

## Investing in Research

BTL has been investing into research during 2007 with a number of new projects to both advance the science and to find innovations in the application of freeze-drying technology. Freeze-drying is an expensive process using expensive equipment so any innovation that can reduce costs but make the process more secure and reliable must be of interest. More news to follow next year!

BTL has also developed its business programme world wide with growth in Asia, particularly Japan and India. Once again, in November a series of courses in freeze-drying technology were run in Mumbai which created a lot of interest in India's growing pharmaceutical and biotech companies. BTL has also been looking at opportunities in China. There has never been a better opportunity to look at good science being used for lyophilisation.



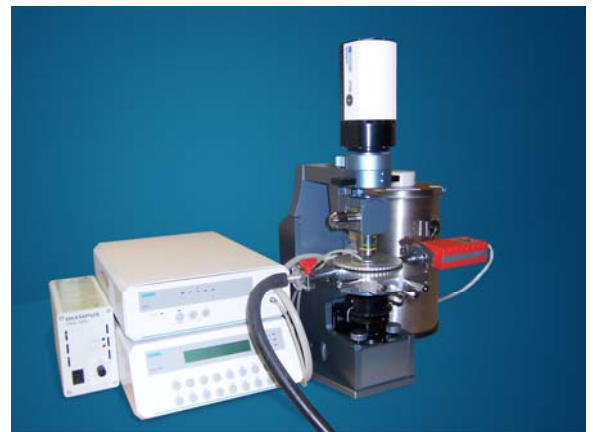
## New Optical Imaging Station for Lyostat

An optical imaging station is now available with the Lyostat2 freeze-drying microscope for the first time.

In standard upright microscopes, the objective lens is very close to the sample, making loading and unloading awkward. With the new imaging station, the viewing optics are mounted in a hinged arm that tilts out of the way, giving unrestricted access to the sample. Two standard microscope objectives can be fitted to the arm, and switching between them is quick and easy.

A long working distance condenser with 10X phase ring and polarizer is mounted above an adjustable diaphragm in the base.

The colour QICAM digital camera offers



1.4m pixels in 12-bit digital output, and installs with a single wire.

The optical imaging station also includes:

- Polariser
- Analyser
- 100W Light source halogen bulb
- Power supply with variable light intensity adjustment.

# University of London Graduation Day

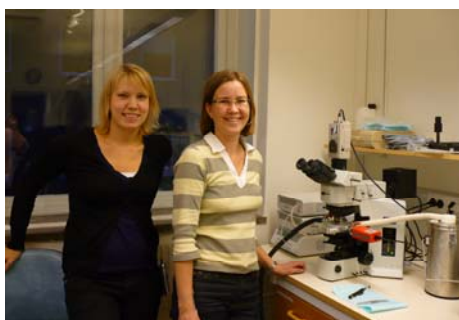
Our Dr Kevin Ward has been an industrial lecturer at the University of London School of Pharmacy (ULSOP) since 2003, where he contributes to the Biopharmaceutics module of the M.Sc in Drug Delivery, as well as introducing freeze-drying as

a unit operation in pharmaceutical production for the M.Pharm course.

Kevin is pictured here with Dr Simon Gaisford, Joint Course Director of Drug Delivery at ULSOP, at the recent graduation day.



## Lyostat Installation in Sweden



Josefin and Ulrika of Octapharma with their new Lyostat2 system

Earlier in the year BTL's Clare Ross was in Sweden to install and provide training on a Lyostat2 system for Octapharma.

Octapharma, a Swiss-based company, is an independent, global plasma fractionation specialist. Its core business is the development, production and sale of high quality plasma derivatives.

Research scientist Josefin Österberg commented:

*"The installation/training was very good, everyone in the group felt that they knew how to*

*work with the equipment afterwards. The Lyostat seems to be a very easy-to-use and "intelligent" system. I got all my questions (and they were plentiful) answered and I felt that the people working at Biopharma were very competent and helpful."*

Other freeze-drying analytical instruments sold this year have gone as far as Austria, India and Japan.

## Upcoming Courses

For more information check online at [www.lyophilizationtechnology.com/training.htm](http://www.lyophilizationtechnology.com/training.htm).



- February 4th-6th 2008, Florida, USA
- March 3rd-5th 2008, Amsterdam, the Netherlands
- June 2nd-4th, Winchester, UK
- September 15th-17th 2008, San Francisco, USA
- October 6th-8th 2008, Amsterdam, the Netherlands
- November 10th-12th 2008, Winchester, UK



# The use of Impedance Analysis for the study of Critical Events

In November Kevin Ward gave a presentation at the International Institute of Refrigeration (IIR) conference in Strasbourg.

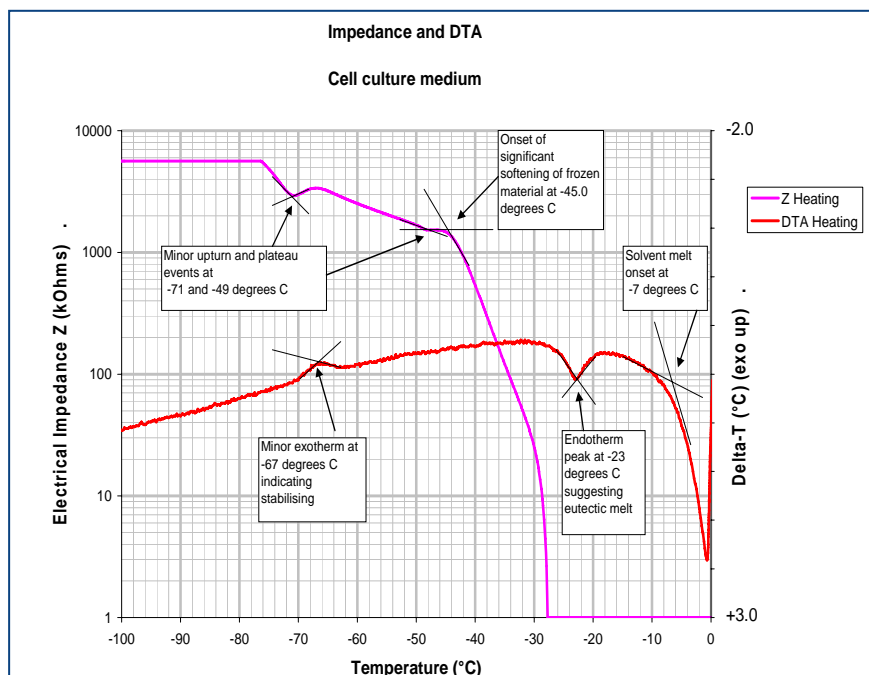
The presentation was entitled “the use of impedance analysis for the study of critical events in the frozen state, for formulation and lyo-cycle development.” It was based on research carried out jointly with the National Institute for Biological Standards and Control (NIBSC), which aimed to describe how data provided by impedance analysis can prove useful in freeze drying, particularly with regard to micro-collapse and similar phenomenon.

Differential scanning calorimetry (DSC) has traditionally been used to look for glass transitions and other key events, but is limited in that it does not always give a complete picture, with parameters such as  $T_g$  remaining elusive. Electrical resistance analysis has also been used for many decades to study frozen materials, but this can often prove to be a relatively crude method that can miss subtle changes that might turn out to be significant. However it has been proved that analysis using a function of impedance can provide more detailed information about the behaviour of frozen solute.

Using impedance ( $z\sin\phi$ ) analysis, changes can be detected below the macroscopic “critical temperature” of a material, and so can indicate “micro-collapse”. Products that have suffered micro-collapse may look outwardly similar to products that have freeze-dried well, but will have a reduced shelf life and be more difficult to reconstitute. Information about micro-collapse within a product can therefore be of great practical use, especially for formulations that contain a mixture of both crystalline and amorphous solutes.

BTL's *Lyotherm 2* instrument, capable of analysing impedance at a frequency of 1000Hz, was used to carry out this research.

Approximately 100 single and dual solute samples were analysed in order to

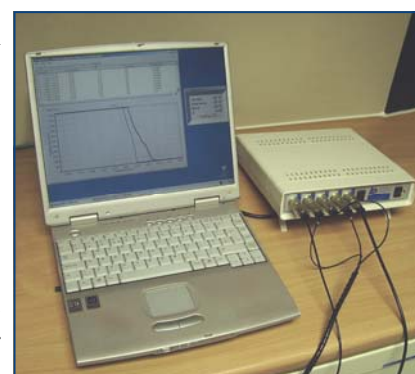


validate the device against published data. For many formulations, a specific temperature indicating the onset of mobility was obtained, even in formulations where modulated temperature DSC was unable to show a thermal event.

The real-life practical implications of these data are currently being determined by freeze-drying some of the sample analysed and examining their appearance, structure, water content, crystallinity, stability, and reconstitution time.

## About the conference

The IIR's mission is to promote knowledge of refrigeration technology and all its applications in order to address today's major issues. The conference, entitled “New Ventures in Freeze-Drying”, focused around key themes in freeze drying such as equipment monitoring and potential developments in the field. For more information, visit their website at [www.iifir.org](http://www.iifir.org).



Top: A typical graph of data generated by Lyotherm2

Middle: The Lyotherm2 instrument

Bottom: Kevin lecturing at the IIR's conference

## Christmas opening hours:

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

**bioforum**  
Biopharma Technology Ltd

# Lyophilization Conference San Diego, 2008

This January the Cambridge Healthcare Institute will be holding their inaugural Lyophilization conference in San Diego, 2008, and BTL's Clare Ross and Tony Gaster will be attending.

The three-day lyophilization event takes place within the CHI's "PepTalk" event, which focuses on proteins. The Lyophilization conference will feature novel case studies and in-depth presentations from industry thought leaders including GSK, Pfizer and Allergan.

BTL's Tony Gaster will be making a presentation at the conference, entitled "The Importance of Critical Temperatures in the Freeze Drying of Pharmaceuticals."

The poster, pictured right, was co-written by Clare Ross and Kevin Ward of BTL and highlights the benefits of knowing a formulation's critical temperatures to successful product drying. Critical temperatures, such as collapse, eutectic, and glass transition, can be determined by use of BTL's Lyostat and Lyotherm analytical instruments.

The poster will be available to download shortly from our website:

[www.lyophilizationtechnology.com](http://www.lyophilizationtechnology.com)

—click on "Publications".

The conference runs from the 9th to the 11th January 2008 in the Hotel Del Coronado, San



Diego. For more information and details on how to register visit the website at

<http://www.chi-peptalk.com>.

## Biopharma is Moving!



Biopharma is moving!

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 with 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 valuing 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