion potential (ODP) but they do have high global warming potential (GWP), hence the regulations.

There are 6 main obligations that affect operators of refrigeration equipment falling within the regulations. These obligations are summarised in the table below.

To establish whether you are affected by the F Gas Regulation, you need to establish information about each separate piece of refrigeration system:-

- ⇒ Does the system use refrigerant containing F gases?
- ⇒ How much HFC refrigerant is in system?

The requirement to use adequately trained staff and to recover refrigerant during servicing, maintenance and retirement applies to all sizes of equipment.

The requirement to check for leakage and to keep records applies to systems holding ≥ 3 kg of refrigerant. The frequency of leak testing is also governed by how much refrigerant:-

<u>Amount of refrigerant</u>	<u>Testing frequency</u>
< 3 kg	None
3 – 30 kg	Annually
30 – 300 kg	6 monthly
> 300 kg	Quarterly

There are caveats to this table based upon if automatic leak detection is fitted and if a system is hermetically sealed.

As a guide, for the freeze driers supplied by our principals

All freeze driers will usually contain F gases:

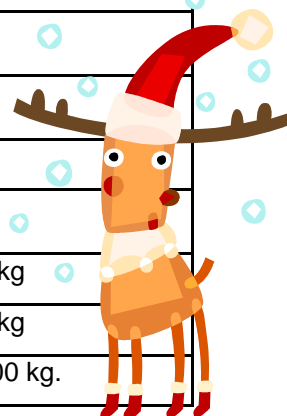
VirTis Freeze Driers up to Ultra size will have < 3 kg of refrigerant gas. VirTis Benchmark models will be dependent upon the model.

Usifroid SMH 45 (Mini Lyos) hold < 3 kg of refrigerant. Other Usifroid models SMH 100 to SMH 700 hold > 3 kg and < 30 kg of refrigerant. Models SMH 800 and above hold > 30 kg and < 300 kg of refrigerant

Note: This is per system and not per machine. For example a large freeze drier may contain 6 refrigeration systems each with 50 kg of refrigerant. The rules treat this as 6 individual systems having 50 kg and not one plant having 300 kg.

If you require assistance in identifying your refrigeration system and how the new regulations might apply to you and your freeze drying equipment, please contact the service department at Biopharma.

Obligation	Applicability
Recovery of gas during servicing and maintenance (including end of plant life)	All stationary systems
Use adequately trained staff to carry out installation, servicing, maintenance and leak testing	All stationary systems
New equipment to be labelled (with gas type)	All stationary systems
Take steps to prevent leakage and repair detected leaks as soon as possible	All stationary systems
Regularly check for leakage	Stationary systems above 3 kg
Keep records of refrigeration plant that uses F gases	Stationary systems above 3 kg
Fit automatic leak detection system	Stationary systems above 300 kg.



Christmas opening hours:
 Open Christmas Eve 8.30am– 12.00pm
 Closed Christmas Day—Jan 1st
 Open Jan 2nd, 8.30am as normal.



Lyophilization of Pharmaceuticals Conference, London

Always keeping abreast of current issues in freeze drying, Biopharma and SP attended the Lyophilization of Pharmaceuticals conference in London this December.

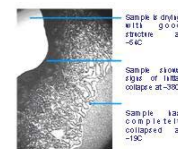
The conference aimed to share the real world experiences of leading industry experts from all areas of the field, including troubleshooting tips, strategies and case studies, and details on the latest regulations and guidelines. Speakers included such world-renowned experts as Dr Paul Matejschuk, whose research on impedance analysis in freeze drying was used to write Kevin Ward's recent presentation in Strasbourg, and Dr Mike Pikal, who helped develop FTS Systems' groundbreaking SMART freeze-drying system.

Biopharma Technology's Kevin Ward and Peter Williams from Biopharma Process Systems attended and also manned a small tabletop exhibit showcasing some of the products and services in freeze drying that the Biopharma Group offers. In particular the aim was to highlight the potential time and cost savings that could be achieved through the use of BTL's Lyostat freeze-drying microscope together with the SMART freeze-drying technology from FTS (see article below).

The conference was well attended, with an international audience including delegates from Sanofi Pasteur, GSK Biologicals, Avecia, West Pharmaceuticals and Wyeth Biopharma.

Accelerate Cycle Development
by 80% or More

Introducing: Lyostat2 and SMART



Sample is drying with good structure at -54°C
Sample shows signs of initial collapse at -30°C
Sample has completely collapsed at -13°C

-pinpoint key parameters such as collapse and eutectic temperatures with the **lyostat2** freeze-drying microscope

Time to Develop One Freeze-Drying Cycle



-develop optimised freeze-drying cycles with intuitive SMART technology

-eliminate the need for multiple expensive, time-consuming, trial-and-error



-run safe, optimised cycles with confidence.

-scale-up to production quickly and simply



Lyostar II with SMART installed

This November a new Lyostar II freeze dryer with SMART technology was installed in Manchester.

Lyostar II, manufactured by FTS Systems, is a laboratory-scale freeze dryer designed for product development. It is the first commercial system to feature the SMART Freeze-Dryer Technology, designed and developed by FTS to accelerate cycle development.

SMART is a breakthrough development tool that enables scientists to accelerate and streamline the time-consuming and repetitive task of developing lyophilization cycles. Its patented algorithms, developed by leading freeze-drying experts, produce a safe, optimised cycle in weeks, rather than months. Instead of running six or seven experimental runs, SMART's intuitive technology can return a safe, optimised cycle in just one or two, saving materials and time and speeding up the path to clinical trials.

SMART also features a unique feedback loop that provides detailed data on the pharmaceutical product and the freeze-

drying process. This data can facilitate scale-up efforts, provide a data trail for regulatory compliance, and free up scientist time for other projects.

The Lyostar itself features powerful, reliable Scroll compressors in a cascade configuration for fast cooling rates, delivering shelf temperature of -40°C from ambient in just 25 minutes and ensuring the capacity is there for even most arduous cycles.

All these features made it the perfect choice for our customers.

This is the first system to be sold in the UK since FTS' inclusion into Biopharma's portfolio this year.

FTS' Matt Dellinger, pictured, and Biopharma's Robert Sharp carried out the installation and customer training at the end of November.

The process went very smoothly and the customer reported that they were happy with the machine and looking forward to using it.

