2nd Annual Pharmaceutical Lyophilisation Summit
#pharmalyo18

VIENNA, AUSTRIA  |  FEBRUARY 1-2, 2018

Key Practical Learning Points of the Summit:

- Novel concepts of freeze-drying
- Current regulatory considerations
- Process optimisation, monitoring and control
- Continuous freeze-drying
- Innovations in formulation development
- QbD and PAT approaches
- Strategies to scale-up from R&D to full production level
- Technologies overview and advantages in manufacturing
- Physicochemical principles

Key Speakers:

Dr. Erik Skibsted, DK
Principal Scientist
Novo Nordisk

Gert Moelgaard, UK
Senior Consultant
Moelgaard Consulting

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

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

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

Richard Denk, CH
Head Sales Containment
Skan AG

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

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

Miguela Vieru, BE
Senior Scientist
DPD – Parenterals
Janssen

Anthony Nye, UK
CQV Project Engineering Contractor/ Consultant
Pfizer

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We are pleased to invite you to the 2nd Annual Pharmaceutical Lyophilisation Summit scheduled for February 1st and 2nd 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, and regulatory agencies.

The summit will be focused on practical considerations for freeze-dried formulation development, process optimization, 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 this coming February!
CURRENT REGULATORY LANDSCAPE

09:10 CASE STUDY
Lyoprocess development and the implementation into regulatory lyophilization - recent experiences

DR. ANDREA WEILAND-WAI BEL
Managing Director
Explicat Pharma GmbH

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

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
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 lyophilized 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 lyophilized 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

12:20 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 lyophilization and spray drying processes
- Best timing/conditions for applying QbD for a lyophilization and spray drying processes

13:00 BUSINESS LUNCH
## FREEZE-DRYING FORMULATION DEVELOPMENT

14:00

**CASE STUDY**
Lyophilization of an oral anti-viral agent

**MIGUELA VIERU**  
Senior Scientist  
DPD - Parenterals  
Janssen

## MANUFACTURING LYOPHILISATION PRACTICES

14:40

**CASE STUDY**
Lyophiliser replacement in an existing aseptic fill/finish facility

**ANTHONY NYE**  
CQV Project Engineering Contractor/Consultant  
Pfizer

- Different approaches to a new build project vs an existing facility refurbishment project
- Project planning & analysis
- Quality development
- Off-site testing
- On-site testing
- Handover for beneficial use

15:20

**CASE STUDY**
New role of sterile and lyophilized products manufacturing in the future?

**GERT MOELGAARD**  
Senior Consultant  
Moelgaard Consulting

- The new role of specialty medicine
- Global perspective on lyophilisation benefits
- Aseptic technology facilities of the future

16:00

**AFTERNOON COFFEE AND NETWORKING BREAK**

16:30

**SPONSORSHIP SPEAKING SLOT**

Reserved for exclusive conference sponsor

17:00

**PANEL DISCUSSION**

- To be Announced

17:30

**CHAIRMAN’S CLOSING REMARKS AND END OF SUMMIT**

18:30

**BUSINESS DINNER**
WORKSHOP SESSION

09:10

CASE STUDY

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

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

09:50

WORKSHOP SESSION

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

GEORG FRINKE
Facility & Process Engineer
Bayer Pharmaceuticals

LYOPHILISATION PROCESS OPTIMIZATION

CASE STUDY

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

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

09:10

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

WORKSHOP SESSION

09:50

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

The session will give a complete overview about 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

CASE STUDY

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

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

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CASE STUDY

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CASE STUDY

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

RICHARD DENK
Head Sales Containment
Skan AG

11:50

• Highly potent product Lyophilisation
• Requirements for highly potent products
• Operator and product protection with isolator technology

12:30

BUSINESS LUNCH
### Day Two
February 2, 2018

<table>
<thead>
<tr>
<th>13:30</th>
<th>CASE STUDY</th>
<th>Complexity of wireless product temperature measurement under isolator conditions</th>
<th>- Roadmap, - Risks and concerns, - Feed-in station, - Preparation of equipment, - Signal routing</th>
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<tr>
<td></td>
<td><strong>FRANZ BOSSHAMMER, MBA</strong></td>
<td>Senior Specialist CD Execution/Experts NNE Pharmaplan</td>
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#### MATERIAL DEVELOPMENT

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<tr>
<th>14:10</th>
<th>CASE STUDY</th>
<th>The impact of elastomeric closures on a freeze-dried cake</th>
<th>- Selection of a rubber stopper design intended for lyophilisation purposes, - Reduction of stopper stickiness to lyophilisation shelves, - Moisture determination using Karl-Fisher versus gravimetical methods, - Low moisture rubber formulations and effect on the freeze-dried cake, combining different measurement methods</th>
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<td><strong>DR. BRAM JONGEN</strong></td>
<td>Head of R&amp;D DATWYLER Sealing Solutions</td>
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**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 has 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 engineer 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 1998, 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 books, chapters, and the co-inventor of 9 patents.

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

After completing 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 working as a Technical Support Manager for Datwyler’s product portfolio since 2003. 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 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 Pharmaplan

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 Pharmaceutical Industry (CMC). Andrea is a pharmacist with a Ph.D. in pharmaceutical technology on biodegradable microspheres and cyclodextrins (Ludwig Maximillians University Münich). 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 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 (I=II=III), development of recombinant proteins, analytical development, and clinical supplies manufacture; she also served as IDEA’s QP. She is the founder of Explicat Pharma GmbH and has been the managing director since 2005. Her 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.

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 a MBA in Management & Technology and a Ph.D. 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.
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.

Anthony Nye is a CQV project engineering contractor/consultant with over twenty years of experience in providing commissioning and validation services to pharmaceutical and biotechnology clients. He has experience in the discipline of CQV project management of facility expansion/refurbishment and new-build projects; initial concept proposal through detailed design, tendering, vendor auditing, procurement, factory acceptance testing, construction/installation, commissioning, validation/verification, and handover for beneficial use.

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 has studied mechanical engineering and did 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 company SKAN AG, headquartered in Alschwil in the position of 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.

Miguela Vieru, BE
Senior Scientist
DPD – Parenterals
Janssen

Anthony Nye, UK
CQV Project Engineering Contractor/Consultant
Pfizer

Richard Denk, CH
Head Sales Containment
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Speakers Biographies

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

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 Lyophilizers for ten years. Among others, he is specialized in the development of customized freeze-drying processes (particularly upscaling with PAT) and in the qualification (PAT, SAT, IQ, OQ, PQ) of pharmaceutical freeze dryers.

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- Using customer insights and feedback from social media to enhance product and service offerings.

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Vonlanthen Conferences

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