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4th Annual

PHARMACEUTICAL LYOPHILIZATION SUMMIT 2022

REGISTER

WEB

October 6-7, 2022

VIRTUAL CONFERENCE

12:00 - 19:00 CET (Prague - UTC/GMT +2 hours)

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Prof. Geoff Smith
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De Montfort University, UK

Dr. Mattia Cassanelli
Technical Manager – Consultancy
Biopharma Group, UK

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

Diana Löber
Global Product Manager Vials
SCHOTT AG, DE

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

Francis Carroll
Specialist, Technical Customer Support, EU
West Pharmaceutical Services, IE

Simon Kervyn, Ph.D.
Manager Surface Development Healthcare
Datwyler, BE

Stefan Schneid
Laboratory Head Formulation Development Parenterals
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Section Head, Standardisation Science, Analytical and Biological Sciences Division
NIBSC, UK

Anton Mangold
Managing Director
Tempris GmbH, DE

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

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

WHO YOU WILL MEET

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SNAPSHOT OF ATTENDEES - VIRTUAL 3rd Annual Pharmaceutical Lyophilization Summit 2021:

Applied Materials, Inc. ▸ Aspen ▸ Azbil Telstar Technologies SLU ▸ Baxter Healthcare ▸ Bayer AG ▸ Biopharma Group ▸ Boehringer Ingelheim ▸ Cambridge Design Partnership ▸ Catalent Biologics ▸ Catalent Pharma LLC ▸ Catalent Pharma Solutions ▸ Cenexi Lt sa ▸ Daiichi-Sankyo Europe GmbH ▸ Datwyler Pharma Packaging International NV ▸ De Montfort University ▸ Dr. Reddy's lab ▸ ELLAB A/S ▸ eTheRNA Immunotherapies NV ▸ Explicat Pharma GmbH ▸ Ferring GmbH ▸ Fresenius Kabi Oncology Ltd. ▸ GEA Lyophil GmbH ▸ GSK ▸ Hemofarm ▸ Illumina ▸ Janssen ▸ Jazz Pharmaceuticals ▸ Laboratorio Reig Jofre, S.A. ▸ LMU Munich, Pharmaceutical Technology and Biopharmacy ▸ Lyofal ▸ Lyomark Pharma GmbH ▸ Medichem Manufacturing (Malta) Limited ▸ Merck ▸ Minapharm for pharmaceutical products ▸ NIBSC ▸ OPTIMA pharma GmbH ▸ Pfizer ▸ PharmaMar SA ▸ RAUMEDIC AG ▸ Sanofi-Aventis ▸ Sirton Pharmaceuticals SpA ▸ Takeda ▸ Tempris GmbH ▸ Terumo BCT ▸ University of Helsinki ▸ West Pharmaceutical Services ▸ World Health Organization ▸ Yuria-Pharm LLC ▸ others.

Agenda: https://qepler.com/agendas/3rd-pharmaceutical-lyophilization-summit-2021.pdf

RECORDINGS

SNAPSHOT OF ATTENDEES - 2nd Annual Pharmaceutical Lyophilization Summit 2020:

Allergan ▸ Aptar Pharma ▸ AZBIL TELSTAR TECHNOLOGIES SLU ▸ Baxalta Manufacturing Sàrl ▸ Bayer AG ▸ BB-NCIPD Ltd. ▸ Biopharma Process Systems Ltd ▸ BLAC-BioPharma UG ▸ Boehringer Ingelheim ▸ Datwyler Pharma Packaging International NV ▸ De Montfort University ▸ DendroPharm GmbH ▸ Elm o Sanat University ▸ Freie Universität Berlin ▸ Ghent University ▸ INDICAL BIOSCIENCE GmbH ▸ Janssen ▸ KSHM-Rezonanca ▸ Lek Pharmaceuticals d.d. ▸ Lonza AG ▸ Martin Christ Gefriertrocknungsanlagen GmbH ▸ Masaryk University ▸ MSD ▸ MSD International ▸ Novartis Global Drug Development / Technical Research & Development ▸ Pensatech Pharma ▸ Pfeiffer Vacuum GmbH ▸ Pfizer ▸ PharmaCept GmbH ▸ Polpharma SA ▸ Rhine Waal University ▸ Sanofi ▸ SCHOTT AG ▸ Shire Austria GmbH now part of Takeda ▸ Surface Measurement Systems Ltd. ▸ Takeda ▸ Tempris GmbH ▸ VLB Berlin ▸ West Pharmaceutical Services Deutschland GmbH & Co KG ▸ others.

Agenda: https://qepler.com/agendas/pharmaceutical-lyophilization-summit-2020.pdf

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DIVISIONS

- Lyophilization
- Pharmaceutical Manufacturing, Engineering & New Technologies
- Laboratory Management
- R&D
- Formulation
- Containment
- Pharmaceutical & Processing Development
- Process Design, Technology, Analytics, Testing, Monitoring & Control
- Aseptic Production, Cleaning & Sterilisation
- Bioprocessing
- QA/QC
- Characterisation
- Regulatory Affairs
- Stability
- Standardisation
- Qualification & Validation
- Scale-up & Technology Transfer
- Cycle Management
- Facility & Site Design & Management
- PAT, QbD
- Media Fills
- Visual Inspection
- Filling & Materials
- Materials Development
- Container Development & Container Closures
- Vials, Stoppers & Dual Chamber Systems
- Devices &Application Systems
- Product Development & Control
- Parenteral Production
- Injection Systems
- Vaccines
- Corporate & Business Development
- External Supply
- Sales & Marketing
- Outsourcing
- Partnerships & Alliances
- Strategic Development
- Other

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- Advisors, Coordinators, Auditors & Consultants
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PHARMACEUTICAL LYOPHILIZATION ONLINE SUMMIT 2022

October 6, 2022 | 1st DAY

Central European Summer Time (CEST, Prague, UTC/GMT +2 hours)

10:00 - 12:00 — **Registration**

12:00 - 12:10 — **Opening Address**

12:10 - 12:50 — **The use of wireless temperature probes to understand heat transfer patterns in primary drying.**

- Present examples of similarities and differences in data from wireless and wired probes
- Discuss shelf mapping data obtained using wireless probes in empty and loaded lyophilisers
- Highlight how accuracy of probe placement enables heat transfer patterns to be established with greater confidence
- Demonstrate how wireless probe data from different cycles can be applied to the calculation of Kv for a series of containers

Dr. Mattia Cassanelli | Technical Manager – Consultancy
Biopharma Group, UK

12:50 - 13:30 — **Easify Your Lyo Process with Tempris** — **SPONSOR**

A powerful PAT tool to pave your way to Pharma 4.0

- Operational excellence through PAT tool Tempris
- Real-time product temperature monitoring during the commercial lyophilization process
- Realization of an automation process for CPV

Anton Mangold | Managing Director
Tempris GmbH, DE

13:30 - 13:50 — **Coffee break**

13:50 - 14:30 — **Application of Product Temperature measurement to monitor and control the Lyocycle using TEMPRIS**

- Examples of application in development (lablyo)
- Examples of application in scale up and transfer into routine production
- Examples of application in process validation/process performance qualification
- Examples of application in ongoing life cycle verification/cpv and deviation handling

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

14:30 - 15:10 — **Freeze drying process design using a Design Space approach**

- Methodology of Product characterization
- Methodology of Equipment characterization
- Methodology of Process Design & Design Space
- Case study presentation

Mostafa Nakach | Head of Formulation & Process Development / Biologics Drug Product Development | Sanofi, FR

15:10 - 15:50 — **We need bigger crystals quo vadis controlled nucleation?**

- Random vs. controlled nucleation and the effects of super cooling
- Technologies for controlled nucleation
- Why do we not see broad adoption?

Michael Dekner | Innovation & External Collaborations
Takeda, AT

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PHARMACEUTICAL LYOPHILIZATION ONLINE SUMMIT 2022

October 6, 2022 | 1st DAY

Central European Summer Time (CEST, Prague, UTC/GMT +2 hours)

15:50 - 16:10 — **Coffee break**

16:10 - 16:50 — **Where's the true sublimation end point in primary drying?**

- An overview of the PAT known as through-vial impedance spectroscopy (TVIS)
- Its application to differentiate between sublimation (primary drying) and diffusive desorption (secondary drying)
- The impact of phase states (crystalline vs amorphous) on the end point profile

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

16:50 - 17:30 — **The influence of formulation in freeze drying biologics**

- The importance of formulation
- Comparison of analytical approaches
- Is NaCl desirable or not?

Paul Matejtschuk, PhD, CChem, FRSC | Section Head, Standardisation Science, Analytical and Biological Sciences Division | NIBSC, UK

17:30 - 18:10 — **Panel Discussion**

18:10 - 18:20 — **Closing remarks and end of day**

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PHARMACEUTICAL LYOPHILIZATION ONLINE SUMMIT 2022

October 7, 2022 | 2nd DAY

Central European Summer Time (CEST, Prague, UTC/GMT +2 hours)

12:00 - 12:10 — **Opening Address**

12:10 - 12:50 — **Anatomy of the Lyophilization Process: Considerations for a Successful Tech Transfer**

- Evaluation of the lyophilization cycle as it relates to tech transfer
- Identifying the critical process parameters
- Understand the impact of equipment on the recipe

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

12:50 - 13:30 — **Electrospinning as a Manufacturing Technique for Biopharmaceuticals**

- Challenges in drying of biopharmaceuticals
- Electrospinning as a manufacturing technology
- Case studies

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

13:30 - 13:50 — **Coffee break**

13:50 - 14:30 — **GMP-ready continuous freeze-drying of pharmaceuticals**

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

14:30 - 15:10 — **Alternative Freeze Drying Technologies and Options for Process Intensification**

- Limitations of Conventional Freeze Drying
- Overview of Novel Technologies
- Practical Experience and Learnings

Stefan Schneid | Laboratory Head Formulation Development Parenterals
Bayer, DE

15:10 - 15:50 — **How different vial concepts can help to avoid breakage due to freezing**

Diana Löber | Global Product Manager Vials
SCHOTT AG, DE

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PHARMACEUTICAL LYOPHILIZATION ONLINE SUMMIT 2022

October 7, 2022 | 2nd DAY

Central European Summer Time (CEST, Prague, UTC/GMT +2 hours)

15:50 - 16:10 — **Coffee break**

16:10 - 16:50 — **Impact of Elastomeric Closures on Freeze-dried Cakes**

Lyo cake colour, aspect and integrity are fundamental quality control criteria to ensure a safe drug products. However, the lyo cake aspect can change after packaging if, for example, moisture content increase. The drug integrity could also be affected by a potential reaction with leachables from the elastomer stopper.
This talk will review the different elastomeric closure selection criteria to prevent modification of the lyo cake.

Simon Kervyn, Ph.D. | Manager Surface Development Healthcare
Datwyler, BE

16:50 - 17:30 — **4040/40 Elastomer Formulation Innovation for Lyo Application**

Francis Carroll | Specialist, Technical Customer Support, EU
West Pharmaceutical Services, IE

17:30 - 17:40 — **Closing remarks and end of summit**

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PHARMACEUTICAL LYOPHILIZATION ONLINE SUMMIT 2022

SPEAKER'S BIOGRAPHIES

Dr. Mattia Cassanelli
Technical Manager – Consultancy
Biopharma Group, UK

Mattia joined Biopharma Group in February 2018 and he currently works as a Technical Manager of the Consultancy Division, providing support through desktop study, cycle audit, characterisation of the material pre- and post- process, formulation development, optimisation of the freeze drying cycle and tech transfer/scale-up.
Mattia's background includes a PhD focussed on drying mechanisms of hydrocolloids in the food industry from a microstructural point of view at the University of Birmingham.
He also gained a Master's Degree in material engineering, and a Bachelor's Degree in industrial engineering completed at the University of Trento, Italy.

Michael Dekner
Innovation & External Collaborations
Takeda, AT

Michael Dekner has studied biotechnology at the University of Life Sciences Vienna. Since graduating 17 years ago he has held positions as scientist in enzyme engineering (Biomin), antibody design (f-Star), since joining Takeda as a supervisor for lyophilization and crimping, manager for process and technology innovation and has lead a team of scientists developing and optimizing fill and finish processes. Currently Michael holds the position of associate director for innovation and external collaboration.

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.

Diana Löber
Global Product Manager Vials
SCHOTT AG, DE

Diana studied business administration and communication in Mainz. After an internship at Merck Millipore, she completed a 2-years trainee program from 2013 – 2015 in Product Management in the medical devices business (Ottobock HealthCare), including training on-the-job in different departments, also abroad.
Followed by an employment as a Portfolio Manager within the Business Unit Development Prosthetics. Since 2018, Diana acts as Global Product Manager Vials in the Strategy & Innovation department at SCHOTT Pharmaceutical Systems.

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. Frieβ). 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.

Simon Kervyn, Ph.D.
Manager Surface Development Healthcare
Datwyler, BE

Simon Kervyn graduated as a PhD in organic chemistry and materials from the University of Namur, Belgium in 2012. After research stays at National Institute of Materials Sciences in Tokyo and at UCLA, Los Angeles, he worked at the Coatings Research Institute in Belgium.
He is now working for Datwyler as manager surface development. In this position he performs customer's dedicated research to optimize the selection of rubber components to their applications. Furthermore, he works on the development of coated products for the Datwyler portfolio. He is a frequent speaker at conferences.

Francis Carroll
Specialist, Technical Customer Support, EU
West Pharmaceutical Services, IE

Francis holds a BSc in Plant and Microbial Biotechnology from University College Cork, Ireland and has close to 20 years' experience working in the Pharmaceutical/Life Sciences sector.
He has a wide breadth of knowledge having gained hands-on experience in a wide variety of industry roles and disciplines including, Quality Control (Microbiology and Chemistry), Sterile Fill Finish, Technical Development, Lyophilization Scale-up and Optimization, Technology Transfer, New Product Introduction and Extractable/Leachables.
Francis joined West in 2017 and currently works in a Specialist Technical Customer Support role supporting EU customers in all market units with technical assistance and guidance related to West products, processes and services.
Prior to joining West he worked for 12 years in Sanofi where he held various roles including Senior Development Scientist (focus areas: Technical transfer, Lyophilisation cycle modelling, design and scale-up using QbD principles, Extractable/Leachables and Solid state characterization of lyophilized biologics) and also as Senior Product Specialist (focus areas: Strategy and Delivery for commercialisation of new lyophilised products, Technical leadership and Lifecycle management).

Stefan Schneid
Laboratory Head Formulation Development Parenterals
Bayer, DE

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.

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REGISTRATION FORM

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SUMMIT NAME: 4th Annual Pharmaceutical Lyophilization Virtual Summit 2022 | October 6-7, 2022

PROMO CODE:

PARTICIPATION PACKAGES	Register by 1.07.2022	Register by 1.08.2022	Register by 1.9.2022	Standard price
VIRTUAL ticket - 2 Days	€ 445 (save € 150) ☐	€ 495 (save € 100) ☐	€ 545 (save € 50) ☐	€ 595 ☐
VIRTUAL Group - 2 Days (*2-3 delegates, per person)	€ 345 (save € 200) ☐	€ 395 (save € 150) ☐	€ 445 (save € 100) ☐	€ 545 ☐
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Opening keynote presentation (optional)			20 min
Case Study		30 min	30 min
Workshop (optional, replacing Case Study)		40 min	60 min
Recognition in chairman's opening address	•	•	•
Opening & closing speech (optional)		•	•
Chairman of Day 1 (optional)			•
Chairman of Day 2 (optional)		•	
Logo and URL on summit website, agenda and pre/post-summit communication activities	•	•	•
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Color advert placement on agenda	1/4 Page	1/2 Page	1 Page
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