



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 all-volunteer, non-profit organization 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 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
- ✓ 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



3 September: Conference, Exhibits, Poster Presentations

- 11:30 - 12:30 Registration & Welcome lunch
- 12:30 - 12:40 Kevin Tebrinke & Jos Corver. Symposium Introduction
- 12:40 - 13:20 KEYNOTE: Past, present, and future in lyophilization
Dr. 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>



3 September: Conference, Exhibits, Poster Presentations (continued)

SESSION 2. Biopharmaceuticals, biologics & medical applications

- 15:20 - 15:45 Preservation of biological activity during freeze drying – challenges and technological advances
Dr. Paul Matejtschuk, The National Institute for Biological Standards and Control
- 15:45 - 16:10 Freeze-drying: not just for injectables
Prof. Victoria Kett, Queen's University of Belfast
- 16:10 - 16:35 Lyophilized diagnostic reagent for cancer detection
Dr. 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

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4 September: Conference, Exhibits, Poster Presentations

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

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4 September: Conference, Exhibits, Poster Presentations (continued)

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

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5 September: Conference, Exhibits, Poster Presentations

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

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5 September: **Conference, Exhibits, Poster Presentations (continued)**

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, Pfizer 12:30 - 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

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5 September: Conference, Exhibits, Poster Presentations

SESSION 7. Industrial session

- 13:15 - 14:00 Nanoparticles API freeze drying using organic solvents
Yossi Shapira, Teva
- 14:00 - 14:25 Freeze dryer recipe process transfer: challenge in heat transfer coefficient between freeze dryers and way-out
Salvatore Carmisciano, Novartis
- 14:25 - 14:50 Lyophilization in bulk of anaerobic bacteria, specificity of the process
Dr. Sophie Declomesnil, 4DPharma plc
- 14:50 - 15:00 Panel discussion
- 15:00 - 17:00 **Poster Session**
- 19:00 - ... **Gala dinner**

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6 September: Conference, Exhibits, Poster Presentations

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

SESSION 8. Regulatory & PAT & Equipment & Troubleshooting

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

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6 September: Conference, Exhibits, Poster Presentations (continued)

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

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FEES (€)

Packages	Standard Rate	Special (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!

VERY IMPORTANT NOTE: 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: isbfd.inc@gmail.com

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 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



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**