



## Lyotherm2 Launched!

Biopharma is pleased to announce the launch of the *Lyotherm2* DTA and “Zsinø” analyser for detailed analysis of freeze drying formulations.

Developed in collaboration with leading authority Professor Louis Rey, this instrument has been designed to determine glass transitions ( $T_g$ ), eutectic ( $T_{eu}$ ) and melting ( $T_m$ ) temperatures but it will also show the effects of heat treatment with regard to annealing or prolonged storage of products. Furthermore, *Lyotherm2*'s new Zsinø impedance technology offers finer pinpointing of the frozen state transitions within a formulation, allowing detailed analysis below the traditional collapse or eutectic temperature.

Lyophilisation parameters can therefore be selected on a rational and product-specific basis to provide maximum resultant product activity and best product aesthetics.



*Lyotherm 2 DTA and zsin analyser in the lab*

## 21CFR11 Compliant Software, IQ and OQ for Lyostat2

BTL has responded to the FDA's guidelines on electronic signatures and 'operator access control' to software-controlled equipment, by providing a new 21CFR11-compliant version of the *Lyostat2* 'integrated image capture and temperature/pressure control'



software. In addition, we have recognised the apparently increasing need for Installation Qualification (IQ) and Operational Qualification (OQ) by some of our customers, for instruments which generate experimental data that are subsequently used to determine production parameters. This has prompted us to add the further options of IQ and OQ for *Lyostat2*, where BTL can prepare (or assist in the preparation of) the documentation which can be tailor-made to customer requirements, as well as carrying out the IQ and OQ testing after delivery.

One BTL customer just outside Paris has already taken advantage of both the software and the IQ/OQ options, with our Dr Ward completing the installation and training programme for their *Lyostat2* and getting the users up and running. If you are interested in any (or all!) of these options, please contact us to let us know your requirements.

### OFFICE HOURS

Please note our office hours are now

8.30am to 5.00 pm GMT Monday to Thursdays 8.30am to 2.30pm GMT on Fridays

# New look website on its way!

An all-new BTL website is currently being completed, with a new look and easier navigation functions. We hope you will like it – any feedback would be appreciated, especially a comparison of the new and old sites. We always try to make things on our website clear, concise and easy to navigate, but it's great to have feedback from the people who actually use the site! To reflect our increasing global presence, we will also have details of worldwide BTL agents on our new site – we currently have agents in France, Scandinavia, India, Japan and some parts of the USA and are taking on local agents in other countries – if there is no agent near you, please deal directly with BTL. We are always happy to help, whether by phone, fax or e-mail!

BTL is now also live on PharmaOnline. Check out this hugely informative site at

<http://www.pharmaceuticalonline.com/ecommceters/biopharma.html>

# BTL reaches the parts (and places)...

2004 has been a bumper year for BTL, both in terms of consultancy and laboratory work and in the number of new countries where people are finding out about us. We have really made use of our new air conditioning system, which we needed to keep cool in the lab with our two lyophilisers running, despite not having the warmest summer!

BTL's customer base has also continued to expand in the Indian market. As well as seeing an increase in the amount of contract research work commissioned, the first installation of a Lyostat 2 system was recently successfully completed.

BTL Researcher David Banks travelled to Sun Pharma Industries in Gujarat to perform the installation and to provide first-hand training and advice.

## Symposia & Exhibition Diary

Since our last newsletter, BTL has continued to present itself on the international stage, including attendance at the Eastern Analytical Symposium (EAS) in Somerset, New Jersey, USA in November. Further meetings planned include the Barnett's Conference on Lyophilization, to be held in Brussels, Belgium, in March 2005, where our Dr Ward will be giving an in-depth seminar on the use of freeze-drying microscopy and thermal analysis to provide essential freezing and drying data that are specific to lyo-products.

## Freeze-drying training courses on track...

BTL's regular November course in Winchester, UK, was well attended, with many participants coming from outside the UK to attend our 3-day comprehensive course in freeze-drying technology. Once again, the historic Guildhall provided a pleasant setting in the centre of England's ancient capital (not a lot of people know that Winchester was the capital of England before London!), with the city giving participants plenty of opportunity to forget freeze-drying in the evenings and explore some of England's cultural heritage.



## Forthcoming Courses for 2005

We are running our comprehensive course in San Francisco (USA) on January 17<sup>th</sup>-19<sup>th</sup> and Amsterdam (NL) on February 7<sup>th</sup>-9<sup>th</sup>. These courses are selling out fast, but there are still a few places left at the time of writing. Please contact us directly for further information, or see the Training Courses page of the BTL website. We are also planning a course in late spring 2005 (in Winchester UK) and are looking into running 2 courses in India in 2005. Please contact us directly for further details, or to suggest new locations for us to run a course! We also provide tailor-made courses at customer sites for those who prefer this option.