



7TH INTERNATIONAL CONFERENCE

6 July: Freeze Dry Course

7 July: Workshops

8-10 July Conference

Barcelona, Spain

<http://islyophilization.org/2015-barcelona/>

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 7th International Conference in Barcelona, Spain. We will have a week-long 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 Freeze Drying Course, two Workshops, student poster session, vendor exhibits, a facility tour, and plenty of time allotted during breaks and lunch for networking opportunities.

Included in the long list of presenters is:

- *Seminar Leader:* Dr. Kevin Murgatroyd, Pharmaceutical Consultant since 1981.
- *Workshop Leader:* Dr. Saša Nikolić, Laboratorio Reig Jofré, S.A.
- *Workshop Leader:* Dr. Paul Stewart, Telstar Life Sciences.
- *Keynote Speaker:* Dr. Gerhard Winter, Ludwig-Maximilian-University of Munich, Department of Pharmacy.
- *Keynote Speaker:* Dr. Tudor Arvinte, University of Geneva, Geneva-Lausanne School of Pharmacy (EPGL).

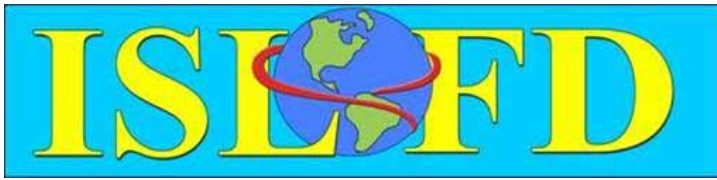
ISL-FD is an all-volunteer, non-profit organization dedicated to promoting and advancing the field of lyophilization (lyophilisation).

I hope to see you in Barcelona.

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 and 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



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DAY 1: Freeze Drying Course - 6 July

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 Course will provide training and discussion of practical above aspects.

The day's topics will include Basic Process, Modeling, Formulation, and Metrology / PAT.

Course leader: Dr. Kevin Murgatroyd

Kevin Murgatroyd, Ph.D. has worked within the pharmaceutical industry since 1981, whilst he is primarily a GMP and steriles specialist with particular expertise in the field of freeze drying, he has practical experience in most dosage forms. We are very excited to have Kevin lead this Course. His course for ISL-FD at the Sao Paulo Conference was a big hit!

Much of his career has been involved with the provision, installation and validation of large items of pharmaceutical processing equipment, notably freeze dryers. Prior to entering consultancy, he worked for the three main freeze dryer vendors and has gained unique "hands on" experience in the specification, design, procurement, installation, commissioning and validation of freeze drying systems in addition to most types of sterile processing equipment. He has also gained a great deal of practical experience in the transfer of freeze drying cycles, both in scale up and in transferring into newer equipment.

For over 20 years, Kevin was the main lecturer at a commercial, international freeze drying course and has given many customer house and society lectures. He has also chaired and lectured at several specialist freeze drying conferences. He is a co-author of a freeze drying textbook, has written many articles in the scientific press and was involved in the writing of all the PHSS freeze drying monographs

What does it include?

A full day of lecturing

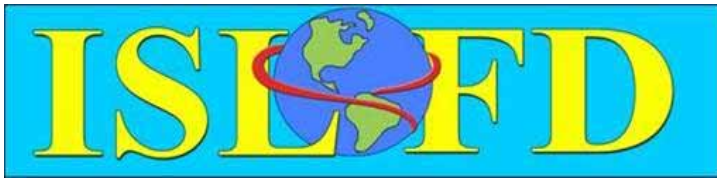
Seminar materials

Morning and afternoon coffee breaks

Lunch



Photo by Miguel-Angel Ramón / maramon



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DAY 2: Workshop 1 - 7 July

Workshop 1

Quality by Design

- Dr. Saša Nikolić (Reig Jofré Group, Barcelona, Spain)

During the Workshop, realization of a freeze-dried injectable product by means of Quality by Design will be presented in form of a case study, with the special emphasis on:

- Definition of Quality Target Profile
- Definition and justification of Critical Quality Attributes
- Freeze-drying process development for the definition of Critical Process Parameters
- Definition of a multidimensional Design Space
- Scale-up of the Design Space
- Development of Near Infrared Models for residual water prediction
- Development of the Process Performance Qualification Strategy
- Development and implementation of multivariate-data-analysis-based Advanced Control Strategy for Continued Process Verification

Participants will leave the workshop with a clear understanding of how to develop and implement Quality by Design and an efficient Advanced Control Strategy for a freeze-dried product.

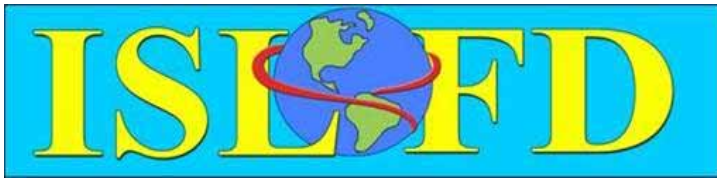
With the non-profit ISL-FD pricing, the workshops are an unequalled value. We hope you will consider attending. Please visit our website to register:

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Saša Nikolić, Ph.D. is Development and Innovation Manager at the Center of Excellence in Freeze Drying (Reig Jofré Group, Barcelona, Spain). He is a licensed pharmacist (University of Perugia, Italy) and he holds an MSc (University of Barcelona, Spain) and a PhD (University of Siena – University of Berlin), both in pharmaceutical technology. During his academic career, prior to joining Reig Jofre, he developed research activities in the field of application of nanotechnologies in the dermal and ophthalmic drug delivery. During his post-doctoral studies at the University of Barcelona, he focused on freeze-drying as means of stabilization of nanosuspensions. In his current role, he focuses on freeze-drying and aseptic process development, as well as the implementation of Quality by Design and continuous process verification strategy development and improvement. Dr Nikolić is also appointed as a lecturer for the post-graduate students at the University of Barcelona. He is author of various peer-reviewed papers and book chapters.



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DAY 2: Workshop 2 - 7 July

Workshop 2

Infrastructure Design and Organization

- Dr. Paul Stewart (Telstar Life Sciences, Barcelona, Spain)

The workshop will explore four elements which should be considered when transitioning the freeze drying process from a laboratory to an industrial scale:

- Formulation influences: potency and the presence of organic solvents;
- Supporting scale-up using advanced modelling;
- Facility layout options for Lyo-only and Lyo-Liquid production in Conventional, RABS and Isolated configurations.

Paul Stewart, Ph.D. has spent the past 25 years working in the Pharmaceutical industry and has held senior roles in R&D, Operations, Business Development, Sales & Marketing and General Management in the UK, the Netherlands, Italy, Spain and the USA. He has been involved in developments in aseptic filling, lyophilization, inspection, containment and automated handling technologies and advanced simulation and has most recently been promoting integrated pharmaceutical processing systems. He is currently President of Telstar North America and General Manager of Business Development for the Pharma Equipment division of Telstar Life Sciences. Paul was born in England and studied at the Universities of Sunderland and Cambridge; obtaining BSc and PhD awards in Engineering.

With the non-profit ISL-FD pricing, the workshops are an unequalled value. We hope you will consider attending. Please visit our website to register:

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DAY 3: Conference Presentations - 8 July

Keynote Address

9:00 **Current trends and challenges in freeze drying of biologics**
- Gerhard Winter

10:00 Coffee Break and Poster Session

Session 1: Formulation, chemistry

10:15 **Theory and Practice on alleged Buffer pH shifting during freezing in Lyophilized protein formulations**

- Dr. Jorge Sassone (PROQUIMO-IMPROVEMENT, Sao Paulo, Brazil)

The role of physical chemistry in freeze drying – from product characteristics to process performance

- Tim McCoy (Genzyme, Waterford, Ireland)

Formulation Related to Proteins

- Dr. Ted Randolph (University of Colorado, Boulder, USA)

11:45 Discussion

12:00 Lunch

Session 2a: Process development, cells and organisms

13:30 **Freeze-drying of Bacteria: State of the Art and New Perspectives**

- Dr. Stephanie Passot (AgroParisTech, Paris, France)

Lessons from Nature: the Role of Sugars in Cell Preservation

- Dr. Rongjun Chen (Imperial College, London, UK)

Formulation and Freeze Drying of Vaccine

- Jeffrey Blue (Merck, Telford, Pennsylvania, USA)

15:00 Discussion

15:15 Coffee Break and Poster Session

Session 2b: Process Development & Modeling

15:45 **Mathematical Models for Freeze-Drying of Granules**

- Dr. Roberto Pisano (Politecnico di Torino, Torino, Italy)

Moisture and Secondary Drying – Surface Area in Freeze Dried Materials

- Dr. Daryl Williams (Imperial College, London, UK)

Mechanics of 3D Cellular Freeze Dried Structures

- Dr. Sharmila McCartney-Devi (Imperial College, London, UK)

17:15 Discussion

Special Session: Facility Tour

17:45 **Facility Tour**

- Dr. Paul Stewart (Telstar, Barcelona, Spain)



DAY 3: Facility Tour – 8 July

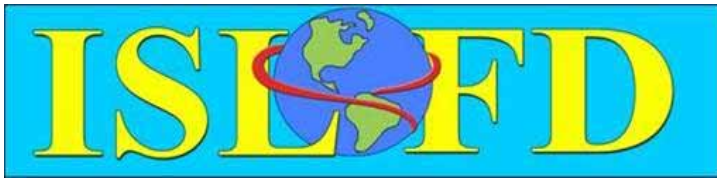


Facility Tour – Telstar

Our Silver Sponsor, Telstar Life Sciences, (Barcelona, Spain) has generously offered to make their facilities available for a tour with a special cocktail and networking session:

- 17:45 Bus to Telstar
- 18:30 Visit (1 h)
- 19:30 Cocktail in Telstar & Networking
- 20:45 Come back to the Hotels





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DAY 4: Conference Presentations - 9 July

Keynote Address

- 9:00 **High Throughput Approaches for the Development of Stable Lyophilized Formulations of Biopharmaceuticals**
- Dr. Tudor Arvinte (Therapeomic Inc., Basel, Switzerland)

10:00 Coffee Break and Poster Session

Session 3: Innovation

- 10:15 **Continuous Freeze Drying**
- Ir. Jos Corver (RheaVita, Eindhoven, Netherlands)
Manufacturing Principles of Freeze Dried Medical Device
- Dr. Sophie Declomesnil (Lyofal-Synerlab Group, Aix en Provence, France)
Containment Systems for Biopharmaceutical Freeze Drying
- Dr. Chris Cherry (Horizonpharma)
- 11:45 Discussion
-

12:00 Lunch

Session 4: Student Presentations

- 13:30 **Presentation 1**
- Student
Presentation 2
- Student
Presentation 3
- Student
- 14:30 Discussion
-

Special Session: Facility Tour

- 14:45 **Facility Tour**
- Dr. Enric Jo (Reig Jofré Group, Barcelona, Spain)
-

Special Session: ISL-FD Inc.

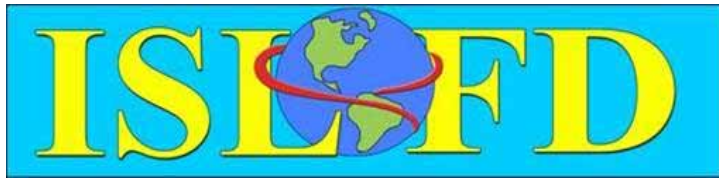
- 17:30 **Annual Meeting**
- Kevin Tebrinke (President ISL-FD Inc., Waunakee, WI, US)
-

Gala Dinner: Celebrate ISL-FD

- 19:30 **Annual Meeting**
- Gran Hotel Princesa Sofia



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DAY 4: Facility Tour – 9 July

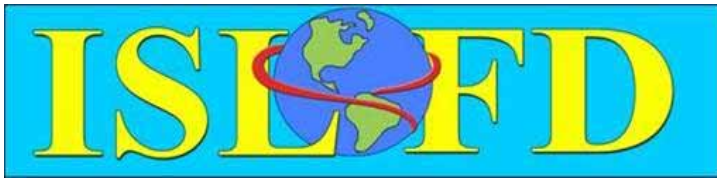
REIG  JOFRE

Facility Tour - Reig Jofré Group

We offer the possibility to visit our Center of Excellence in Lyophilization (CoEL). The CoEL has 2 pilot plant freeze driers, FDM, NIR, and so on.

The visit includes the possibility to see the industrial plant with 4 large scale freeze driers in two different sterile rooms.





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DAY 5: Conference Presentations - 10 July

Session 5: Developments in Freeze Drying

8:00 **Title To Be Announced**

- Maik Guttzeit (GEA Lyophil, Hürth, Germany)

Title To Be Announced

- Michele Arduini (IMA, Bologna, Italy)

Title To Be Announced

- Open

Title To Be Announced

- Open

10:00 Discussion

10:15 Coffee Break and Poster Session

Session 6: Regulatory, Quality by Design and PAT

10:30 **Dynamic Design Space Approach for the Validation of Pharmaceutical Freeze-Drying**

- Dr. Thomas de Beer (Ghent University, Ghent, Flanders, Belgium)

Process Analytical Technology and the Question of Scale

- Dr. Geoffrey Smith (De Montfort University, Leicester, UK)

Regulatory Issues

- Manuel Ibarra (Spanish Agency of Medicines and Medical Devices)

12:30 Discussion

12:45 Lunch

Closing Session

14:00 **Thomas Jennings Award Presentation**

Louis Rey Award Presentation

Jos Corver, Program Committee Chairperson

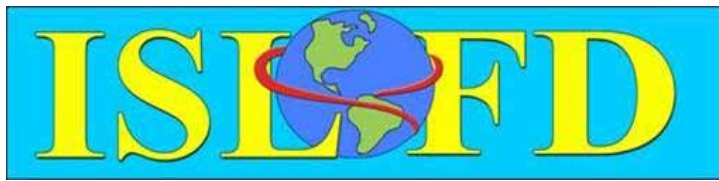
Closing Remarks

- Eric Jo, Organizing Committee Chairperson

- Kevin Tebrinke, President ISL-FD Inc.



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Location

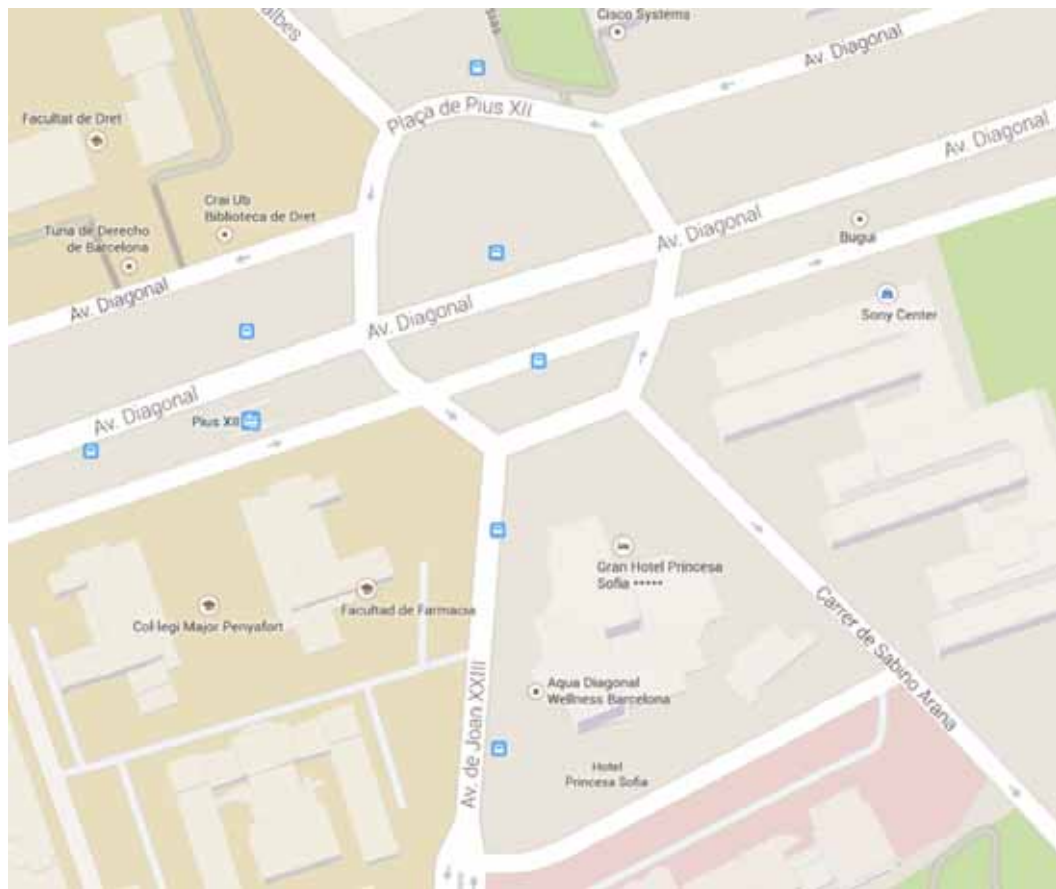
Facility

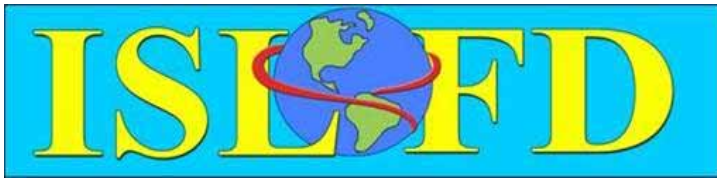
ISL-FD Inc. is pleased to work with Universitat de Barcelona to provide a very favorable setting for our Seminar. Located across the street from the Gran Hotel Princesa Sofia.

Diagonal Campus | Joan XXIII, 27-31 | 08028 Barcelona



Barcelona College of Pharmacy





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Directions

From Aeropuerto de Barcelona

Taxi: The cost is approximately 20-30€.

Train + metro: The cost is 2€ unless you buy a ticket of 10 trips (T-10), that has a cost of 9,95€ (0.95€/trip). You can use the same ticket for the train and the metro.

Aerobús + metro: the price of aerobús is 5.90€ single trip or 10.20€ round-trip. The price of the metro is 2€ unless you buy a ticket of 10 trips (T-10), that has a cost of 9,95€ (0.95€/trip)



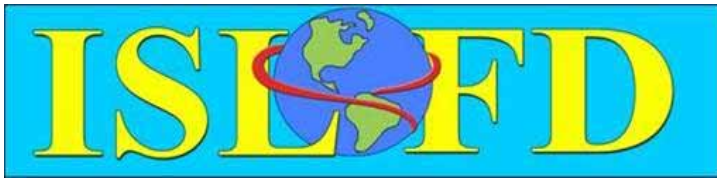
From Airport Girona

90 km distance (airlines Transavia, Ryanair, Wizz Air, Jetairfly, Transaero) to Barcelona center

Aerobus: 25€ ticket, 60 minutes

Taxi: 140€





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I would like to extend a personal thanks to these Sponsor Companies, who have supported our non-profit work with their financial and other efforts. They make it possible for us to provide various assistance to students and other lyo based education. Please visit them and let them know that you also appreciate their support.

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

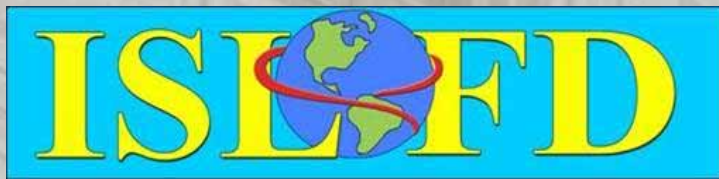
Gold Sponsor



Silver Sponsor



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	by June 10th		after June 10th	
	Members & Non Members ISLFD	Government/ Health Authorities /Academic	Members & Non Members ISLFD	Government/ Health Authorities /Academic
Seminar	450 €	150 €	495 €	165 €
Workshop	450 €	150 €	495 €	165 €
Conference	750 €	350 €	825 €	385 €
Gala dinner	80 €	0 €	88 €	0 €
Table top	1,600 €	0 €	1,760 €	0 €
Special Combination Discount:				
Confer + Semin + Wshop	1,485 €	585 €	1,634 €	644 €
Confer +Sem (or Wshop)	1,080 €	450 €	1,188 €	495 €

Visit our Conference Website for details, registration, and discounted hotel

<http://islyophilization.org/2015-barcelona/>

International Society of Lyophilization – Freeze Drying Inc.

The Society is a non-profit all – volunteer organization (registered in the State of Delaware in the United States) whose mission is to promote and advance the field of lyophilization (lyophilisation) by personal interaction using the Internet and supporting programs that provide financial and/or material assistance to those who need it. It is also dedicated to the promotion of friendship and understanding throughout the International Community by conducting meetings at various locations throughout the world. Our mission includes help for students who are studying in the field of lyophilization – freeze drying.

Questions? Email us at islfid.inc@gmail.com