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 8th International Conference in La Habana, Cuba. 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 one-day Lyo Training Course, two Workshops, student poster session, vendor exhibits with plenty of time allotted during breaks and lunch for networking opportunities as well as a very attractive touristic plan.

**Seminar Leaders:**
- Mike Pikal
- Steve Nail

**Workshop Leaders:**
- Serguei Tchessalov
- Kevin Murgatroyd

**Keynote Speakers:**
- Alina Alexeenko
- Antonello Barresi
- Stephanie Passot
- Wolfgang Friess
- Peter van der Wel
- Ali Afnan
- Ernesto Renzi
- Ali Afnan
- Ernesto Renzi

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 La Habana.

Kevin. R Tebrinke, PE. President, ISL- FD Inc.
This session is mainly dedicated to those professionals from the pharmaceutical industry involved with freeze dryer engineering, process design, and troubleshooting. The one-day Freeze Drying Seminar will provide training and discussion of practical above aspects. The day’s topics will include Basic Process, Modeling, Formulation, and Metrology / PAT.

Course leaders: Mike Pikal & Steve Nail

What does it include?
✓ A full day of lecturing
✓ Workshop materials
✓ Internet connection into meeting room
✓ Morning and afternoon coffee breaks
✓ Lunch
Title: Scale up and Validation

Workshop leader: Serguei Tchessalov

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?

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- Workshop materials
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- Morning and afternoon coffee breaks
- Lunch
Title: Instrumentation and PAT

Workshop leader: Kevin Murgatroyd

Main topics:

✓ Background of PAT
✓ PAT tools and how to apply them
✓ Implement PAT tolos
✓ Cases

What does it include?
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✓ Morning and afternoon coffee breaks
✓ Lunch
DAY 3, 4 and 5 - April 26th, 27th and 28th: Conference and Exhibition

What does it include?
✓ 3 full days of lecturing
✓ Conference materials
✓ Internet connection into meeting room
✓ Morning and afternoon coffee breaks
✓ Lunch
✓ A tour to Old Havana at the end of Wednesday April 26th
✓ A special Gala Dinner at night April 27th
✓ A full day in Varadero beach on Saturday April 29th

PROGRAM IN PROGRESS – APRIL 26th - Morning

General Keynote: Alina Alexeenko: Germs, Blood and Spies: The Stories and Lessons from Early Freeze-Drying Era

Complex molecules and cells, formulation

Keynote: Stephanie Passot/Fernanda Fonseca The challenges for freeze-drying of complex biological systems: state of the art and future

• Alexis Labrada: Freeze drying allergen extracts: reviewing 20 years of an unique experience
• Bakul Bhatnagar: Reconstitution of Highly Concentrated, Lyophilized proteins – Challenges, Mitigation Strategies, Lessons Learned, and Future Questions
• Jorge Sassone: Novel Lyophilized liposomal approach feasible for production of industrial large scale volume at discreet or continuous fashion
• PhD: Sandeep Zode: Differential effect of mannitol concentration on the solid form behavior of Gemcitabine HCl during freeze concentration
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PROGRAM IN PROGRESS – APRIL 26th - Afternoon

Model based process engineering

Keynote: Antonello Barresi: Model based process engineering: Recent advances in freeze-drying

• Michael Pikal: Optimization of primary drying by construction of a graphical design space: advantages and limitations
• Thomas DeBeer: Uncertainty analysis as essential step in the establishment of the dynamic Design Space of primary drying during freeze-drying
• PhD: Pieter Jan VanBockstal: Mechanistic modelling of the infrared mediated heat transfer during the primary drying step of a continuous freeze-drying concept for unit-doses

• At 18:00 get ready at hotel door for tour to Old Havana
Development and Innovation

Keynote: **Wolfgang Friess**: Freeze-Drying in Dual Chamber Cartridges - from Energy Transfer to Process Control

- **Jos Corver**: Progress in continuous freeze drying
- **Roberto Pisano**: Freeze-drying of suspended vials as a way to promote the transition to continuous manufacturing
- **Geoff Smith**: Recent Advances in Through Vial Impedance Spectroscopy (TVIS) for Process Parameter Determination in Freeze-Drying Method Development
- **Kyuya Nakagawa**: In-situ observation of glass transition during freeze-drying by X-ray computed tomography using synchrotron radiation
- **PhD: Arnold Duralliu**: Humidity Induced Collapse in Freeze Dried Cakes: A Direct Visualization Study using DVS
- **PhD: Luigi Capozzi**: Looking inside the ‘black box’: freezing engineering for assuring quality of freeze-dried biopharmaceuticals

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DAY 3, 4 and 5 - April 26th, 27th and 28th: Conference and Exhibition

PROGRAM IN PROGRESS – APRIL 27th - Afternoon

Industrial Implementation

Keynote: Ernesto Renzi: Aseptic Processing Freeze Drying History and Evolution

- Toni Lorente: Presentation Title TBD
- Maik Guttzeit: Lyophilizer Design for High Potent Products
- Ed Trappler: Approaches to Using Statistical Process Control Techniques for Continuous Monitoring of the Lyophilization Process

ISL-FD Annual Meeting
Kevin Tebrinke, President ISL-FD

Gala Dinner

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PROGRAM IN PROGRESS – APRIL 28th – First Session

Competing technologies

Keynote: Peter van der Wel: Active Freeze Drying
• Arnab Ganguly: Presentation Title TBD
• Serguei Tchessalov: Drying of Biotherapeutics: Evaluation of Alternative Drying Technologies to Lyophilization
Program in Progress – April 28th – Second Session

Regulation, PAT

Keynote: Ali Afnan: Process Analytical Technology (PAT): Controlling manufacturing processes, ensuring quality, meet the requirements of process Validation (21CFR211) and managing change (21CFR314.70) efficiently

- Steve Nail: Recommended best practices for process instrumentation
- Sasha Nikolic: Quality by re-Design of a Legacy Product – Strategy, Execution, and Regulatory Experience
- PhD: Pablo Nuno: FDA process validation approach applied on Fludarabin 50 mg lyophilized powder for injectable solution

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**FEES**

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**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: islfd.inc@gmail.com

You can pay by wire transfer or credit card, but please fill the registration form on: [http://islyophilization.org/conference-2017-havana/](http://islyophilization.org/conference-2017-havana/)

To get details to proceed with payment, contact Zhongping Huang: zhuang@mail.widener.edu
SPONSORS

The ISL-FD is inviting potential sponsors to contribute with our 8th International Conference on Lyophilization and Freeze Drying to be celebrated in Havana, Cuba from April 24th to April 28th, 2017. Sponsors may contribute in many ways; however, those who make relevant contributions will get special benefits from the conference. The Organizing Committee will take care the logo mark of every Sponsor be included in every publication concerning the Conference.

PROPOSED BENEFITS FROM ISL-FD

Supporting partner: USD 5,000:
✓ Promotion on Conference brochure as Supporting Partner.
✓ 1 free registration for Conference.

Silver Sponsor: USD 10,000:
✓ Promotion on Conference brochure as Silver Sponsor.
✓ 1 free registration for Conference and $500,0 the rest for attendees invited by Sponsor.
✓ 1 free booth exhibition.

Gold Sponsor: USD 25,000:
✓ Promotion on Conference brochure as Gold Sponsor.
✓ 1 free registration for Conference and $500 the rest for attendees invited by Sponsor.
✓ 1 free booth exhibition.
✓ 1 oral presentation of 30 min in Conference + free registration of the speaker.
✓ A copy of full list of attendees to Conference.

In case you want to be one of our Sponsors, please contact:
Jorge Sassone
Email: jorge@improved.com.br
Phone: 00 55 11 4056-5193 or 4048-2818
VENUE: FOUR POINTS BY SHERATON

Special room rate/night for conference attendees:
✓ Single: 130.00 CUC
✓ Double: 230.00 CUC

Including:
✓ Welcome cocktail at arriving time
✓ Breakfast buffet
✓ 10% discount at hotel restaurants and bars

Internet connection is **not included**. To get it you should pay a 12.00 CUC ticket to cover 6 hours of connection

To book, contact with:
Thais Aballi Viera
Email: reservas@fourpoints.co.cu
Phone: (537) 2141470
1. **Visas for Cuba:**
You can either buy yours through your local Cuban embassy. Your airline may include the visa on the price of your flight tickets – you’ll still need to collect the visa at the Cubana Air counter before you check in.
US Citizens – Your airline will provide help with the tourist card and insurance.

2. **Travel Insurance:**
You need to have travel insurance to enter Cuba. They do spot checks at Customs and if you can’t produce policy documentation, they make you to buy insurance there.

3. **Take some cash with you:**
Not all services accept payment by credit cards. In case to bring cards, check to see if your bank has any alliances in Cuba.

4. **Come with euros instead of USD:**
The exchange rate for USD is not good and you will have to pay an extra fee every time.

5. **Cuba has two currencies:**
CUC (Cuban convertible peso) aligned to USD which tourists must use, and,
CUP (Cuban national peso) worth around 1 CUC = 24 CUP. You will find dual pricing in most places: CUP and CUC.
6. Where to get money:
Try to get money out of the ATM upstairs on level 1 of Havana International Airport. Avoid using the bureau change at the airport though. Hotels usually have a bureau to change. Four Points by Sheraton Hotel has one.

7. Tipping is Socially Accepted:
Like many places in the world, it’s a common and polite practice to tip your wait staff, tour guides, hotel staff, or bartenders for good service in Cuba by leaving a few Cuban Convertible Pesos.

8. Cuban weather:
In April most days in Cuba are sunny, and there is very little precipitation. Afternoons can be hotter, as the sun reaches its peak at midday, and the average higher temperature rises to 30°C.

9. Galileo Offline Maps:
The internet hasn’t really taken off in Cuba yet, but you can still use your smartphone to get around. Galileo Offline Maps allows you to use your phone’s GPS to show where in the world you are. You can even set Galileo to record your movements so you can see where you went! You can also upload maps from elsewhere into Galileo. You need to download maps onto the app first before you get to Cuba and go offline. This is a paid app but worth every penny.

10. Power Conversion:
All of the outlets on the island of Cuba, including hotels use 2 pronged 220 V outlets.
SOME TIPS BEFORE TRAVEL TO CUBA

And don’t forget:

✓ Learn as much Spanish as you can: Even simple words and sentences will go a long, long way in Cuba. People love to talk to you and if you know a little of their lingo, they’ll be even friendlier.

✓ Take salsa lessons: Everyone in Cuba knows how to dance salsa. Even if you just learn the basic steps, you won’t feel left out stood at the edge of the dance floor while everyone else is enjoying themselves. You can take lessons in Cuba while you’re there, but by then it might be too late.

WELCOME TO ISL-FD CONFERENCE IN CUBA
THIS CONFERENCE WILL BE UNFORGETTABLE
BE PART OF THIS EXPERIENCE