

Lyophilization Society Update – January 8, 2012

Dear Society Member or Guest,

Happy new year from the ISL-FD! Remember, this is YOUR organization. The International Society of Lyophilization – Freeze Drying Inc. is a non-profit professional organization dedicated to sharing knowledge at all levels. Please feel free to write if you want to contribute in any way!

ISL-FD 2012 CONFERENCE

Now is the time to sign up for our 2012 conference. This will be a very special conference, as we will honor the memories of Dr. Louis Rey and Dr. Thomas Jennings. Won't you join us on March 28-30 in Bologna? You can sign up on our web site at:

http://www.islyophilization.org/Html/Conference%202012/Conference_2012.html

The workshop will be on March 28th. **Miguel Galán** will be the workshop leader for the morning session, which is titled “*Novel issues in control process for Lyophilization*”. **Jos Corver** will lead the afternoon session, entitled “*Turning Freeze Drying from a batch process into a continuous process*”.

Dr. Michael Pikal of the University of Connecticut will be the keynote speaker. His Day 1 topic is “*The Scientific Basis of QbD: Developing a Scientifically Sound Formulation and Optimizing the Lyophilization Process.*” Other speakers planned for Day 1 include **James Drinkwater** (Bioquell/PHSS), **Thomas de Beer** (University of Gent), **David Fissore** (Politecnico di Torino), **Miguel Galán** (Telstar), and **Oscar Fernando Otalora Gomez** (H.B. Human Bioscience S.A.S)

Kicking off Day 2 will be **Dr. Heiko Schiffer** of the University of Oxford. His planned topic is “*FTIR Chemical Imaging guided lyophilization formulation and cycle development*”. Other speakers planned for Day 2 include **Stephanie Passot** of INRA, **Yitzchak Grant** of Kraft Foods UK R&D Ltd, **Mike Stella** of Toftlon, **Gerhard Schramm** of Wilco AG, **Maik Guttzeit** of GEA Pharma Systems, and **Dr. Renaud Janssen** of Helovet Pharma.

When you're there, be sure to thank the Program Committee for their hard work. Ivette Novoa Espinosa (Vice President and Chairperson of the Program Committee), Jos A.W.M. Corver, Jorge Sassone, Zhongping Huang, and Greg Alterson continue to work to make the conference a success. We are expecting a large turn-out. Can I ask you to register as soon as possible?

ISL-FD extends a special thank-you to IMA LIFE for graciously offering to host and sponsor this year's event!



LOCAL CHAPTERS

At the Conference in Bologna we plan on discussing the potential to start up European chapters. Please be sure to attend if you have an interest!

USA – MIDWEST. The Midwest Chapter meeting will be **Thursday, April 12th, 2012**. That chapter typically has about 80 attendees. Do you have suggestions for the meeting? Please contact any of the Planning Committee Members: Midwest Chapter President Dr. Robert Sever, Vice President Timothy McCoy, Secretary Sherry Kim, and Donations Committee Chairperson Mark Meluso.

DISCUSSIONS

We STRONGLY suggest that you join LinkedIn. We are managing the LinkedIn group called "Lyophilization and Freeze Drying: ISL-FD". The discussion group now has over 860 members; the ISL-FD has about 2,000. Some of you haven't signed up yet! LinkedIn is a professional network that is also free to join. You can learn more at www.linkedin.com. After you join, select the "groups" tab and join the "Lyophilization and Freeze Drying: ISL-FD" group. We operate this as a "Closed Group" which means that site manager Tim McCoy or I screen applicants prior to approval to help protect our members.

Recent LinkedIn discussions include:

- Mick S. started a discussion on the analysis of the headspace gases for absence of Oxygen.
- Ashoka G. asked about the Application of partial vacuum in FD during APS for Lyo products.
- Amit J. began a discussion on the critical parameters for freeze drying of self emulsifying formulations.
- Parvish Kumar generated discussion on the question of the factors which directly effect the particle size of lyophilized powder and optimizing the lyo cycle to get desired particle size.
- Jordi asked about liofilization of a molecule with a mix water / t-butanol. He was using 15-35% of t-Butanol, and 15-22% product. The point is how to achive levels of t-Butanol<1000 ppm ?
- Sohail Arshad generated a healthy discussion when he asked how to quantify the sublimation contributions from the heat exchange through the walls and base of the glass vials positioned at the edge of shelf.
- Dr. Dan Moran asked about a loss of protein during drying.
- Bent P. started a discussion on the use of spacers on partially filled shelves.

ARTICLES

Would you like to contribute an article to our newsletter?

Has Freeze Drying Changed

By: T.N. Thompson, President, Millrock Technology, Inc.

In the 1960's my father, Taylor Thompson, Sr., was worried that freeze drying would soon be replaced by some new technology that would be better, faster, and less expensive. Well, more than 50 years later the demand for freeze drying continues to grow and the technology continues to advance at a rapid rate.

The process of freeze drying is based on standard physical properties of water and therefore aren't likely to change. However, our understanding of the process and the equipment continues to evolve and just when we think we know it all or have the best widget we find a better way.

Let's start with a quick discussion on one of the major equipment components; refrigeration compressors.

Douglas Fraser developed the first -60C mechanically refrigerated freeze dryer in the 1950's when he discovered that the gas propellant used in fire extinguishers would be a great refrigerant. He experimented with the gas, called 13B1, and created a truly viable method for maintaining condenser temperatures well below -40C without the use of liquid nitrogen or dry ice.

Initially, the compressor manufacturers didn't really like the idea of using 'unapproved' refrigerants and they refused to provide a warranty on the compressor. As time has passed, the compressor companies have embraced low temperature refrigeration and now offer great solutions for the temperatures that are needed to freeze dry.

The evolution of compressors has changed the industry. From semi-hermetic reciprocating compressors to hermetic reciprocating to scroll and screw style compressors, each is now designed to operate reliably for long periods under demanding conditions.

I believe one of the most important improvements comes from Scroll compressors. Scrolls have significantly improved the reliability of refrigeration systems. Based on experience, roughly 1 in 200 scroll compressors have a problem during the warranty period, this is a significantly lower failure than 20 years ago when the majority of compressors were semi-hermetic.

What temperatures do we need in freeze drying? Temperature is the driving force behind the freeze drying cycle. First, the product must be 'frozen' or cooled to a state where there is no molecular mobility. This temperature is called the 'critical

temperature'. As long as the product is below the critical temperature throughout the freeze drying cycle, the end product will form an elegant cake.

Water based products with no salts, sugars or other excipients may only require freezing to -15C, while more complex formulations with solvents or excipients that lower the freezing point may require -40C or lower temperatures on the shelf to fully freeze the product.

The condenser must always be lower in temperature than the product to produce the differential in pressure for vapor flow from the product to the condenser. Although a condenser temperature of -50C may work for simple formulations, more complex formulations require condenser temperatures much lower, for example -60C to -70C. Formulations with solvents also require lower condenser temperatures to keep the vacuum levels low and to prevent contamination of the vacuum pump.

Condenser temperatures are typically offered at -53C, -75C or -85C. To obtain -75C or -85C, special refrigerants and compressors are required. The compressor manufacturers have taken charge of developing compressors that can run at much higher pressures while providing condenser temperatures to -85C.

The lower temperatures and higher reliability of today's refrigeration compressors provides a higher level of performance, which is important, as we place more complex and higher valued products in our freeze dryers.

ISL-FD WEBSITE

www.islyophilization.com

ISL-FD LinkedIn Site

<http://www.linkedin.com>

Join the group "Lyophilization and Freeze Drying: ISL-FD"

SPONSORSHIP

The ISL-FD is a non-profit professional organization. We charge no dues to members, and so we rely heavily on sponsor donations. If you would like to sponsor a newsletter, please respond to me. For other donations please contact Dr. Jorge Sassone (jorge@improved.com.br), who is the Chairperson of the Donations Committee.

I hope you meet you in Bologna!

Best regards,
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