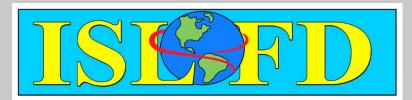


#### Dear Lyo Professional,

On behalf of the International Society for Lyophilization and Freeze-Drying (ISL-FD Inc.), I would like to cordially invite you to attend our 9th International Conference in Ghent, Belgium. We will have a weeklong event filled with presentations given by some of the leading academic and industrial researchers in lyophilization science. In addition to the Conference technical presentations, there will be a seminar, a workshop, student and professional posters, vendor exhibits, and plenty of time allotted during breaks and lunch for networking opportunities. We plan on visiting industrial facilities, touring the area's fine beer purveyors, and we will have a gala dinner as well.

ISL-FD is an <u>all-volunteer, non-profit organization</u> dedicated to promoting and advancing the field of lyophilization (lyophilisation). I hope to see you in Belgium!

Kevin. R Tebrinke, PE. President, ISL- FD Inc.



9th INTERNATIONAL CONFERENCE Ghent, Belgium 2 Sep pm: Seminar: Freeze Dry Fundamentals

3 Sep am: Process Development / QbD / PAT 3-6 Sep: Conference, Exhibits, Posters

Our Conference will provide value for **Business, Science, Engineering, and Operations Leaders and Technicians** for those involved in the art and science of lyophilization:

- Freeze-drying process
- Cycle Development
- Optimization
- Product Modeling
- Quality by Design
- Infrastructure Design
- Process Chemistry
- Cells and Organisms

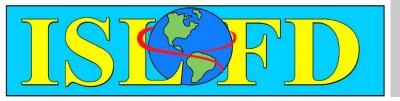
- Latest Concepts in Development
- Freeze Drying Equipment
- Regulatory Aspects and Compliance
- Medical Devices
- Sterile Manufacturing
- Pharmaceutical Production
- Engineering Considerations
- Measurements
- Formulation Chemistry





http://islyophilization.org

LinkedIn ISL-FD Group



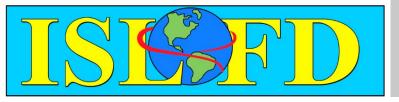
## **2** September: Seminar: Fundamentals of Freeze Drying and Formulation

14:00 – 17:00 Seminar leader: Dr. Steven Nail

This session is mainly dedicated to those professionals from the pharmaceutical industry involved who are newer to the industry. The one-day Freeze Drying Seminar will provide training and discussion of practical aspects, including Freeze Drying Basics, Equipment Design and Functionality, and Process and Machine Concepts What does it include?

- ✓ Interactive Seminar Environment
- ✓ Related materials
- $\checkmark$  Internet connection into meeting room





9th INTERNATIONAL CONFERENCE Ghent, Belgium 2-6 September, 2019

# 3 September – Workshop: From drug to process development, QdD, PAT

# 8:30-11:30 Workshop leader: *Prof. Thomas De Beer*

This session will be of interest to those professionals who are experienced in the development process and wish to gain insight into advanced concepts and current thinking in the industry.

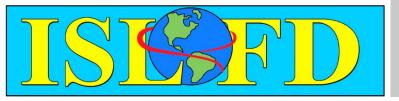
# Main topics:

- $\checkmark$  Modeling of the process
- ✓ Scale up parameters
- Optimize the process
- $\checkmark\,$  Verification of the process
- $\checkmark$  How to satisfy the authorities
- ✓ Cases

What does it include?

- $\checkmark~$  A morning of lecturing
- ✓ Workshop materials
- ✓ Internet connection into meeting room
- ✓ Morning coffee break
- ✓ Lunch





#### 11:30 - 12:30 Registration & Welcome lunch

- 12:30 12:40 Kevin Tebrinke & Jos Corver. Symposium Introduction
- 12:40 13:20KEYNOTE: Past, present, and future in lyophilizationDr. Steven Nail, Baxter Biopharmaceuticals

#### **SESSION 1. Formulation & Chemistry**

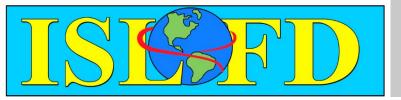
13:25 – 13:45 Solid-state hydrogen deuterium exchange (ssHDX-MS) in the development of lyophilized protein formulations.

Prof. Elizabeth Topp, Purdue University

- 13:45 14:10 Understanding the freeze-concentrate in lyophilization of Mabs *Prof. Wolfgang Friess*, Ludwig-Maximilians-Universität München
- 14:10 14:35 Freeze-drying of protein pharmaceuticals: use of information on component mixing for formulation and process development
  *Dr. Ken-ichi Izutsu*, National Institute of Health Sciences
- 14:35 14:50 Panel discussion
- 14:50 15:20 Coffee & Networking break

Conference Location: Het Pand Onderbergen 1 9000 Gent https://www.ugent.be/het-pand/en/contact





#### SESSION 2. Biopharmaceuticals, biologics & medical applications

15:20 - 15:45Preservation of biological activity during freeze drying – challenges and<br/>technological advances

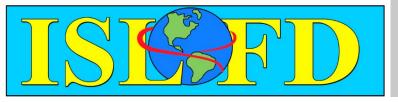
*Dr. Paul Matejtschuk*, The National Institute for Biological Standards and Control

- 15:45 16:10Freeze-drying: not just for injectablesProf. Victoria Kett, Queen's University of Belfast
- 16:10 16:35Lyophilized diagnostic reagent for cancer detectionDr. Jorge Sassone, Proquimo Improvement
- 16:35 17:00 Physical events during cryopreservation: consequences on cells' post-thaw performance and on cryobiological protocols optimisation
  Dr. Fernanda Fonseca, AgroParisTech INRA
- 17:00 17:15 Panel discussion
- 17:15 17:20 Kevin Tebrinke & Jos Corver. Day 1 wrap up

19:00 - ... Ghent & "Beer" tour







8:15 - 8:20 Kevin Tebrinke & Jos Corver. Reflections on Day 1

#### SESSION 3. Process development, monitoring & scale-up

- 8:30 9:10 Keynote: Model-based tools in lyophilization of pharmaceuticals *Prof. Antonello Barresi,* Politecnico di Torino
- 9:10 9:35 IoT PAT for Lyophilization

Prof. Alina Aleexenko, Purdue University

9:35 - 10:00 A QbD based model predictive control strategy of the dynamic primary drying settings for a batch freeze-drying process

Prof. Thomas De Beer, Ghent University

10:00 - 10:25 Integrated use of mechanistic models, targeted experiments and modern analytical tools for development and troubleshooting of lyophilisation cycles: packing of vials approach

Prof. Pavol Rajniak, Slovak Technical University

10:25 - 10:40 Panel discussion

10:40 - 11:10 Coffee & Networking break

**Conference Location:** 





#### SESSION 4. Equipment & design & control

- 11:10 11:35 Electrical Impedance methods for developing a lyophilization cycle *Prof. Geoff Smith*, De Montfort University
- 11:35 12:00 Freeze drying from organic co-solvent systems: thermal analysis and process design

*Prof. Henning Gieseler,* Friedrich Alexander University Erlangen-Nürnberg

12:00 - 12:25 Specificity of vaccine freeze-drying

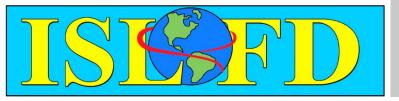
Dr. Yves Mayeresse, GlaxoSmithKline

- 12:25 12:40 Panel discussion
- 12:40 13:00 Lunch box
- 13:00 17:00 Visit to Pfizer and GSK facilities

17:00-18:00 ISL-FD Annual Meeting

#### **Conference Location:**





8:25 – 8:30 Kevin Tebrinke & Jos Corver. Reflections on Day 2

SESSION 5. Competing technologies for lyophilization (Part 1)

- 8:30 9:10 Keynote. Challenges in continuous lyophilization *Ing. Jos Corver*, RheaVita
- 9:10 9:35 From batch to continuous: the lyophilization of suspended vials for pharmaceuticals in unit doses

Prof. Roberto Pisano, Politecnico di Torino

9:35 - 10:00 Atmospheric freeze-drying of food products: practical modeling and quality assessment

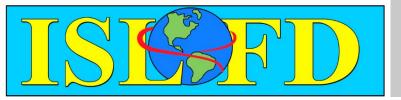
Prof. Kyuya Nakagawa, Kyoto University

10:00 - 10:15 Panel Discussion

10:15 – 10:45 Coffee & Networking break

#### **Conference Location:**





SESSION 6. Competing technologies for lyophilization (Part 2)

10:45 - 11:10 Active freeze-drying

André Hermsen, Hosokawa

11:10 - 11:35 Dynamic spray freeze-drying of pharmaceuticals: model validation and product characterization

Dr. Israel Borges Sebastiao, Pfizer12:30 - 12:55

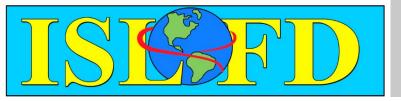
11:35 – 12:00 Accelerating freeze-drying through continuous aseptic spray freeze-drying Dr. *Arnab Ganguly,* IMA Life

12:00 - 12:15 Panel discussion

12:15 - 13:15 Lunch

**Conference Location:** 





#### **SESSION 7. Industrial session**

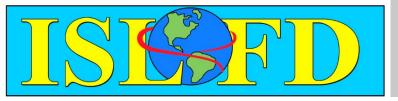
- 13:15 14:00Nanoparticles API freeze drying using organic solventsYossi Shapira, Teva
- 14:00 14:25Freeze dryer recipe process transfer: challenge in heat transfercoefficient between freeze dryers and way-out

Salvatore Carmisciano, Novartis

- 14:25 14:50Lyophilization in bulk of anaerobic bacteria, specificity of the processDr. Sophie Declomesnil, 4DPharma plc
- 14:50 15:00 Panel discussion
- 15:00 17:00 Poster Session
- 19:00 ... Gala dinner

**Conference Location:** 





8:25 - 8:30 Kevin Tebrinke & Jos Corver. Reflections on Day 3

SESSION 8. Regulatory & PAT & Equipment & Troubleshouting

8:30 – 8:55 Title TBD

Dr. Ali Afnan, Step Change Pharma

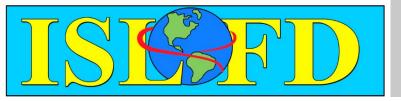
8:55 – 9:20 Title TBD

Byorkis Yañez, CECMED

- 9:20 9:45 Quantification of the physical robustness of lyophilized biotherapeutics Dr. *Kevin Ward*, Biopharma
- 9:45 10:10 Design requirements for shelf temperature control and testing *Maik Guttzeit,* Bayer Pharmaceuticals
- 10:10 10:20 Panel discussion
- 10:20 10:40 Coffee & Networking break

**Conference Location:** 





#### SESSION 9. Young Researcher in Life Sciences & Lyophilization

10:40 - 11:00 Surface-driven denaturation of proteins during freeze-drying: An insight into the role of surfactants

Andrea Arsiccio, Politecnico di Torino

11:00 - 11:20 Evaluation of cracking and shrinkage of freeze-dried cakes when using a continuous freeze-drying method

Gust Nuytten, Ghent University

11:20 - 11:40 Effect of Vacuum Induced Surface Freezing on the physical and chemical characteristics of freeze-dried strawberry pulp

Catalina Alvarez Campuzano, Universidad Nacional de Colombia

11:40 - 12:00 Application of a novel impedance-based freeze-drying microscope for the product formulation development

Anand Vadesa, De Montfort University

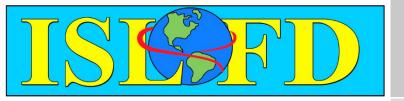
12:00 - 12:20 Formulation strategies and modelling approaches to successfully develop lyophilised high concentration protein formulations

Valeria Gervasi, University College Cork

12:20 -12:40 Kevin Tebrinke & Jos Corver. Awards & Symposium conclusions & proposed next steps







### FEES (€)

	Standard	Special
Packages	Rate	(Gov / Academic)
Seminar	600	450
Workshop	600	450
Conference*	1500	1125
Seminar + Workshop, no conference	800	600
Conference* (Poster Discount)^	1300	975
Seminar or Workshop + Conference*	1800	1350
Seminar or Workshop + Conference* (Poster Discount)^	1600	1200
Full Package*	2000	1500
Full Package* (Poster Discount)^	1800	1350

\* - The Gala Diner is included with all Conference Packages!

^ - We provide a financial incentive to those who are Poster Presenters!

<u>VERY IMPORTANT NOTE</u>: It is the intention of ISL-FD to maximize the possibility to learn, share, and impart knowledge on freeze drying through the Society's meetings, therefore, the ISL-FD can possibly offer financial support for those who may be eligible for a fee reduction based on need. So please, consult us for a possible reduction at: <u>islfd.inc@gmail.com</u>

You can pay by wire transfer or credit card, but please fill the registration form on: http://islyophilization.org/ For payment details please contact Zhongping Huang: zphuang@hotmail.com



### **SPONSORS**

The ISL-FD is inviting potential sponsors to contribute with our 9<sup>th</sup> International Conference on Lyophilization and Freeze Drying to be celebrated in **Ghent, Belgium on 2-6 September, 2019**. Sponsors may contribute in many ways; however, those who make relevant contributions will get special benefits from the conference. The Organizing Committee will include the logo of every Sponsor in our publications concerning the Conference.

# **SPONSOR BENEFITS**

#### Supporting partner: € 5,000:

- ✓ Promotion on Conference brochure as Supporting Partner.
- ✓ 1 free registration for Conference.

#### **Silver Sponsor:** € 10,000:

- ✓ Promotion on Conference brochure as Silver Sponsor.
- ✓ 1 free registration for Conference and 50% discount for Registered Staff.
- ✓ 1 free stand in the exhibition hall.

### **Gold Sponsor: €** 20,000:

- ✓ Promotion on Conference brochure as Gold Sponsor.
- ✓ 1 free registration for Conference and 50% discount for Registered Staff.
- ✓ 1 free stand in the exhibition hall.
- ✓ 1 oral presentation of 30 min in Conference + free registration of the speaker.
- ✓ A copy of full list of attendees to Conference.

To become a Sponsor, please contact: Jorge Sassone Email: jorge@improved.com.br Phone: 00 55 11 4056-5193 or 4048-2818





### HOTELS

We are very excited to be in Belgium this year. It is a very popular place, so it is important that you make reservations early to attend the event! We've collected information on suggested hotels, with discounts where possible.

#### 1. Hotel Ibis Gent Kathedraal

- · single room: € 117 per room per night (breakfast + city tax included)
- · double room: € 135 per room per night breakfast + city tax included)
- $\cdot$  Please make reservation before July 26
- · email: H0961-re@accor.com
- $\cdot$  Mention booking code <code>ISLFD2019</code>
- 2. Pillows Grand Hotel Reylof (Book ASAP)
- · Luxury Room Middle: € 165,00 per room, per night
- $\cdot$  Luxury Room Grand: € 185,00 per room, per night
- · Pillows Suite: € 225,00 per room, per night
- · Supplement breakfast: € 25,00 per person
- $\cdot$  Supplement city tax:  ${\bf \xi}$  3,00 per person, per night
- · email: groupsandevents.grandhotelreylof@pillowshotels.com
- $\cdot$  Mention booking code <code>ISLFD2019</code>
- 3. NOVOTEL Gent Centrum
- · website:
- http://www.accorhotels.com/accorhotels/fichehotel/gb/nov/0840/fiche hotel.shtml
- $\cdot$  Mention booking code: **SC372063412**
- 4. Erasmus hotel Gent
- · email: info@erasmushotel.be
- · website: www.erasmushotel.be

- 5. Historic Hotels Belgium Monasterium Poortackere
- · email: peter@monasterium.be
- · Mention booking code ISLFD2019
- 6. Europahotel Gent
- · website: www.europahotel-gent.be
- · email: Monique@europahotel-gent.be
- 7. Holiday Inn Express
- · UGent
- 8. 1898 The Post
- website: http://www.zannierhotels.com/1898thepost/en/
- · Booking code: UGHENT
- 9. Hotel Gent Marriott (hotel where speakers will stay)
- $\cdot$  Book your group rate for FFW Universiteit Gent

#### 10<u>.Park hotel</u>

- · website: www.parkhotelgent.be
- · email: parkhotel@telenet.be
- · Booking code: ISLFD2019