qepler

BRONZE SPONSOR

CHRIST

BRONZE SPONSOR

偉博海泰 Weibo Hi-Tech

goethe biotechnology

BRONZE SPONSOR

PiGo®

- 10+ Program Hours | 8+ Networking Hours
- Refreshments & Coffee Breaks
- Business Lunches & Dinner
- Case Studies
- Panel Discussions | Q & A

PHARMACEUTICAL LYOPHILIZATION SUMMIT 2019

February 13-14, 2019 | Prague, Czech Republic

Venue:

Novotel Praha Wenceslas Square Hotel

Katerinska 38, 120 00 Prague

ACCOR HOTELS
Feel Welcome

qepler

SPEAKERS BOARD

Bram Jongen — CHAIR
Head of R&D, PPS
Datwyler Pharma Packaging International NV, BE

Patrick Garidel
Head of Process, Purification and Pharma Development, Biopharma
Boehringer Ingelheim, DE

Stefan Schneid
Laboratory Head Formulation Development Parenterals
Bayer, DE

Richard Denk
Head of Sales Containment
Skan AG, CH

Michael Dekner
Head Fill&Finish Life Cycle Management support
Shire Austria GmbH
now part of Takeda, AT

Prof. Geoff Smith
Professor of Pharmaceutical Process Analytical Technology
De Montfort University, UK

Hewei Li
Chief Engineer & CEO
Weibo Hi-Tech Group, CN

Orla McGarvey
Principal Group Leader, Drug Product Process Development
Lonza AG, CH

Anthony Cannon
Regional Director, ExM, Global Tech Ops, Sterile
MSD International, CH

Florent Peral
Formulation Scientist - Bioprocess R&D
Sanofi Pasteur, FR

Dr. Frank Harms
Managing Director
Martin Christ Gefriertrocknungsanlagen GmbH, DE

Mire Zloh
Honorary Professor
UCL School of Pharmacy, UK

Georg Frinke
Facility & Process Engineer
Bayer Pharmaceuticals, DE

Martin Frei
Process expert, Novartis Technical Operations
Novartis, CH

Thomas De Beer
Professor at Ghent University – CTO of RheaVita
Ghent University, BE

Dr. Sune Klint Andersen
Principal Scientist DPD – Oral Solid Dosage
Janssen, BE

BRONZE SPONSOR

CHRIST

Martin Christ Freeze Dryers is a world leader in the development and manufacturing of freeze dryers, with over 70 years of experience. Our product portfolio encompasses laboratory units, pilot systems and production systems as well as vacuum concentrators for an extremely wide range of applications and process requirements.

The name Christ stands for utmost customer satisfaction everywhere in the world. We develop and manufacture our products in accordance with the most stringent quality requirements to provide superior customer benefits. Our corporate strategy is focussed on your applications.

We see ourselves as a worldwide leader in innovation, and we regard our commitment to research and development as a major duty. Even more importantly, it is our greatest passion. We constantly secure our position as an international leader by means of technological innovations in freeze drying and rotational vacuum concentration – and dozens of patents held by our company and our employees provide irrefutable evidence of this.

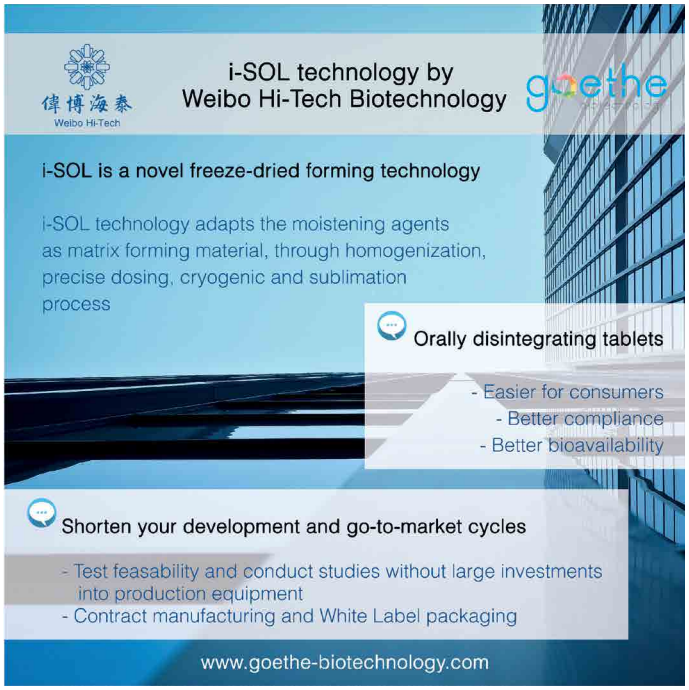
The corporate group headquartered in Osterode (Germany) consists of Martin Christ Freeze Dryers and Sigma Laboratory Centrifuges. The unique complementary nature of the individual business and research areas of the two companies leads to a constant transfer of expertise as well as uniform resource management, and ultimately to highly efficient synergy effects appreciated by our customers. Trust our competence.

BRONZE SPONSOR

偉博海泰 Weibo Hi-Tech goethe biotechnology

In close co-operation with the Beijing University of Chinese Medicine Beijing Wei Bohai Tai (WeiBo) has developed the i-SOL Technology.
Company foundation and completion of first laboratory and production site in 2010 in Beijing.
Offering for product development and contract manufacturing for health care and cosmetical products.
Second, high-volume production site according to GMP Standards started operations in 2012 in Changzhou, with a capacity of 100 Mio. blister p.a.
A third production site and campus with separate pharmaceutical production is in construction stage and will go live 2019 in Changzhou.

GOETHE Biotechnology is the European representative of WEIBO and offers development and production outsourcing for new products to health and cosmetics companies. This represents not only a very cost efficient, but a unique method unmatched in the market.
As a contract manufacturer we offer the pharmaceutical, cosmetics and nutritional supplements industries the development of products as freeze-dried dosage forms. This approach proves very efficient for companies and will complement many established products in the future, if not even replace them.
Secure your innovative edge against your competitors and benefit already today of tomorrow's technology.
With us you can determine very quickly, if one of your products is suitable for this technology without the need of large investments on your side.
We manufacture all products as White Label with your complete brand design and packaging.



BRONZE SPONSOR

PiGo®

PIGO is specialized in building FREEZERS, FREEZE DRYERS AND CONTINUOULS MULTISTAGE BELT ADIABATIC DRYERS, as well as fruit and vegetable processing equipment, product line which includes a broad range of standard and custom units with an extensive experience in both freezing and fruit & vegetable processing. Together with our partners, we have installed our machines throughout the world. Our systems have been supplied to companies in Europe, Africa, Australia, USA and Asia by our company and our partners in the industry. Strong internationalization and worldwide market targeting have lead PIGO to endorse and exploit the concept of flexibility in manufacturing of its products.

Our production process is precisely structured and divided in phases, thus ensuring top quality of each component/phase. The entire manufacturing and installation process is led by a strong team of engineers that over the years designed and developed our machines to their current features.
Strength of our concepts and top quality of our products are further confirmed by numerous references and satisfaction of our clients.

qepler

PHARMACEUTICAL LYOPHILIZATION SUMMIT 2019

February 13 | Prague, Czech Republic

07:50 - 08:30 — Registration and Welcome Coffee

08:30 - 08:40 — Opening Address from the Chairman

MANUFACTURING & PROCESS DEVELOPMENT

08:40 - 09:20

Evaluation of an innovative spray freeze drying method and comparison to standard lyophilization

- Introduction and application examples
- Case study for pharmaceutical development
- Pro's and Con's of each technology, Outlook

Stefan Schneid | Laboratory Head Formulation Development Parenterals | Bayer, DE

09:20 - 10:00 — Speed Networking

10:00 - 10:40

MTM / BTM – a perpetual PAT Tool for Batch Based Lyo-Cycles

- History, Current state and Latest development

With the beginning of industrial freeze drying in the late 40ies, a dynamic control procedure has been introduced. Based on steady scientific efforts, the performance of this procedure has been continuously improved. Though, this method has now become a robust detection procedure for the sublimation pressure at the ice front, there is still optimization potential remaining. The presentation will provide an historical overview and will discuss pro & cons of this measurement procedure. Finally an outlook will be provided.

Georg Frinke | Facility & Process Engineer | Bayer Pharmaceuticals, DE

10:40 - 11:10 — Morning coffee and networking break

11:10 - 11:40

Overview and practical use of PAT-tools for the freeze drying process development

BRONZE SPONSOR

- Importance of PAT-tools during the freeze drying process
- From product temperature measurement to Controlled Nucleation – standards and latest development in PAT-tools
- The use of PAT-tools in practice – examples and comparison of results
- Summary

Dr. Frank Harms | Managing Director |
Martin Christ Gefriertrocknungsanlagen GmbH, DE

11:40 - 12:20

Impedance Spectroscopy : Recent Developments as a Process Analytical Technology for Pharmaceutical Freeze-Drying

- Impedance spectroscopy for beginners
- Through Vial Impedance Spectroscopy (TVIS)
- In situ determination of: (i) ice nucleation temperature; (ii) solidification end point, (iii) glass transition temperature; (iii) Primary drying end point

Prof. Geoff Smith | Professor of Pharmaceutical Process Analytical Technology |
De Montfort University, UK

12:20 - 13:30 — Business lunch

13:30 - 14:10

Freeze-Drying of High Concentration Biologics

- What are high concentration biologics?
- CMC issues for high concentrated biologics
- Challenges encountered for freeze drying thereof

Patrick Garidel | Head of Process, Purification and Pharma Development, Biopharma |
Boehringer Ingelheim, DE

qepler

PHARMACEUTICAL LYOPHILIZATION SUMMIT 2019

February 13 | Prague, Czech Republic

14:10 - 14:50

Ever tried. Ever failed. No matter. Try again. Fail again. Fail better! A (more) rational approach to lyo cycle development

- From trial and error to rational design
- Experimental setup
- Mathematical modelling of additional parameters
- Lessons learned

Michael Dekner | Head Fill&Finish Life Cycle Management support | Shire Austria GmbH now part of Takeda, AT

14:50 - 15:20 — Afternoon coffee and networking break

15:20 - 16:00

Anatomy of the Lyophilization Process: Considerations for a Successful Tech Transfer

- Tech transfer of a lyophilized product
- Overview of the lyophilization process and the critical process parameters
- Specific focus on the technical considerations with analysis of the impact on the lyophilization recipe
- Impact of deviations to the CPPs on the product quality during transfer activities

Anthony Cannon | Regional Director, ExM, Global Tech Ops, Sterile | MSD International, CH

16:00 - 16:40

Scale-Up, Process Transfer and Improving Predictive Outcome for Lyophilized Drug Product

- Key considerations in Scale-up of a Freeze-Drying Cycle
- Review of advancements in the Industry over the last 15 years
- Case Study: 'Development Scale to Pilot Scale and Beyond'

Orla McGarvey | Principal Group Leader, Drug Product Process Development | Lonza AG, CH

16:40 - 17:20

A Continuous and Controlled Pharmaceutical Freeze-Drying Technology for Unit Doses

Driven by growing needs in the biopharmaceutical market and regulatory pressure, a continuous and controlled freeze-drying technology for unit doses to preserve biopharmaceuticals has been developed. Such continuous process allows a more efficient, cheaper, greener and controllable manufacturing method compared to traditional batch production systems, offering competitive advantages and business opportunities. Pharmaceutical freeze-drying (lyophilization) is a low-temperature drying process in which aqueous solutions of heat-labile biopharmaceuticals are converted into solids with sufficient stability for distribution and storage. Similar to all manufacturing processes of drug products (solids, semi-solids and liquids), conventional pharmaceutical freeze-drying is generally accomplished using batch processing that is considered time-consuming, costly, non-flexible and lacking robust quality control and real-time release. Four major industrial drivers are demanding a more efficient and better controllable pharmaceutical freeze-drying technology for unit doses: cost-cutting, regulatory pressure, a fast growing biopharmaceutical market and an ageing population requiring more personalized medicines. The continuous and controlled freeze-drying technology, developed following the principle of model based design, offers clear advantages over current batch production such as cost reduction (up to 50%), track-and-trace product quality control, and a significant reduction of processing time (> 40 times faster, e.g. 1 hour instead of 5 days at a vial level), reduced need for clean room and a substantial sustainability gain.

Thomas De Beer | Professor at Ghent University – CTO of RheaVita | Ghent University, BE

17:20 - 17:50 — Panel Discussion

- Space design application in lyophilization cycle development and scale-up.
- Process Analytical Technology, Scale-Up and Technology Transfer, Process Development and Characterization.
- Validation strategies.
- Open source approach to development of freeze drying processes.
- How important are the interactions between the formulation components (solutes, ions) and the glass forming the container (vial)?
- Future of Dual chamber prefilled syringes and cartridges.
- Current regulatory expectations for extractables & leachables on lyophilized drug products.
- How to overcome stickiness of vials to the lyophilization shelve upon opening?
- Continuous freeze-drying as alternative for batch freeze-drying.

17:50 - 18:00 — Chairman's closing remarks and end of day one

19:00 - 21:00 — Business dinner

qepler

PHARMACEUTICAL LYOPHILIZATION SUMMIT 2019

February 14 | Prague, Czech Republic

08:00 - 08:30 Registration and Welcome Coffee

08:30 - 08:40 Opening Address from the Chairman

FORMULATION DEVELOPMENT

08:40 - 09:20

Inactivated Zika virus vaccine – fast track drug product development – formulation and lyophilization design space study

The Zika virus (ZIKV) epidemic which occurred throughout Latin America, led The World Health Organization (WHO) to declare a Public Health Emergency of International Concern (PEIC) in February 2016. An inactivated Zika vaccine, developed by the Walter Reed Army Institute of Research, was found to be protective in animal models. This vaccine was transferred to Sanofi Pasteur where the viral seed was regenerated in serum-free Vero cells and process development was carried out to produce material to be used for further pre-clinical and clinical evaluation. The case study reported here focuses on the fast track drug product development with a strategy driven by a process/ product risk analysis to support the selection of the appropriate stabilizing formulation and freeze-drying process. Finally a Design of experiment approach is presented where the combination effect of formulation and lyophilization parameters are assessed in a design space study.

This project has been funded in whole or in part with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, under Contract No. HHSO1002016000039C.

Florent Peral | Formulation Scientist - Bioprocess R&D | **Sanofi, FR**

SANOFI PASTEUR Empowering Life

09:20 - 10:00

In silico modelling of freeze drying processes

Development of protein therapeutics formulation relies on the selection of excipients that stabilize protein and/or prevent aggregation. Experimental strategies to optimize formulations use force degradation studies and involve screening many combinations of excipients and buffers. However, these effective methods do not readily provide information on intermolecular interactions responsible for the protective effects of excipients. *In silico* methods may be employed to evaluate interactions that may form between selected therapeutics during freeze drying pharmaceutical formulations. A combination of molecular docking methods has been successfully utilized to predict hotspots for protein excipient interfaces on a model protein, which were confirmed by molecular dynamics in presence of explicit solvent and buffer components. Furthermore, simulated annealing simulations of freezing and drying processes provide insights into protective effects of formulations on a molecular level.

This combination of approaches could provide information about the interactions of excipients in formulations and guide the computer aided development of future formulations.

Mire Zloh | Honorary Professor | **UCL School of Pharmacy, UK**

UCL SCHOOL OF PHARMACY

10:00 - 10:30 Morning coffee and networking break

10:30 - 11:10

A new Freeze dried forming technology, a new type of fast consumable products

BRONZE SPONSOR

- A new Freeze dried forming preparation which has higher drug loading will suitable for fast consumable products.
- Brief introduction of I-sol Technology.
- Technical Achievements of Weibo Hi-tech Group.
- Future Development trend: Freeze-dried product, which is preservative free and high activity, will replace traditional liquid forms of skin care products & health food supplement.

Hewei Li | Chief Engineer & CEO | **Weibo Hi-Tech Group, CN**

伟博海泰 Weibo Hi-Tech

TESTING & MONITORING

11:10 - 11:50

Container Closure Integrity Testing using deterministic techniques like He-leak

- Revision of USP <1207>, 'Sterile Product Packaging – Integrity Evaluation'
- Highlights of the different test methodologies
- He-leak & Laser Based Headspace Analysis techniques

Bram Jongen | Head of R&D, PPS |
Datwyler Pharma Packaging International NV, BE

DATWYLER

qepler

PHARMACEUTICAL LYOPHILIZATION SUMMIT 2019

February 14 | Prague, Czech Republic

11:50 - 13:00 — Business lunch

SAFETY & RISKS MITIGATION

13:00 - 13:40

GMP and Occupational Safety Requirements for Lyophilization of high potent/toxic substances

- What are high potent/toxic substances
- GMP Requirements for high potent/toxic substances
- Cleaning and Cross Contamination Requirements for Lyophilization based on the PDE (Permitted Daily Exposure)
- Occupational Safety Requirements

Richard Denk | Head of Sales Containment | Skan AG, CH

13:40 - 14:20

Lyophilization: Silicon oil contamination risk and mitigation strategies

- Silicone oil in the freeze-drying process
- Mass spectroscopy
- Case study Silicon oil leakage
  - Detection
  - Remediation
  - Learnings and improvements

Martin Frei | Process expert, Novartis Technical Operations | Novartis, CH

14:20 - 14:50 — Afternoon coffee and networking break

INNOVATIONS & ADVANCED TECHNOLOGIES

14:50 - 15:30

Smart rubber stopper selection for Lyophilization

- Selection of a rubber stopper design intended for lyophilisation purposes
- Reduction of stopper stickiness to lyophilisation shelves
- Effect of the rubber formulation on moisture content
- Low moisture rubber formulations and effect on the freeze-dried cake, combining different methods

Bram Jongen | Head of R&D, PPS |
Datwyler Pharma Packaging International NV, BE

15:30 - 16:10

Innovations in Drying Processes for Biopharmaceuticals

- Challenges in drying of biopharmaceuticals
- Low temperature and low shear drying methods
- Continuous drying methods
- Mathematical modelling

Dr. Sune Klint Andersen | Principal Scientist DPD – Oral Solid Dosage |
Janssen, BE

16:10 - 16:50 — Panel Discussion

16:50 - 17:00 — Chairman's closing remarks and end of day two

qepler

PHARMACEUTICAL LYOPHILIZATION SUMMIT 2019

BIOGRAPHIES

Bram Jongen
Head of R&D, PPS
Datwyler Pharma Packaging International NV, BE

After his Masters in Polymer Chemistry at the University of Louvain, Belgium, Bram Jongen acquired a Ph.D. in Water Soluble Polymers used for advanced drug administration.

Bram started as Technical Support Manager for Datwyler about 14 years ago, supporting customers in a vast area, from Western European countries to countries like India, Korea, and South Africa. Thereafter, he headed the Global Product Introduction & Support team, a global team of highly experienced and educated people, having each their own expertise in the world of pharmaceutical closures. Bram himself acquired profound Extractables & Leachables expertise. His team managed customer projects of technical nature and supported Datwyler's product and portfolio management.

Since end of 2012, he has been acting as Head of R&D, leading a group that focuses on developing new rubber and new coating materials.

Richard Denk
Head of Sales Containment
Skan AG, CH

Richard Denk has studied mechanical engineering and did examination on Experts of GMP, Qualification and Validation, Pharmaceutical Auditing, Pharmaceutical Engineering, Quality Control on the University of Applied Sciences in Albstadt/Sigmaringen Germany. Richard Denk is working at the company SKAN AG, headquartered in Allschwil CH in the position Head Containment. Mr. Denk founded 10 years ago the expert Containment group CoP of the ISPE D / A / CH. The ISPE CoP Containment published the ISPE Containment Manual in September 2015. The ISPE Containment Manual does provide a full overview on Containment. Furthermore, Mr. Denk is author at Maas & Peither GMP Publishing on containment and hygienic design and one of the authors of the ISPE Oral Solid Dosage Baseline Guide Volume 2 and Volume 3. Mr. Denk has spent more than 20 years with the subject production of highly active / highly hazardous substances and has developed the containment pyramid.

Michael Dekner
Head Fill&Finish Life Cycle Management support
Shire Austria GmbH now part of Takeda, AT

Michael Dekner
10/2017 – present: Head Fill&Finish Life Cycle Management support. Leading a team of senior manufacturing scientists responsible for process monitoring, technical product stewardship and process development, audit support, knowledge brokers, risk management (QbD) and linking to industrial and academic networks.
04/2015 – 10/2017: Shire (Baxalta), Innovation Manager, Lead Enhanced Process Control establishing innovation management process, communication, development of technology strategy and roadmap for real time release, technology scouting, linking to industrial and academic networks.
02/2014 - present: Lecturer for University of applied sciences Campus Wien, Downstream Processing - Lyophilization.
10/2011 – 04/2015: Baxter Bioscience AG, Supervisor Lyophilization and Crimping LA24B, aseptic processing, lyophilization, crimping, material flow, trouble shooting and maintenance, change management, NCR, leading 26 FTEs, coordination of an internal community of practice (Lyophilization), SME in projects on lyophilization and crimping, presenting at audits (FDA,…), continuous improvement.
06/2006 – 09/2011: f-star Biotechnologische Forschungs und Entwicklungs Ges.m.b.H; Scientist - screening, selection, expression and purification of binding antibody fragments, cell culture, protein engineering, immunology, analytics, microbial cultivation, cell sorting, molecular biology, fire safety, biological safety.
04/2006 - 05/2006: University of Natural Resources and Life Sciences, Vienna / Department of Biotechnology , Scientist - strain improvement
09/2004 - 03/2006: Biomin Gesunde Tierernährung International Ges.m.b.H, Scientist - enzyme production, fluidized bed coating, large scale cell cultivation, enzyme analytics, scientific support of master students
05/2004 - 05/2006: Lecturer for University of applied sciences Wiener Neustadt / Tulln, Biotechnology and Applied Microbiology

Prof. Geoff Smith
Professor of Pharmaceutical Process Analytical Technology
De Montfort University, UK

Geoff Smith is Professor of Pharmaceutical Process Analytical Technology in the Leicester School of Pharmacy at De Montfort University (UK). His research group focusses on pharmaceutical applications for impedance, dielectric and terahertz spectroscopies alongside optical techniques such as laser speckle and optical flow.
He is responsible for the development of through-vial impedance spectroscopy (TVIS) as a PAT tool for monitoring phase behaviour (ice formation and eutectics), ice interface temperatures, primary drying rates and end points. This development marks the first time that impedance spectroscopy has been used to characterize materials within conventional glass freeze-drying vials, without having to insert the electrodes into the product (i.e. the solution under-going freeze-drying). This feature of the technology sets it apart from other in-process impedance measurement systems, in which a bulky electrode assembly is inserted into the solution being freeze-dried, to provide a product-non-invasive technology.

Florent Peral
Formulation Scientist - Bioprocess R&D
Sanofi Pasteur, FR

Florent Peral studied bioprocess in Ecole de Biologie Industriel –EBI in Cergy Pontoise, France and received his MSc in 2009. He spent 2 years in Genzyme Lyon as bioprocess associate on polyclonal antibodies DSP manufacturing. Subsequently, he held a position for 3 years at LFB Biotechnologies, focusing on formulation and lyophilization process development on plasmatic and recombinant proteins. After 18 months working on lentiviral vector used for gene transfer at the biotech startup Theravectys, he joined Sanofi Pasteur as a formulation scientist in October 2016.

Anthony J. Cannon
Regional Director, ExM, Global Tech Ops, Sterile
MSD International, CH

Tony is currently Regional Director of Global Technical Operations, External Manufacturing for Sterile Products at MSD International located in Lucerne, Switzerland. He is responsible for all technical support of sterile drug products for external manufacturing operations for the European Region. He has held various positions throughout his career in Sterile Drug Product development and manufacturing with a focus on formulation and process development of both liquid and lyophilized parenterals, final container development and optimization, medical devices and drug delivery. He has over 20 years' in the industry with experience in biologics (plasma products, proteins, peptides, liposomes, vaccines; viral and bacterial), small molecules, nanocrystals, medical devices, reagents, nutriceuticals and cytotoxics, focused on lyophilization development and manufacturing. He has also presented on the fundamental of lyophilization, formulation, process development, thermal characterization, finished product analysis, and scale up and tech transfer at various conferences, seminars and pharmaceutical and biotech companies in North America, Europe and Asia.

Stefan Schneid
Laboratory Head Formulation Development Parenterals
Bayer, DE

Stefan Schneid, Ph.D.
Bayer AG, Pharmaceuticals, Wuppertal, Germany.
Stefan Schneid is currently a laboratory head in the formulation development department at Bayer AG. In this function, he develops formulations and processes for novel biological entities and small molecules, and is involved in development projects from pre-clinical stage up to transfer to commercial production.
Previously Dr. Schneid worked as R&D Manager at Syntacoll GmbH in Saal, Germany, where he was responsible for the development of novel formulations and analytical methods for drug-containing biodegradable implants for parenteral application. Until 2010, he was a post-doctoral research fellow in the Freeze Drying Focus Group at the University of Erlangen, and spent one year as a visiting scientist in Prof. Michael Pikal's lab at the University of Connecticut.
Stefan Schneid holds a degree of pharmacy from the University of Munich, and received his Ph.D. in Pharmaceutics from the University of Erlangen in 2009 for his dissertation thesis titled "Investigation of Novel Process Analytical Technology (PAT) Tools for Use in Freeze-Drying Processes". He developed and optimized the formulation and manufacturing process of various predominantly lyophilized pharmaceuticals including proteins, peptides, vaccines and small molecules.

Hewei Li
Chief Engineer & CEO
Weibo Hi-Tech Group, CN

Dr. Li had led a R&D team to develop an innovative freeze-dried forming technology (i-sol technology)from 2002, and 72 patents had been applied for this technology.
According to i-sol technology, Dr. Li designed an innovation production routes, and cooperated with well-known international pharmaceutical equipment enterprises to break the monopoly of international companies on the production technology. At the same time, he established the first freeze-dried forming production workshop in China with the requirements of industrial production capacity, and passed the GMP certification of CFDA drug production.
In 2013, Dr Li established the first domestic production line of freeze-dried forming product with an annual production capacity of 600 million pieces, which realized large-scale production, and expanded the application field to fast consumable products, such as skin care, make up, health supplement, etc.

qepler

PHARMACEUTICAL LYOPHILIZATION SUMMIT 2019

BIOGRAPHIES

Thomas De Beer
Professor at Ghent University – CTO of RheaVita
Ghent University, BE

Thomas De Beer graduated in pharmaceutical sciences in 2002 at the Ghent University in Belgium. He obtained his PhD at the same university in 2007. For his PhD research, he examined the suitability of Raman spectroscopy as a Process Analytical Technology tool for pharmaceutical production processes. Within his PhD research period, he worked four months at University of Copenhagen in Denmark, Department of Pharmaceutics and Analytical Chemistry (Prof. Jukka Rantanen). After his PhD, he was an FWO funded post-doctoral fellow at the Ghent University (2007-2010). Within his post-doc mandate, he worked 9 months at the Department of Pharmacy, Pharmaceutical Technology and Biopharmaceutics from the Ludwig-Maximilians-University in Munich, Germany (Prof. Winter and Prof. Frieß). In February 2010, he became professor in Process Analytics & Technology at the Faculty of Pharmaceutical Sciences from the university of Ghent. His research goals include bringing innovation pharmaceutical production processes (freeze-drying, hot-melt extrusion, continuous from-powder-to-tablet processing etc.). More specifically, Prof. De Beer contributes to the development of continuous manufacturing processes for drug products such as solids, semi-solids, liquids and biologicals (continuous freeze-drying of unit doses). Thomas De Beer is also director of Ghent University's Center of Excellence in Sustainable Pharmaceutical Engineering (CESPE) which is founded in 2016. In 2018, Thomas De Beer became co-founder and CTO of the Ghent University spin-off company RheaVita which provides a continuous freeze-drying technology for the pharmaceutical market.

Orla McGarvey
Principal Group Leader, Drug Product Process Development
Lonza AG, CH

As a leader in Contract Development and Manufacturing, Lonza Pharma & Biotech is recognised for high quality service, global capacity, an innovative tech platform and extensive experience. Lonza has a broad expertise in biologics, small molecules, bio-conjugates and cell & gene therapy, supporting pre-clinical stage through to commercialisation, for both drug substance and drug product. Orla McGarvey is Principal Group Leader in Lonza's Drug Product Services Division, supporting DP Process Development. Orla's career to date in the pharmaceutical and biotech industry spans over 16 years working in the field of formulation and drug product development, with extensive experience in lyo cycle development, scale up and tech transfer while working in the USA with the world's leading experts and pioneers in the field of freeze-drying.

Martin Frei
Process expert, Novartis Technical Operations
Novartis, CH

Martin Frei, Process expert, Novartis Technical Operations

Martin has completed his training as senior scientific laboratory technician.
For over thirty years, Martin has been working in the pharmaceutical development of active substances and dosage forms.
Martin is a senior expert in the field and was part of the Team, which constructed and built our facility 10 years ago for aseptic filling of sterile drug products in conventional clean rooms and isolator technology. Since than he serves as senior process expert with focus on freeze drying, cleaning strategies and carry over risks.

Mire Zloh
Honorary Professor
UCL School of Pharmacy, UK

Mire Zloh is a Honorary Professor at the UCL School of Pharmacy. Previously, Prof. Zloh has worked as Research Professor and Head of Pharmaceutical Chemistry at the University of Hertfordshire as well as a Senior Lecturer and Director of the Centre for Structural Chemistry at the UCL School of Pharmacy. He was awarded an MSc in Physical Chemistry by University of Belgrade and earned a PhD in Chemistry at the University of London. Prof. Mire Zloh has authored more 110 scientific publications and reviews. His research interests include drug design, structural chemistry and rational development of dendrimers as drug delivery systems. He is currently working on the method development for computer aided design of formulations.

Georg Frinke
Facility & Process Engineer
Bayer Pharmaceuticals, DE

Georg holds an Engineering degree (Technical University/Cologne). He works as facility & process engineer at Bayer Pharma and with responsibility responsible for the technical operation of the parenteral facility. Previously, he worked as Process Engineer for Optima (Klee) and GEA Lyophil / Steris. Among others, he is specialized in the development of customized Freeze-Drying processes (particularly upscaling with PAT) and in the qualification (FAT, SAT, IQ, OQ, PQ) of pharmaceutical freeze dryers.

Dr. Frank Harms
Managing Director
Martin Christ Gefriertrocknungsanlagen GmbH, DE

After his study of mechanical and process engineering at the University of Hanover he achieved his PhD in thermodynamics in 1994. After this Frank worked in different technical and management positions in international companies manufacturing and selling equipment and systems for the process industry worldwide. Since 2010 Frank is working as a Managing Director for Martin Christ Gefriertrocknungsanlagen GmbH; his focus areas are R&D, technology and business development.

Dr. Sune Klint Andersen
Principal Scientist DPD – Oral Solid Dosage
Janssen, BE

Dr. Andersen is a principal scientist in spray drying and enabling technologies at Janssen Research & Development, Belgium. He has an MBA in management & technology and a PhD in chemical engineering, with a specialization in nanoparticle technology. His main interests and experience include the development of drying processes for drug products, drug substances, intermediates, excipients for both R&D and industrial scale purposes, application of quality-by-design in drying processes, validation and qualification of spray dryers, advantages & disadvantages of spray vs freeze-drying processes, continuous manufacturing, and enabling technologies for drug products

Patrick Garidel
Head of Process, Purification and Pharma Development, Biopharma
Boehringer Ingelheim, DE

Dr. Patrick Garidel is currently employed as associate director protein science at Boehringer Ingelheim Pharma GmbH & Co. KG. His activities are focused on the development biologics from the downstream process to drug product (liquid and solid formulations, freeze-drying). His expertise covers: development of drug delivery system and formulations, packaging/devices, process development, bio-analytic, and protein purification. He is responsible for the establishment of innovative platform technologies for e.g. powder inhalation, gene therapy, in silico based predictive tools for molecule properties, and particle analytics. Additionally, he is interested in the development of new concepts and strategies for protein purification, stabilisation, delivery and protein/ colloid chemistry in general. PG studied chemistry and biotechnology at the University of Kaiserslautern and pharmaceutical sciences at the University of Strasbourg. He has a PhD in biophysics. During his academic career, he took over various post doc positions at the Institute for Pharmaceutical Technology and Biopharmacy, physical chemistry at the Martin Luther University Halle/ Wittenberg, DESY, Rutgers University and Hospital for Special Surgery

REGISTRATION FORM

This registration form is editable.
When you have completed the form - please save and email it to register@qepler.com

SUMMIT NAME: Pharmaceutical Lyophilization Summit 2019, Novotel Praha Wenceslas Square Hotel ACCOR HOTELS Feel Welcome

REGISTRATION DATE:

TOTAL PRICE:

PROMOCODE:

PACKAGE NAME:

PACKAGE NAME	Register by 16.11.2018	Register by 14.12.2018	Register by 31.01.2019	Standard price
Individual ticket (2 Days)	€1195 (save €500) ☐	€1395 (save €300) ☐	€1495 (save €200) ☐	€1695 ☐
Individual ticket (1 Day)	€795 (save €200) ☐	€845 (save €150) ☐	€895 (save €100) ☐	€995 ☐
Group ticket (2-3 delegates)	€995 (save €600) ☐	€1195 (save €400) ☐	€1295 (save €300) ☐	€1595 ☐
Group ticket (4+ delegates)	€795 (save €700) ☐	€895 (save €600) ☐	€995 (save €500) ☐	€1495 ☐
Non-profit organizations	€695 (save €300) ☐	€795 (save €200) ☐	€895 (save €100) ☐	€995 ☐
Documentation €499 ☐	Promotional materials distribution €699 ☐	Speaker €2495 ☐	Pop up stand €3495 ☐	Bronze €4095 ☐
Booth €5495 ☐	Silver €6995 ☐	Gold €7995 ☐		

ATTENDEE DETAILS	1ST ATTENDEE	2ND ATTENDEE	3RD ATTENDEE	4TH ATTENDEE	5TH ATTENDEE	6TH ATTENDEE
Title:						
Name:						
Surname:						
Company:						
Country:						
Job Title:						
Direct phone:						
Email:						
Special Requirenments: (If you have any special dietary requirements or other needs that would enhance your enjoyment of this summit, please specify)						

INVOICE DETAILS

Title: Name: Surname:

Job Title:

Direct Phone: Mobile: Email:

Company: Country: City: EU VAT #:

Address: Postcode:

Payment Method:

Bank Transfer ☐ Credit Card ☐ Pay Pall ☐

Signature:
«I agree to be bound by Terms and Conditions of registratin»

TERMS & CONDITIONS

REGISTRATION & PAYMENT

Upon receiving the signed registration form, we will process your application. The registration confirmation and the invoice will be sent to you within one (1) working day with the relevant payment instructions and terms. The registration fee includes access to all sessions, coffee breaks, lunches, dinner and conference materials. Payment is due 10 working days from the invoice date. Payment should be made by Credit Card, Pay Pall or by Bank Transfer. The delegate is responsible for any bank charges/fees associated with the payment.

CANCELLATION & SUBSTITUTION POLICY

You may substitute a delegate at any time and at no extra cost. Cancellations must be in a written notice. Cancellations made 30 days or more before the event start date will be refunded less than 50% of the registration fee. Cancellations made less than 30 days before the event start date will receive no refund. If you cannot attend an event due to illness or other unforeseen circumstances, you may transfer your delegate pass to another upcoming event within one year from original event start date.

EVENT CHANGES & CANCELLATIONS

While all effort will be made to adhere to the advertised package, Qepler s.r.o. reserves the right to change event dates, sites or location, omit event features, or merge the event with another event as it deems necessary without penalty. In such situations no refunds, part refunds or alternative offers will be made. In the event that Qepler s.r.o. permanently cancels the event for any reason, and provided that the event is not postponed to a later date nor is merged with another event, you will receive a credit note or refund for 100% of the conference fee paid. Please note, Qepler s.r.o. will not be held liable for any accommodation or associated travel costs should the event be canceled or rescheduled.

DATA PROTECTION

The personal information provided by you will be held in the Qepler database. It may be used to infrom you about other Qepler products and services. Unless you click here ☐, your details may be made available to third parties for marketing purposes. For data update please write to databasemanager@qepler.com.

© All rights reserved Qepler s.r.o. 2018

PACKAGES

ONLINE PACKAGES

If you are unable to attend, you may purchase these packages:

PACKAGE NAME	PRICE
DOCUMENTATION Post-event presentations and other materials. Presentation content is subject to speaker's approval for distribution.	€499
PROMOTIONAL MATERIALS DISTRIBUTION (Distribution of your company's promotional materials to all attendees)	€699

SPONSORSHIP PACKAGES

BENEFITS	SPEAKER €2495	POP UP STAND €3495	BRONZE €4095	BOOTH €5495	SILVER €6995	GOLD €7995
Number of passes included	1	1	2	2	3	4
Registration fee for additional company representatives	€1295	€1295	€1195	€1195	€1095	€1095
Coupon (1 free pass for the other Qepler events)					•	•
Pop up stand in the break area (3m wide x 3m height; includes 1 table, chairs, 1 electrical socket)		•	•			
Exhibition booth with LCD monitor for video presentations in the break area (3m wide x 3m deep; includes 1 table, chairs, 1 electrical socket)				•	•	•
Pull-up banner at the entrance to the auditorium (to be provided by sponsor)					•	•
Speaking slot	20 min		20 min	20 min	30 min	30 min
Opening keynote presentation						15 min
Recognition in chairman's opening address	•	•	•	•	•	•
Seat on a panel discussion			•	•	•	•
Opening & closing speech						•
Chairman of Day 1						•
Chairman of Day 2					•	
Logo and URL on summit website, agenda and pre/post-summit communication activities	•	•	•	•	•	•
Recognition on Qepler social media channels (LinkedIn/Facebook/Twitter/Instagram)	•	•	•	•	•	•
Colour advert in placed in agenda			1/4 Page	1/4 Page	1/2 Page	1 Page
Company flyer/brochure included in conference folder (to be provided by sponsor)			•	•	•	•
Online distribution of your company's promotional materials to all attendees			•	•	•	•
Lanyards for summit badges, notepads, pens and other promotional materials (max. 5) given to all participants and speakers (to be provided by sponsor)						•

MARKETING CAMPAIGN

✓Website ✓Email Marketing ✓Digital Advertising ✓Social Marketing ✓Press ✓Direct Sales

PARTICIPATION FEE

Fees are inclusive of the 2-day summit, materials, online post-event documentation/presentation package, lunches, snacks, refreshments and business dinner.

TRAVEL AND ACCOMMODATION

Hotel accommodation and travel expenses are not included in the fee. Special rates for the event venue will be sent upon availability.

VENUE

Event venue will be announced online and sent to the delegates within a reasonable period before the summit start date.

POST-EVENT DOCUMENTATION

Presentations and other materials will be sent to the attendees within 72 hours after the event. Presentation content is subject to speaker's approval for distribution.

DISCOUNTS

Early booking discounts are not valid in conjunction with any other offer.

qepler