ONLINE SUMMIT | February **17-18**, 2021 | **ZOOM** | #VLFreezeDrying

2nd FREEZE-DRYING TECHNOLOGY Online Summit

Welcome to the 2nd edition of the Freeze-Drying Technology Summit, this time Online! This event provides the appropriate platform for industry leaders to discuss process innovation and technical aspects in lyophilization for the pharmaceutical industry, manufacturers, regulatory agencies, and academia.

With the industry professionals, we will focus on practical considerations for freeze-dried formulation development, process optimization, validation, and control. We will discuss the novel concepts and regulatory considerations for lyophilized biologics, vaccines, and highly potent products.

Key Practical Learning Points:

- Current regulatory considerations
- GMP and occupational safety for the freeze-drying process
- Process optimization, monitoring, and control
- PAT in lyophilization process development
- Strategies for scale-up from R&D scale to full production level
- Technologies overview and advantages in manufacturing
- Spray-drying applications
- Alternative technologies to conventional freeze-drying
- Freeze-drying for the food industry

Moderator of Day 1

Dr. Sune Klint Andersen, BE
Principal Scientist
Spray Drying
Janssen Pharmaceutica NV

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

Dr. Paul Matejtschuk, UK
Principal Scientist & Section Head,
Standardization Science /
Analytical & Biological Sciences Division
National Institute for Biological Standards & Control (NIBSC)

Franz Bosshammer, DE
Global Technology Partner
Pharmaplan GmbH

Richard Denk, CH
Senior Consultant Aseptic Processing & Containment
Skan AG, Switzerland

Dr. Nga Le, DE
Process Engineer
Fluid Air, a Division of Spraying Systems Co.

Moderator of Day 2

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

Dr. Mostafa Nakach, FR
Head of Formulation & Process Development
Biologics Drug Product Development
Sanofi

Dr. Stefan Schneid, DE
Laboratory Head Development Parenterals
Bayer

Xulei Wu, US
Deputy Contractor Manager
Space Food Systems Laboratory
Human Health and Performance Contract
KBR | NASA

Giel De Winter, BE
Process Development Scientist MSAT
Pfizer

Dr. Christoph Strubl, DE
Owner and General Manager
STRUBL GmbH & Co. KG Packaging

Sponsors:

VONLANTHEN CONFERENCES

12:30

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

Experiences with the Continuous Process Verification Strategy during the Routine Production of Lyoproducts

- Experiences with the Routine Production of Lyoproducts - the Validated Process including the Lyocycle and its CPV
- Continuous Process Verification to maintain the validated status and judge each production, including the lyocycle for release
- The Handling of Deviations – how modern development and the use of PAT Technologies help to navigate the deviation and allows for the release decision

13:00 **Q&A** with Dr. Andrea Weiland-Waibel | 10min

13:10

Richard Denk, CH
Senior Consultant Aseptic Processing & Containment
Skan AG, Switzerland

Gmp and Occupational Safety for the Freeze-Drying Process

- What are GMP Requirements for Loading and Unloading the Freeze Dryer according to the new Draft EU GMP Annex 1
- Safety requirements for processing highly potent substances
- Cleaning and Cross Contamination Requirements

13:40 **Q&A** with Richard Denk | 10min

13:50

Dr. Mostafa Nakach, FR
Head of Formulation & Process Development
Biologics Drug Product Development
Sanofi

Scale-up of Freeze-Drying Manufacturing Process

Heat transfer coefficient characterization versus pressure for each manufacturing scale

- Parameters determination for scaling up
- Temperature profile comparison
- Product quality comparison (t0 + t1m) (visual aspect, residual moisture, particle analysis)

14:20 **Q&A** with Dr. Mostafa Nakach | 10min

14:30

Sponsors speaking slot

Dr. Christoph Strubl, DE
Owner and General Manager
STRUBL GmbH & Co. KG Packaging

Cleanroom Packaging For Pharmaceutical Applications

- Plastic packaging materials for pharmaceutical applications
- Potential risks of plastic packaging materials in a GMP-environment
- Regulations and requirements for plastic packaging materials
- PE-Trays simplify cleaning and avoid contamination in the freeze-drying process

14:50 **Q&A** with Dr. Christoph Strubl | 10min

15:00

Franz Bosshammer, DE
Global Technology Partner
Pharmaplan GmbH

Natural Cooling Agents in Freeze-Drying or How to Shape the Future

- Warmup
- Current technologies, trends, and supplier strategies
- Fit for future – options to improve the existing process
- Case study: do everything the first time
- Resume

15:30 **Q&A** with Franz Bosshammer | 10min

15:40	**Dr. Stefan Schneid, DE** Laboratory Head Development Parenterals Bayer	**Alternative Technologies to Conventional Freeze Drying – Recent Advancements:** • Overview of different technologies • Practical experience and learnings • Outlook for future application
16:10	**Q&A** with Dr. Stefan Schneid | 10min	
16:20	**Xulei Wu, US** Deputy Contractor Manager Space Food Systems Laboratory Human Health and Performance Contract KBR | NASA	**The Science Behind the Space Food System** • Past, current, and future production of space food • Critical review of freeze-dried space foods • Outlook of advances in alternative drying technologies
16:50	**Q&A** with Xulei Wu | 10min	
17:00	**END OF DAY ONE**	

Sponsor:

STRUBL GmbH & Co. KG *is a German family company with more than 70 years of experience in the packaging industry and specialist in cleanroom packaging for the pharmaceutical / medtec / healthcare market.*

The packaging products, f.e. bags, zip bags, films, tubes, are fully customized and used as primary packaging materials, f.e. for API / chemical substances / medical devices / bottles / implants / plastic components.

To meet the high-quality requirements of these markets, the products are produced in an ISO-cleanroom and GMP-environment. STRUBL also supplies a flexible and highly efficient Plug&Pack System for automating packaging processes.

Sponsorship-related questions to:
register@vonlanthengroup.com

Schedule

DAY 2 | February 18, 2021

MANUFACTURING TENDENCIES

13:00

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

Applications for Electrical Impedance Spectroscopy Process Analytical Technology (EIS-PAT) in Lyophilization Process Development

- Electrical impedance and material attributes
- Non-invasive measurements (in-process and for individual vials)
- Measurement frequency selection for ice fraction and unfrozen fraction
- Dielectric relaxation of ice: quantification of ice mass and calibration for ice temperature
- High-frequency capacitance, a marker for the in-vial glass transition and other phase changes

13:30 **Q&A** with Prof. Geoff Smith | 10min

13:40

Dr. Paul Matejtschuk, UK
Principal Scientist & Section Head,
Standardization Science /
Analytical & Biological Sciences Division
National Institute for Biological Standards & Control (NIBSC)

Identifying Key Parameters in Freeze Drying Cycle Design – Established and New Approaches

- Why knowing your formulation is key to successful freeze drying
- Use of Process Analytical Technologies to facilitate freeze drying cycle design
- Experience with Through Vial Impedance Spectroscopy (TVIS) in freeze drying of complex biological formulations

14:10 **Q&A** with Dr. Paul Matejtschuk | 10min

14:20

Sponsors speaking slot

Dr. Nga Le, DE
Process Engineer
Fluid Air, a Division of Spraying Systems Co.

Electrostatic Spray Drying Polardry® For Pharmaceutical Applications

- The patented PolarDry® technology harnesses the electrostatic effect to improve spray drying
- Low operation temperature for living microorganism and other thermal sensitive products
- Microencapsulation of API and actives to eliminate degradation or denaturalization
- Tabletatibility, compressibility, and flowability for pharmaceutical applications
- A continuous and fast process for time and energy saving

14:40 **Q&A** with sponsor's speaker | 10min

14:50

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

Continuous Drying Technologies for Biopharmaceuticals – The Journey Continues

- Challenges in drying of biopharmaceuticals
- Potential for continuous manufacturing for various technologies
- Formulation considerations
- Case Study

15:20 **Q&A** with Dr. Sune Klint Andersen | 10min

15:30

Giel De Winter, BE
Process Development Scientist MSAT
Pfizer

Stopper Moisture/Cake Moisture Correlation

- Case studies on the impact of high moisture containing lyo stoppers on drug product quality
- Overview of stopper moisture measuring techniques
- Development Cake Moisture/Stopper Moisture correlation model

16:00 **Q&A** with Speaker from Pfizer | 10min

16:10 **END OF DAY TWO**

Dr. Andrea Weiland-Waibel, DE

Managing Director
Explicat Pharma GmbH

Andrea Weiland, Ph.D., is managing director of Explicat® Pharma GmbH, a company providing technical project management services and pharmaceutical development services to the Pharmaceutical Industry (CMC). Andrea is a pharmacist with a Ph.D. in pharmaceutical technology on biodegradable microspheres and cyclodextrins. She held several leadership positions within Pfizer, working as a 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 lyophilization projects). Hers and her explicat team`s experience cover the development of biopharmaceuticals (e.g., recombinant factor VIII), development of lyoformulations and lyocycles, analytical development, and related QA as well as regulatory issues. Explicat Pharma has been assigned several projects involving the modern process validation approach, including lyocycle robustness testings that led to successfully approved drug products on the market.

Xulei Wu, US

Deputy Contractor Manager
Space Food Systems Laboratory
Human Health and Performance Contract
KBR | NASA

Xulei Wu serves as KBR Deputy Contractor Manager in the Space Food Systems Laboratory at NASA Johnson Space Center. In this role, she supports the space food production and delivery to International Space Station to support Human Space Exploration with safe, nutritious, palatable, and sufficient food. Prior to this role, she worked for over two years in the same lab as a Sr. Food Scientist, led the freeze-drying production, reformulated products to improve safety/efficiency/sensory profile, and conducted R&D work to optimize the freeze-drying cycle. Xulei recruited and trained an R&D sensory panel to support freeze-drying cycle optimization and shelf-life study. Prior to supporting NASA, she was with Oregon Freeze Dry in various QA and R&D roles. Her specialty is in freeze-drying technology, low moisture food, sensory evaluation, and shelf-life study. She earned a B.S. in food science and engineering from Shanghai Jiao Tong University and an M.S. in food science and technology from Oregon State University.

Dr. Stefan Schneid, DE

Laboratory Head Development Parenterals
Bayer

Dr. 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. He is involved in development projects from the preclinical stage up to transfer to commercial production. Previously, Stefan worked as R&D manager at Syntacoll GmbH in Saal, Germany, where he was responsible for developing 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. He spent one year as a visiting scientist in Prof. Michael Pikal's lab at the University of Connecticut. Stefan holds a degree in 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.

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.

Dr. Paul Matejtschuk, UK

Principal Scientist & Section Head,
Standardization Science /
Analytical & Biological Sciences Division
National Institute for Biological Standards & Control (NIBSC)

Dr. Paul Matejtschuk leads a formulation and freeze-drying team at NIBSC focused on delivering lyo solutions for biological reference materials. Many of them WHO international reference preparations (joined NIBSC in 2001). He has over 30 years' postdoctoral experience in downstream processing and analysis of biologics, and has co-authored over 40 peer-reviewed papers and co-supervised several Ph.D. students with Prof. Paul Dalby (UCL, London). Paul is one of a number of directors of the International Society for Lyophilization Freeze Drying, a not-for-profit society whose aim is to enhance global understanding and uptake of best lyophilization practices. Co-edited (2019) with Dr. Kevin Ward (Biopharma Technology Ltd, UK) a recent volume on "Lyophilization of Pharmaceuticals & Biopharmaceuticals" for Springer in the "Methods in Pharmacology & Toxicology" series.

Franz Bosshammer, DE

Global Technology Partner
Pharmaplan GmbH

Franz Bosshammer has a degree in mechanical engineering, as well as an 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 a 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 the 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 finishes projects over the course of his career.

Dr. Mostafa Nakach, FR

Head of Formulation & Process Development
Biologics Drug Product Development
Sanofi

Dr. Mostafa Nakach is a Ph.D. from Toulouse University. He has prepared his thesis on the stabilization and production of nanocrystalline suspension. He is also a Master II graduate from Paris-Sud University in pharmaceutical technology, bio pharmacy, and a pharmaceutical engineer from École des mines d'Albi. Mostafa has been working within the Sanofi Group for 32 years. His current position is a head of the formulation and process development section within biologics drug product development. His mission is to build and manage the required skills and capabilities in order to support R&D projects development mainly for fill and finish commercial process development of biotech products, including freeze-drying.

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Speakers Biographies

February 17-18, 2021

Richard Denk, CH
Senior Consultant Aseptic Processing & Containment
Skan AG, Switzerland

Richard Denk has studied mechanical engineering and did an examination on experts of GMP, qualification and validation, pharmaceutical auditing, pharmaceutical engineering, 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 eight years ago. The Containment Group published the Containment Manual in September 2015. Mr. Denk has spent nearly 20 years working with highly active/highly hazardous substances and has developed the containment pyramid.

Giel De Winter, BE
Process Development Scientist MSAT
Pfizer

Giel De Winter obtained a Master's degree in Bioscience Engineering, with an emphasis on surface chemistry, (bio-)catalysis, and biotechnology. Giel has over 6 years of experience in several focus areas of the pharmaceutical industry. He currently works at the Pfizer Aseptic Manufacturing site in Puurs, Belgium, as a Process Development Scientist in the Manufacturing Science and Technology (MSAT) department. There he is responsible for Tech Transfers, troubleshooting, and process optimizations. His work primarily focuses on lyocycle development and optimization for both small and large molecule formulations, aseptic process development, and product and process characterization initiatives.

Dr. Christoph Strubl, DE
Owner and General Manager
STRUBL GmbH & Co. KG Packaging

Dr. Christoph Strubl is the owner and General Manager of STRUBL GmbH & Co. KG Packaging, Germany, a family company supplying cleanroom packaging materials for the pharmaceutical / medical devices / healthcare industry. He has more than 20 years of experience in the plastic packaging market. Since 2015 he is a speaker of the board of the Workgroup "Pharmaceutical Packaging" and a Member of the Steering Committee of IK Industrievereinigung Kunststoffverpackungen e.V., the German Association for Plastics Packaging and Films. He holds a Ph.D. in business and management sciences from the University of Erlangen, Germany.

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 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.

Dr. Nga Le, DE
Process Engineer
Fluid Air, a Division of Spraying Systems Co.

Dr.-Ing. Nga Le is the Process Engineer at Fluid Air, a division of Spraying Systems Co®. She got a doctorate in mechanical engineering and a Master's degree in chemical engineering. She was a lecturer at Hanoi University of Science and Technology, Vietnam, from 2009 to 2012; and a researcher at the Technical University of Dresden, Germany, from 2012 to 2018. Joining Fluid Air in 2019, she will be responsible for the production lab in North Rhine-Westphalia, Germany. Her expertise is spray drying, advanced oxidation processes, and the isolation of active compounds from natural products.