

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

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</u>, <u>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.

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

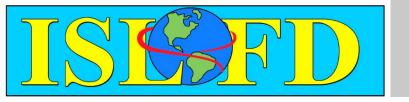
- Latest Concepts in Development
- Freeze Drying Equipment
- Regulatory Aspects and Compliance
- Medical Devices
- Sterile Manufacturing
- Pharmaceutical Production
- Engineering Considerations
- Measurements
- Formulation Chemistry





http://islyophilization.org

LinkedIn ISL-FD Group



2 September: Seminar: Fundamentals of Freeze Drying

14:00 – 17:00

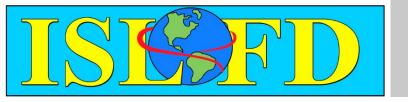
Seminar leader: Dr. Steven Nail

This seminar is primarily intended for those new to pharmaceutical freeze drying. It includes a broad overview of unit operations in the manufacture of a freeze-dried injectable product. The presentation then breaks down the process into three phases: freezing, primary drying, and secondary drying. Relevant physical/chemical principles are reviewed, including phase diagrams, eutectic crystallization, and the glass transition curve. Characterization of formulations intended for freeze drying is reviewed, including thermal analysis and freeze dry microscopy. Primary drying is reviewed with an eye toward construction of a graphical design space. We also include an overview of process monitoring techniques, freeze drying equipment, and some broad guidelines for formulation of products intended to be freeze dried.

What does it include?

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





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.

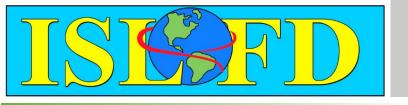
Main topics:

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

What does it include?

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





11:45 - 13:30

3 September: Conference, Exhibits, Poster Presentations

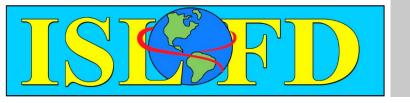
11.13 13.00	Registration & Welcome landin (Room Refeel)
13:30 - 13:40	Kevin Tebrinke & Jos Corver. Symposium Introduction
13:40 - 14:20	KEYNOTE: Past, present, and future in lyophilization
	Dr. Steven Nail, Baxter Biopharmaceuticals
SESSION 1. Form	nulation & Chemistry
14:20 – 14:45	Solid-state hydrogen deuterium exchange (ssHDX-MS) in the development of lyophilized protein formulations.
	Prof. Elizabeth Topp, Purdue University
14:45 – 15:10	Understanding the freeze-concentrate in lyophilization of Mabs
	Prof. Wolfgang Friess, Ludwig-Maximilians-Universität München
15:10 – 15:35	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
15:35 - 15:45	Panel discussion
15:45 - 16:15	Coffee & Networking break (Kapittelzaal)

Registration & Welcome lunch (Room Refter)

Conference Location:

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





SESSION 2. Biopharmaceuticals & Biologics

16:15 - 16:40 Preservation of biological activity during freeze drying – challenges and technological advances

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

16:40 - 17:05 Freeze-drying: not just for injectables

Prof. Victoria Kett, Queen's University of Belfast

17:05 - 17:30 Lyophilized diagnostic reagent for cancer detection

Dr. Jorge Sassone, Proquimo Improvement

17:30 - 17:55 Physical events during cryopreservation: consequences on cells' post-thaw

performance and on cryobiological protocols optimisation

Dr. Fernanda Fonseca, AgroParisTech INRA

17:55 - 18:05 Panel discussion

18:05 - 18:10 Kevin Tebrinke & Jos Corver. Day 1 wrap up

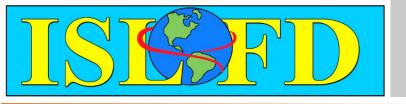
19:00 - ... Ghent & "Beer" tour

Beer Tasting and finger foods – Dinner Not Included.

Conference Location:

Het Pand Onderbergen 1 9000 Gent





4 September: Conference, Exhibits, Poster Presentations

7:45 – 8:15 Coffee and Networking

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

SESSION 3. Competing Technologies (Part 1)

8:20 - 9:00 Keynote. Challenges in continuous lyophilization

Ing. Jos Corver, RheaVita

9:00 - 9:25 From batch to continuous: the lyophilization of suspended vials for

pharmaceuticals in unit doses

Prof. Roberto Pisano, Politecnico di Torino

9:25 - 9:50 Dynamic spray freeze-drying of pharmaceuticals: model validation and

product characterization

Dr. Israel Borges Sebastiao, Pfizer

9:50 - 10:00 Panel discussion

10:30 – 10:55 Coffee & Networking break (Kapittelzaal)

Conference Location:

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SESSION 4. Competing Technologies (Part 2)

10:30 – 10:55	Accelerating freeze-drying through continuous aseptic spray freeze-drying
	Dr. Arnab Ganguly, IMA Life

10:55 - 11:20 A SMART technology for the continuous manufacturing of lyophilized orally disintegrating tablets

Prof. Thomas De Beer. Ghent University

11:20 - 11:45 Atmospheric freeze-drying of food products: practical modeling and quality assessment

Dr. Kyuya Nakagawa, Kyoto University

11:45 - 11:55 Panel discussion

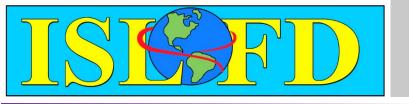
11:55 - 12:15 Sandwich Lunch

13:00 - 19:00 Visit to Pfizer and GSK facilities

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5 September: Conference, Exhibits, Poster Presentations

7:45 – 8:10 Coffee & Networking

8:10 – 8:15 Kevin Tebrinke & Jos Corver. Reflections on Day 2

SESSION 5. Process development, monitoring & scale-up (Part 1)

8:15 – 8:55 Keynote: Model-based tools in lyophilization of pharmaceuticals

Prof. Antonello Barresi, Politecnico di Torino

8:55 - 9:20 IoT PAT for Lyophilization

Andrew Strongwich, Purdue University

9:20 – 9:45 Active Freeze Drying

Bert Dekens, Hosokawa

9:45 - 10:10 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

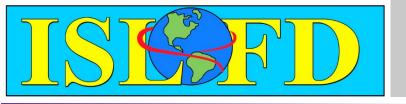
10:10 - 10:20 Panel discussion

10:20 - 10:50 Coffee & Networking break (Kapittelzaal)

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SESSION 6. Process development, monitoring, & scale-up (Part 2)

10:50 - 11:15 Electrical Impedance methods for developing a lyophilization cycle *Prof. Geoff Smith*, De Montfort University

11:15 – 11:40 Freeze drying from organic co-solvent systems: thermal analysis and process design

Prof. Henning Gieseler, Friedrich Alexander University Erlangen-Nürnberg

11:40 - 12:05 Specificity of vaccine freeze-drying

Dr. Yves Mayeresse, GlaxoSmithKline

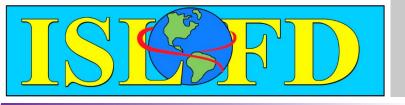
12:05 - 12:15 Panel discussion

12:15 - 14:15 Lunch (Room Refter)

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SESSION 7. Industrial session (Part 1)

14:15 – 15:15	Nanoparticles API freeze drying using organic solvents

Yossi Shapira, Teva

15:15 - 15:40 Lyophilization in bulk of anaerobic bacteria, specificity of the process

Dr. Sophie Declomesnil, 4DPharma plc

15:40 - 15:50 Panel discussion

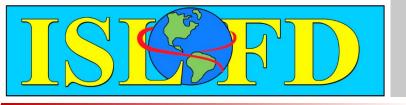
16:00 – 18:00 Poster Session (Kapittelzaal)

19:00 - ... GALA DINNER at Ghent Marriot Hotel

Conference Location:

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6 September: Conference, Exhibits, Poster Presentations

7:45 – 8:10 Coffee & Networking

8:10 - 8:15 Kevin Tebrinke & Jos Corver. Reflections on Day 3

SESSION 8. Industrial session (Part 2)

8:15 – 8:40 Freeze dryer recipe process transfer: challenge in heat transfer coefficient between freeze dryers and way-out

Salvatore Carmisciano, Novartis

8:40 – 9:05 Title TBD

Dr. Ali Afnan, Step Change Pharma

9:05 - 9:30 Quantification of the physical robustness of lyophilized biotherapeutics

Dr. Kevin Ward, Biopharma

9:30 – 9:55 Design requirements for shelf temperature control and testing

Maik Guttzeit, Bayer Pharmaceuticals

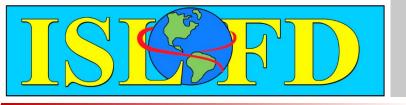
9:55 - 10:05 Panel discussion

10:05 – 10:35 Coffee & Networking break (Kapittelzaal)

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SESSION 9. Young Researcher in Life Sciences & Lyophilization

10:35 – 10:55	Surface-driven denaturation of proteins during freeze-drying: An insight
	into the role of surfactants

Andrea Arsiccio, Politecnico di Torino

10:55 - 11:15 Evaluation of cracking and shrinkage of freeze-dried cakes when using a continuous freeze-drying method

Gust Nuytten, Ghent University

11:15 - 11:35 Effect of Vacuum Induced Surface Freezing on the physical and chemical characteristics of freeze-dried strawberry pulp

Catalina Alvarez Campuzano, Universidad Nacional de Colombia

11:35 – 11:55 Application of a novel impedance-based freeze-drying microscope for the product formulation development

Anand Vadesa, De Montfort University

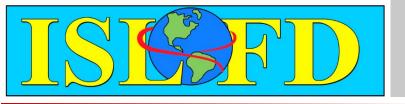
11:55 - 12:15 Formulation strategies and modelling approaches to successfully develop lyophilised high concentration protein formulations

Valeria Gervasi, University College Cork

Conference Location:

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SESSION 9. Young Researcher in Life Sciences & Lyophilization (continued)

12:15 – 12:25 Panel Discussion

12:25 -12:40 Kevin Tebrinke & Jos Corver

Awards & Symposium conclusions & proposed next steps

12:40 - 14:00 Lunch (Room Refter)

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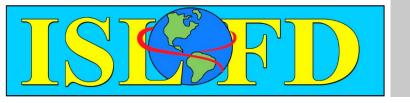


FEES (€)

	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>



SPONSORS

The ISL-FD is inviting potential sponsors to contribute with our 9th 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





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

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)
- · Please make reservation before July 26
- · email: H0961-re@accor.com
- · Mention booking code ISLFD2019

2. Pillows Grand Hotel Reylof (Book ASAP)

- · Luxury Room Middle: € 165,00 per room, per night
- · Luxury Room Grand: € 185,00 per room, per night
- · Pillows Suite: € 225,00 per room, per night
- · Supplement breakfast: € 25,00 per person
- · Supplement city tax: € 3,00 per person, per night
- · email: groupsandevents.grandhotelreylof@pillowshotels.com
- · Mention booking code ISLFD2019

3. NOVOTEL Gent Centrum

· website:

http://www.accorhotels.com/accorhotels/fichehotel/gb/nov/0840/fiche hotel.shtml

· 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)
- · Book your group rate for FFW Universiteit Gent

10.Park hotel

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