2nd Annual Pharmaceutical Lyophilisation Summit

#pharmalyo18

Vienna, Austria | May 24-25, 2018

Rainers Hotel Vienna | Gudrunstrasse 184 | 1100 Vienna, Austria

Key Practical Learning Points of the Summit:

- Current regulatory considerations
- First introduction in Europe of cleaning and cross-contamination requirements for none product contact surfaces
- Novel concepts of freeze-drying
- Process optimisation, monitoring, and control
- Innovations in formulation development
- QbD and PAT approaches
- Strategies for scale-up from R&D scale to full production level
- Technologies overview and advantages in manufacturing
- What is the new role of sterile and lyophilized products manufacturing in the future?

Key Speakers:

Chairman:

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

Dr. Andrea Weiland-Waibel, DE
Managing Director
Explicat Pharma GmbH

Dr. Bram Jongen, BE
Head of R&D
DATWYLER Sealing Solutions

Franz Bosshammer, MBA, DE
Senior Specialist CD Execution/ Experts
NNE

Dr. Miguela Vieru, BE
Senior Scientist
Research & Development,
PDMS - Parenterals & Liquids
Janssen

Ilona Vollrath, CH
Post Doc Researcher
Lonza / University Basel

Dr. Paul Matejtschuk, UK
Principal Scientist Standardisation Science
National Institute for Biological Standards and Control (NIBSC)

Dr. Erik Skibsted, DK
Principal Scientist
Novo Nordisk

Dr. Jean René Authelin, FR
Global Head of
Pharmaceutical Engineering
Sanofi-Aventis

Georg Frinke, DE
Facility & Process Engineer
Bayer Pharmaceuticals

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

Richard Denk, CH
Head of Sales Containment
Skan AG

Claudia Kunz, DE
Principal Scientist
Merck KGaA

VONLANTHEN CONFERENCES

2nd Annual Pharmaceutical **Lyophilisation** Summit

Vienna, Austria
May **24** - **25**, 2018

We are pleased

*to invite you to the **2nd Annual Pharmaceutical Lyophilisation Summit** scheduled for May 24th and 25th 2018, in **Vienna, Austria.***

***This event provides** the appropriate platform for industry leaders to discuss process innovation and technical aspects in lyophilisation for the pharmaceutical industry, manufacturers, regulatory agencies, and academia.*

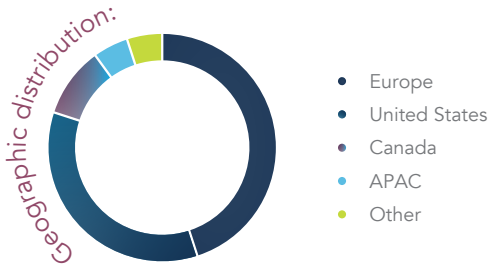
***The summit will be focused on** practical considerations for freeze-dried formulation development, process optimisation, validation, and control. We will discuss the novel concepts and regulatory considerations for lyophilised biologics, vaccines, and highly potent products.*

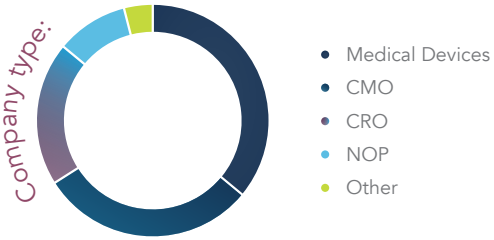
We are looking forward to your participation in this engaging Summit in Vienna in May!

Who Should Attend:

Chief Executives, Directors, Vice Presidents, Department Heads, Leaders, Senior Managers, Scientists, Chemists, Engineers, and Fellows specialising in:

- *Bioprocess*
- *Characterisation*
- *Container Development*
- *CMC*
- *Drug Development*
- *Engineering*
- *Freeze-drying*
- *Formulation*
- *Licensing*
- *Lyophilisation*
- *Nanomaterials*
- *Parenterals*
- *Packaging & labelling*
- *Process Technology*
- *Process Monitoring & Control*
- *Process Analytics*
- *Product Innovation*
- *Packaging*
- *QA/QC*
- *R&D*
- *Risk Management*
- *Regulatory Affairs*
- *Research & Development*
- *Stability*
- *Standardisation*
- *Sterilisation*
- *Validation*
- *Vaccines*
- *Cell Manufacturing*





ABOUT US

***Vonlanthen Group of Companies is made for** innovative and senior business leaders focused on confronting challenges and seizing opportunities. We conduct extensive research and connect deal-makers and risk-takers across Europe and emerging markets to help propel companies to the next level. Our conferences, events and training schemes are designed for senior decision-makers working at the top of their industries with cutting-edge strategies, products, processes and technologies.*

***Vonlanthen Group of Companies is** the natural home for companies always on the lookout for opportunities, always searching for the next deal, and always with an eye on the competition.*

VONLANTHEN CONFERENCES

08:30 Registration and Welcome Coffee
09:00 Opening Address from the Chairman

1 2

CHARACTERIZATION OF BIOLOGICAL REFERENCE MATERIALS

09:10

CASE STUDY

The challenge of delivering stable biological materials in lyophilised form

DR. PAUL MATEJTSCHUK
Principal Scientist Standardisation Science
National Institute for Biological Standards and Control (NIBSC)

- Instability in biological materials
- The range of challenges presented by biologics
- A generic approach to freeze-drying reference preparations
- Illustrations of the benefits of using freeze-dried biological reference materials

09:50 SPEED NETWORKING

An innovative approach to maximize networking capabilities through two minute periods, where delegates can meet their peers and exchange business cards before rotating to the next company representative.

QBD AND PAT APPROACHES

10:30

CASE STUDY

Through-vial impedance spectroscopy (TVIS): a novel process analytical technology for monitoring and/or controlling the freeze-drying of pharmaceutical products

PROF. GEOFF SMITH
Professor of Pharmaceutical Process Analytical Technology
Leicester School of Pharmacy
De Montfort University

- Critical temperatures (Tg', Teu, Tc)
- Product temperature and drying rate
- Heat transfer coefficient
- Dry layer resistance
- Strength/fragility of the unfrozen fraction

11:10 MORNING COFFEE AND NETWORKING BREAK

11:40

CASE STUDY

Innovative techniques for lyophilisation – controlled nucleation and heat flux measurements

ILONA VOLLRATH
Post Doc Researcher
Lonza/University Basel

- Impact of controlled nucleation on physicochemical properties and long-term stability of lyophilised products
- Effects on batch homogeneity by controlled nucleation
- Determination of the vial heat transfer coefficient (Kv) by heat flux measurements
- Heat flux measurements as a non-invasive tool to monitor lyophilisation cycles

12:20

CASE STUDY

Near-infrared spectroscopic detection of different mannitol polymorphs formed during lyophilisation

DR. ERIK SKIBSTED
Principal Scientist
Novo Nordisk

- Near-infrared spectral analysis is a fast and non-destructive method for quantification of residual water in lyophilised drug products
- The NIR spectrum also contains information about other critical quality attributes of the products e.g. protein concentration, product cake integrity, and polymorphism
- Mannitol is a common excipient in lyophilised drug products that exists in different polymorphic forms depending on thermodynamic process conditions
- This study shows how NIR spectral data can be analysed to get insight into the different mannitol polymorphs that were formed depending on process conditions and formulation

13:00 BUSINESS LUNCH

14:00

CASE STUDY

Quality-by-design for drying technologies

DR. SUNE KLINT ANDERSEN, BE
Principal Scientist
DPD – Oral Solid Dosage
Janssen

- Quality-by-design approaches for drying processes
- Typical sources of variation for lyophilisation and spray drying processes
- Best timing/conditions for applying QbD for a lyophilisation and spray drying processes

FREEZE-DRYING FORMULATION DEVELOPMENT

14:40

CASE STUDY

Lyophilization of an oral anti-viral agent

DR. MIGUELA VIERU
Senior Scientist
Research & Development,
PDMS - Parenterals & Liquids
Janssen

- Lyophilisation of an oral anti-viral agent in a viscose formulation,
- Spray drying as an alternative to other lyophilisation techniques,
- Characterisation of the dried product obtained by freeze-drying or spray drying

15:20

CASE STUDY

Procedure for freeze-drying of highly potent agents

CLAUDIA KUNZ
Principal Scientist
Merck KGaA

- Early process development in laboratory freeze dryers
- Safety considerations
- Opportunities and limitations

16:00 AFTERNOON COFFEE AND NETWORKING BREAK

MATERIAL DEVELOPMENT

16:30

CASE STUDY

The impact of elastomeric closures on a freeze-dried cake

DR. BRAM JONGEN
Head of R&D
DATWYLER Sealing Solutions

- Selection of a rubber stopper design intended for lyophilisation purposes
- Reduction of stopper stickiness to lyophilisation shelves
- Moisture determination using Karl-Fisher versus gravimetrical methods
- Low moisture rubber formulations and effect on the freeze-dried cake, combining different measurement methods

17:00 PANEL DISCUSSION

How do you navigate the global regulatory landscape?

- New process validation requirements
- PAT expectations/possibilities
- Quality-by-Design

17:30 CHAIRMAN'S CLOSING REMARKS AND END OF SUMMIT

18:30 BUSINESS DINNER

08:30 Registration and Welcome Coffee
09:00 Opening Address from the Chairman

1 2

CURRENT REGULATORY LANDSCAPE

09:10

CASE STUDY

Lyoprocess development and the implementation into regulatory lyophilisation - recent experiences

DR. ANDREA WEILAND-WAIBEL
Managing Director
Explicat Pharma GmbH

explicat® pharma GmbH
Consulting and Development

- Analysis of critical quality attributes and their related critical process parameters
- Lyorobustness testing to establish process boundaries
- Modern lyoprocess validation and the implementation of regulatory lyophilisation
- Recent experience with the handling of deficiencies

LYOPHILISATION PROCESS OPTIMIZATION

09:50

CASE STUDY

Freeze-drying: optimisation elements, tech-transfer, and scale-UP

DR. JEAN RENÉ AUTHELIN
Global Head of
Pharmaceutical Engineering
Sanofi-Aventis

SANOFI

- Presentation of a methodology to develop a lyophilisation cycle based on first principle
- What should be studied at which scale
- Real life example

10:30 MORNING COFFEE AND NETWORKING BREAK

11:00 WORKSHOP SESSION

Shortening & optimization of turn around cycles - increase yield by improved efficiency

GEORG FRINKE
Facility & Process Engineer
Bayer Pharmaceuticals

BAYER

- Interactive presentation of turn around cycle time/what is the optimum turn around cycle?
- What can be parallelised
- Discover time reduction potential
- What is the optimum?

The session will give a complete overview of the standard requirements for a turn-around cycle. Process requirements & technological limits will be compared and time reduction potential vs. equipment cost quantified.

For:
- Project engineers
- Production leads & site manager
- Facility/production engineers
- Floor manager/operator leads
- Production planner

12:30 BUSINESS LUNCH

13:30

CASE STUDY

Cleaning and cross-contamination requirements for none product contact surfaces (first introduction in Europe)

RICHARD DENK
Head of Sales Containment
Skan AG

SKAN

- Highly potent product lyophilisation
- Requirements for highly potent products
- Operator and product protection with isolator technology

14:10

CASE STUDY

Complexity of wireless product temperature measurement under isolator conditions

FRANZ BOSSHAMMER, MBA
Senior Specialist CD Execution/Experts
NNE

nne
Focused pharma engineering

- Roadmap
- Risks and concerns
- Feed-in station
- Preparation of equipment
- Signal routing

14:50 AFTERNOON COFFEE AND NETWORKING BREAK

15:20 PANEL DISCUSSION

Increasing the demand for lyophilisation and emerging freeze-drying technologies

- Trends in lyophilisation processes and technology developments
- Pressure from continuous manufacturing techniques
- PAT implementations

15:50 CHAIRMAN'S CLOSING REMARKS AND END OF SUMMIT

What We Do

Vonlanthen Group of Companies *is the premier forum for deal-makers and business leaders.*
We help industry experts and investors find the next opportunity, strike the next deal and enter growing markets by:

- *Hosting summits, conferences and workshops for senior decision makers, with a focus on sharing practical advice and experience to source opportunities and confront challenges*
- *Putting top executives together to share insights on the outlook for their industry in our cutting edge leadership forums*
- *Helping businesses - large and small - fund investment and growth by arranging capital-raising meetings*
- *Conducting bespoke executive training courses to ensure management teams are operating at the highest possible level*

Everybody who attends a Vonlanthen Group event has been pre-screened to ensure the highest quality of delegates and to kick-start the deal-making process.

Dr. Erik Skibsted, DK
Principal Scientist
Novo Nordisk

Erik Skibsted studied chemical engineering at the Technical University of Denmark. After working with fluorescence sensor development, he started a PhD project at the University of Amsterdam in cooperation with Novo Nordisk in Denmark. In his PhD research, he worked with developing algorithms for near-infrared spectroscopic applications in the manufacturing of solid dosage forms and multivariate modelling of the entire manufacturing process variables. He joined Novo Nordisk after his PhD work, which included: protein characterisation, spectroscopic data analysis, troubleshooting manufacturing problems with multivariate modelling, process analytical technology, and implementation of quality by design (QbD).

Dr. Jean René Authelin, FR
Global Head of
Pharmaceutical Engineering
Sanofi-Aventis

Jean René Authelin has an engineering degree in chemical engineering from ENSIC (Nancy France), and a PhD from The Institut National Polytechnique de Lorraine (France). He joined Rhone Poulenc in 1988 as a chemical engineer. In the 90s, he founded the Physical Quality function, dedicated to the API crystallisation, drying, and polymorphism, where he was the global head in Rhone Poulenc Rorer, Aventis, and finally Sanofi for a total of 10 years. In 1988, Jean René Authelin was nominated to be global head of pharmaceutical engineering. Jean René's interests include thermodynamics of hydrates, drug polymorphism, amorphous solids physics, drug stability, crystallisation, nanoparticles engineering and processing, drying, milling, spray drying, fluid bed granulation, roller compaction, and freeze-drying. Jean René Authelin is the author/co-author of 20 publications, book chapters, and the co-inventor of 9 patents.

Dr. Bram Jongen, BE
Head of R&D
DATWYLER Sealing Solutions

After completing his master's in polymer chemistry at the University of Louvain, Belgium, Bram Jongen acquired a PhD in water soluble polymers used for advanced drug administration. Bram started working as a technical support manager for Datwyler about 14 years ago, supporting customers in a vast area that spanned 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, each having 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 the 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.

Franz Bosshammer, MBA, DE
Senior Specialist CD Execution/
Experts
NNE

Franz Bosshammer has a degree in mechanical engineering, as well as a Master of Business Administration (MBA). Prior to joining NNE Pharmaplan in October 2012, Franz has filled various positions, such as process engineer and sales director in the supplying industry for pharmaceutical, aseptic fill, and finish machines. His latest employment was as general manager at Optima Group Pharma. He started his career in the field of process engineering in 1986. Franz has more than 30 years of experience in development and manufacturing of machines for aseptic pharmaceutical operations, with a special focus on freeze-drying technology. Franz has been engaged in various international fill and finish projects over the course of his career.

Dr. Andrea Weiland-Waibel, DE
Managing Director
Explicat Pharma GmbH

Andrea Weiland, Ph.D., is managing director of Explicat® Pharma GmbH, a privately-owned company providing technical project management services and pharmaceutical development services to the pharmaceutical industry (CMC). Andrea is a pharmacist with a PhD in pharmaceutical technology on biodegradable microspheres and cyclodextrins (Ludwig Maximilians University Munich). She held several leading roles within Pfizer, working as project manager in process technology and being responsible for technology transfer & process development, mainly on sustained release solid dosage forms. Within R&D she was a responsible scientist for pharmaceutical development (Phase I - III, candidate characterization, and lyophilisation projects). After joining IDEA AG, a biotechnology company based in Munich, Andrea Weiland held the position of director of pharmaceutical development and was responsible for process technology development, drug delivery system development (liposomes, patches), formulation of recombinant proteins, analytical development, and clinical supplies manufacturing. She also served as IDEA`s QP and is the founder of Explicat Pharma GmbH and has been the managing director since 2005. She and her team`s experience cover the development of biopharmaceuticals (e. g. recombinant factor VIII), development of lyoformulations and lyocycles, analytical development, related QA, and regulatory issues. Explicat Pharma has been assigned several projects involving the modern process validation approach, including lyocycle robustness testing. Andrea Weiland is a qualified individual and a member of AAPS and several other professional institutions based in Europe including APV, DphG, Bay. LAK, and A3P.

Ilona Vollrath, CH
Post Doc Researcher
Lonza / University of Basel

Ilona Vollrath graduated in pharmacy from Julius-Maximilians University in Würzburg and received her license as a pharmacist in 2013. For her PhD studies, she went to Munich and joined Prof. Dr. Winter at the Department of Pharmaceutical Technology and Biopharmaceutics (LMU Munich). In collaboration with Coriolis Pharma Research GmbH, she was working on controlled nucleation and novel PAT tools in freeze drying. In July 2017, Ilona joined Lonza`s Drug Product Services as a postdoctoral fellow in collaboration with Prof. Dr. Huwyler at the University of Basel. Her current projects focus on formulation development of advanced therapy medicinal products.

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

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. His expertise has allowed him to give several presentations on international courses, while also publishing articles on the mentioned subjects. He has extensive experience in design and development of spray drying equipment and processes, bulk freeze-drying processes, GMP production, nanoparticles, powder processing in general, DoE and application of quality-by-design, validation and qualification of spray dryers, scale-up of spray drying processes, particle engineering, aseptic spray drying, project management, and early and late stage projects. Dr. Andersen has been with Janssen since April of 2017 and prior to his time at Janssen, he worked at Novo Nordisk for 10 years at GEA Niro A/S for 8 years.

Georg Frinke, DE
Facility & Process Engineer
Bayer Pharmaceuticals

Georg holds a degree in engineering from UAS, Cologne, Germany. He works as a facility & process engineer at the parenteral facility of Bayer Pharma in Leverkusen. Previously, he worked in a similar role for the Pilot Fill & Finish Facility of Janssen Pharma in Schaffhausen. Before 2012, he worked for Optima (Klee) and GEA Lyophil/Steris in the mechanical & process engineering of Lyophilisers for ten years. Among others, he is specialised 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. Miguela Vieru, BE
Senior Scientist
Research & Development,
PDMS - Parenterals & Liquids
Janssen

Miguela is a senior research and development scientist at The Janssen Pharmaceutical Companies of Johnson & Johnson. She is an expert in pharmaceutical formulations and drug/vaccine delivery systems, where she is responsible for end-to-end drug product development for oral and parenteral delivery. Miguela is a Marie Curie PhD fellow and she received her PhD from the University of Florence, Frankfurt, and Utrecht for structural investigations on human proteins related to neurodegenerative disorders. Prior to joining Janssen, Miguela worked at Novartis Vaccines as a formulation scientist.

Richard Denk, CH
Head of Sales Containment
Skan AG

Richard Denk has studied mechanical engineering and did an examination on experts of GMP, qualification and validation, pharmaceutical auditing, pharmaceutical engineering, and quality control at the University of Applied Sciences in Albstadt/Sigmaringen, Germany. Richard Denk works at SKAN AG, headquartered in Allschwil as the head of sales containment. Mr. Denk founded the expert Containment group of the ISPE DACH 8 years ago. The Containment Group published the Containment Manual in September 2015. Mr. Denk has spent nearly 20 years with the subject production of highly active/highly hazardous substances and has developed the containment pyramid.

Dr. Paul Matejtschuk, UK
Principal Scientist Standardisation Science
National Institute for Biological Standards and Control (NIBSC)

Dr. Paul Matejtschuk (BSc Biochemistry, University of York UK, PhD Chemistry, University of Warwick UK, CChem) has over 30 years postdoctoral experience in the downstream processing and characterisation of biological materials. Since joining NIBSC in 2001, he has set up and runs the Standardization Section, responsible for the formulation and freeze-drying development of the Institute's biological reference materials, many of them WHO International Standards. His research interests include protein structural/function relationships, use of analytical and monitoring technologies in lyophilisation, and the application of thermal analysis to biologics while maintaining an active research programme in collaboration with several UK universities. He is a director of the International Society for Lyophilization/Freeze Drying (www.islyophilization.org), is a committee member of the Thermal Methods Group (www.thermalmethodsgroup.org.uk) of the Royal Society of Chemistry, and co-ordinates NIBSC involvement with the UK National Measurement System and the Bioanalysis Working Groups of the BIPM. He lectures and publishes widely in the area of the freeze-drying of biologics.

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

Geoff Smith is researching PAT applications for process development and manufacturing process control based on impedance spectroscopy, electrostatic noise, and more recently optical techniques such as laser speckle texture analysis and optical flow. Since developing a novel technique for monitoring the freeze-drying cycle (Through Vial Impedance Spectroscopy, TVIS), his Group has gone on to investigate PAT applications in roller compaction, tablet compaction, and powder flow. He is currently involved in BioStaRT and AtlasBio which are industrial consortia working together to develop new technologies for the freeze-drying of proteins.

Claudia Kunz, DE
Principal Scientist
Merck KGaA

Claudia Kunz received her license as a pharmacist from Julius-Maximilians University in Würzburg in 2011. In 2013, she joined Priv.-Doz. Dr. Gieseler's Freeze Drying Focus Group at the Friedrich-Alexander-University in Erlangen as a PhD student. Her research interests were focused on freeze drying from organic co-solvent systems as well as dynamic vapour sorption of freeze-dried products. Since August 2017, she is a principal scientist at Merck KGaA, where she is working on the characterization and early formulation development of NBEs and ADCs. Her current projects focus on the strategy for freeze-drying of highly potent agents and high concentration formulations.