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- 10+ Program Hours | 8+ Networking Hours
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- Case Studies & Workshops
- Roundtable Discussions | Q & A

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SPEAKER SPONSOR

biopharma group
intelligent freeze drying

2nd Annual

PHARMACEUTICAL LYOPHILIZATION SUMMIT 2020

February 12-13, 2020 | Berlin, Germany

Venue:

NH Collection Berlin Friedrichstrasse
Friedrichstraße 96

NH COLLECTION
HOTELS

SPEAKERS BOARD

CHAIR DAY 1

Michael Dekner
Head of Process Sciences Formulation, Fill and Finish
Baxter AG
now part of Takeda, AT

CHAIR DAY 2

Georg Frinke
Independent Consultant

Evgenyi Shalaev
Executive Director
Allergan, USA

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

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

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

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

Dr. Mattia Cassanelli
International Technical Sales Executive
Biopharma Group, UK

Martin Frei
Process expert, Sterile DP Stein
Lonza AG, CH

Dr. Bettine Boltres
Principal Scientific Affairs, Packaging & Delivery Systems
West Pharmaceutical Services Deutschland GmbH & Co KG, DE

Dr. Simon Kervyn
Manager Materials Development
Datwyler Pharma Packaging International NV, BE

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

Diana Löber
Global Product Manager Vials
SCHOTT AG, DE

Salvatore Carmisciano, Msc.
Head Project and Process Sciences
Novartis Global Drug Development / Technical Research & Development, AT

Rameez Ahmad
Sales and Business Development Manager
Surface Measurement Systems, DE

WHO YOU WILL MEET

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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.

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Surface Measurement Systems
World Leader in Sorption Science

Surface Measurement Systems develops and engineers innovative experimental techniques and instrumentation for physico-chemical characterisation of complex solids. We are the world leaders in Dynamic Vapor Sorption technology and Inverse Gas Chromatography instrumentation and solutions, providing professional world-class scientific and technical support for our international customers. By carefully controlling, measuring and analysing the physico-chemical interaction of vapors with solid samples such as powders, fibres and films. Surface Measurement Systems can help solve problems in research and development, such as stability studies and drying performance, through to manufacturing and quality control.

Our range of characterization instruments and scientific/engineering techniques has helped solve difficult problems in the pharmaceuticals, biomaterials, polymers catalysts, chemical, cosmetics and food industries, and are used by hundreds of leading laboratories and universities throughout the world..

POSITIONS

- C-Level, Presidents, Chairs, Members of the Board & VPs
- Vice presidents, Directors, & Heads
- Leaders & Managers
- Principals, Engineers, Analysts & Scientists
- Instructors & Trainers & Teachers
- Advisors, Coordinators, Auditors & Consultants
- Other Professionals, Experts & Specialists

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
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PHARMACEUTICAL LYOPHILIZATION SUMMIT 2020

February 12 | Berlin, Germany

08:00 - 08:30 — **Registration and Welcome Coffee**

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

08:40 - 09:40

WORKSHOP: **Use of refrigereants in Freeze Dryers – Discussion and impact of current solutions**

- Overview of refrigeration concepts
- Development of common refrigerants and specific environmental impact
- Comparison of energy efficiency of refrigeration principes
- Energy consumption of a Lyophilization cycle and resulting CO2 emission – with examples of existing installations and lyo-cycles
- Outlook of future refrigeration development
- Refitting the refrigeration system and Impact on cycle validation

Georg Frinke | Independent Consultant

09:40 - 10:20 — **Speed Networking**

10:20 - 11:00

You don´t need to be great to start, but you need to start to be great – A pilot on multivariate monitoring for a lyophilized product

- Multivariate monitoring for Fill and Finish
- Challenges and roadblocks
- Future plans

Michael Dekner | Head of Process Sciences Formulation, Fill and Finish | Baxter AG now part of Takeda, AT

11:00 - 11:30 — **Morning coffee and networking break**

11:30 - 12:10

Crystallization during freezing and drying: practical importance and characterization methods

- Many excipients and active pharmaceutical ingredients can crystallize during freezing and freeze-drying,
- Crystallization behavior depends on multiple factors, e.g., the nature of a particular molecule, presence and concentration of other solutes, and freezing/annealing conditions
- Crystallization can be either beneficial (e.g., bulking agent), or detrimental (e.g., cryo/lyoprotector) for manufacturing process efficiency and the product quality
- Analytical methods to monitor crystallization on both small scale (e.g., DSC and low-temperature X-ray diffraction) and in-situ during manufacture (e.g., heat flux sensors) are discussed.

Evgenyi Shalaev | Executive Director | Allergan, USA

12:10 - 12:50

Z-FDM : A new instrument combining impedance spectroscopy with a freeze drying microscope

- Theory : broad band dielectric relaxation spectroscopy of frozen solutions
- Z-FDM : A description of the new measurement system
- Applications in freezing (nucleation temperature, ice growth rates, solidification end point)
- Applications in primary drying (drying rate, product collapse)
- Future applications for high throughput screening (concurrent product and process design)

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

12:50 - 14:00 — **Business lunch**

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February 12 | Berlin, Germany

14:00 - 14:40

Considerations to Freeze-Dry Concentrated Protein Solutions

- Challenges for processing highly concentrated protein formulations
- Freeze-drying of concentrated protein solutions
- Analytics & stability properties of HCFDF
- Impact on reconstitution

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

14:40 - 15:10

Development of a lyophilised protein product using a QbD approach. SPONSOR

The presentation will describe a case study about the product and process development of a freeze dried protein product. The different phases from formulation to cycle optimisation and technology transfer will be covered, highlighting challenges and commercial benefits.

- Case study: lyophilised protein product
- Pre- and post- product characterisation
- QbD approach

Dr. Mattia Cassanelli | International Technical Sales Executive | Biopharma Group, UK

15:10 - 15:40 Afternoon coffee and networking break

15:40 - 16:20

Electrospinning of Biopharmaceuticals

- Challenges in drying of biopharmaceuticals
- Electrohydrodynamic drying methods
- Morphology and size control
- Formulation considerations for electrospinning

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

16:20 -17:00

Impact of Freeze-Drying Conditions on the Stability of Protein-Sugar Formulations SPONSOR

- Vapor sorption techniques (DVS) have proven to be valuable techniques for studying the impact of lyophilization conditions on stability of food and pharmaceutical materials
- DVS proves to be an extremely sensitive technique for the investigation of protein-sugar interactions and the determination of moisture-induced phase transitions
- DVS can be used to characterize crystalline and disordered materials including polymorphs, hydrates, defect sites, and amorphous materials
- The unique information accessed through DVS and IGC SEA experiments can add important insight for characterizing and developing solid pharmaceutical materials

Rameez Ahmad | Sales and Business Development Manager | Surface Measurement Systems, DE

17:00 -17:50 Panel Discussion

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

19:00 - 21:00 Business dinner

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PHARMACEUTICAL LYOPHILIZATION SUMMIT 2020

February 13 | Berlin, Germany

08:00 - 08:30 — **Registration and Welcome Coffee**

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

08:40 - 09:20

Lyophilization Equipment - Design Requirements and Technical Solutions

- General description of the lyophilization process and how the equipment design relates .
- Scale up considerations based on the equipment design and how it applies to the processing conditions.
- General overview of the main components of a Lyophilizer (chamber, condenser, refrigeration skid, vacuum skid, shelves, etc.).

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

INVENTING FOR LIFE

09:20 - 10:00

Continuous and controlled freeze-drying technology for (bio-)pharmaceutical products for and orally disintegrating tablets

This presentation will present two innovative continuous freeze-drying technologies: (i) A Continuous and Controlled Pharmaceutical Freeze-Drying Technology for Unit Doses (e.g., vials, syringes, dual chamber cartridges); and (ii) A SMART technology for the continuous manufacturing of lyophilized orally disintegrating tablets. These continuous processes allow a more efficient, cheaper, greener and controllable manufacturing compared to traditional batch production systems, offering competitive advantages and business opportunities.

Three major industrial drivers are demanding a more efficient and better controllable pharmaceutical freeze drying technology: cost-cutting, regulatory pressure and need for new types of formulations for different increasing target populations.

The in this talk presented continuous freeze drying technologies offer 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), a substantial sustainability gain and an opportunity to manufacture new types of products which cannot be processed using the current batch-wise technology.

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

GHENT UNIVERSITY

RheaVita

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

10:30 - 11:10

Lyophilization cycle development and scale-up for recipe conditions where Rp changes as function of shelf temperature

Lyophilization is a complex process including several stages (freezing, primary and secondary drying).The selection of process conditions for each lyophilization step is extremely important with regards to the overall cycle duration and product quality attributes (e.g. appearance).
By using a mathematical modelling approach which requires measuring the heat transfer coefficient (Kv) and resistance to mass flow (Rp), the design space is constructed to predict the primary drying duration and maximum product temperature. Lyophilization recipe is then selected based on the defined design space. Conventionally, the approach used for the design space calculation takes into account that Rp change over time is not a function of the shelf temperature in the design space area.
The case study elaborates a model-assisted development and scale up of a lyophilization cycle with primary drying conditions where the temperature of the shelf exceeds the glass transition temperature (Tg') and Rp over time is changing as a function of shelf temperature due to microstructural cake changes known as 'cake micro-collapse'.

Salvatore Carmisciano, Msc. | Head Project and Process Sciences |
Novartis Global Drug Development / Technical Research & Development, AT

NOVARTIS

11:10 - 11:50

Solutions to avoid sticky stoppers on lyophilisator shelves.

The presentation will review the different options to avoid sticky rubber stoppers on lyophilisator shelves at the end of the cycle, namely:
- Change of lyophilisator parameters.
- Product design change.
- Compound change.
- Use of coated products.

Dr. Simon Kervyn | Manager Materials Development |
Datwyler Pharma Packaging International NV, BE

DATWYLER

11:50 - 13:00 — **Business lunch**

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PHARMACEUTICAL LYOPHILIZATION SUMMIT 2020

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13:00 - 13:40

Risk Factors to Consider when Choosing the Optimal Stopper for Lyophilization

- Evaluation of influencing factors like e.g. rubber formulation, stopper design, moisture transmission and moisture uptake, risk for volatiles
- Comparison study to underline the influence of the different mentioned factors

Dr. Bettine Boltres | Principal Scientific Affairs, Packaging & Delivery Systems | West Pharmaceutical Services Deutschland GmbH & Co KG, DE

13:40 - 14:20

No compromises - vial strength by design

In order to avoid breakage on filling lines or weaken the vials on their way to lyophilization, vial's optimal strength characteristic plays a crucial role during the fill/lyo and finish process. Especially if the decision is taken to freeze-dry the product, the vial should not be the "disturbing factor" of the process in terms of yield.

There is a solution to increase vial's strength, but at the same time compromising inner surface characteristics and therefore deteriorating its breaking behavior. This treatment is making the vial that though, that machine parts might break or wear out faster. New machine concepts need to be developed.

We at SCHOTT worked on a solution to increase vial's strength whilst keeping its superior surface properties, and standard dimensions – no re-registration necessary. Finite element analysis – especially with strengths playing a role during lyophilization, strength testings/ fractography and study outcomes will be presented in this session.

Diana Löber | Global Product Manager Vials | SCHOTT AG, DE

14:20 - 15:00

Lyophilization: Silicon oil contamination risk and mitigation strategies

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

Martin Frei | Process expert, Sterile DP Stein | Lonza AG, CH

15:00 -15:10 Chairman's closing remarks and end of day two

15:10 - 15:40 Afternoon coffee and networking break

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PHARMACEUTICAL LYOPHILIZATION SUMMIT 2020

BIOGRAPHIES

Dr. Simon Kervyn
Manager Materials Development
Datwyler Pharma Packaging International NV, 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 materials 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.

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.

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.

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.

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

Georg Frinke
Independent Consultant

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.

Evgenyi Shalaev
Executive Director
Allergan, USA

Evgenyi Shalaev, Ph.D., AAPS Fellow, is an executive director in Pharmaceutical Development, Allergan plc, Irvine, California, USA, and an adjunct professor in the Department of Pharmaceutics, University of Minnesota. Dr. Shalaev held the Royal Society Fellowship in Pafra Biopreservation and the University of Cambridge, UK, postdoctoral research appointments at the University of Wisconsin-Madison and Cornell University, and worked at the Institute of Carbon (Russia), Institute of Molecular Biology (Russia), and Pfizer Inc. (USA), before taking his present position. His responsibilities in Allergan are focused on biological drug products covering both controlled release dosage forms and conventional formulations such as solutions and freeze-dried powders. Dr Shalaev's research interests include: amorphous and other disordered solids; phase transitions in aqueous systems during freezing and drying; chemical and physical stability of small molecules and biologicals; development and scale-up of freeze-drying processes. He has published over a hundred peer-reviewed papers, book chapters, and patent applications.

Rameez Ahmad
Sales and Business Development Manager
Surface Measurement Systems, DE

Rameez is a Nanoscience and technology expert with more than 7 years of research experience. His expertise lies in the characterization of powders and particles. Currently, he is serving in Surface Measurement Systems Ltd. as a sales and business development manager. In the recent years, he has been managing activities related to the sale of capital equipment and covering more than 50 countries around the globe, enabling researchers and businesses to acquire the latest technology.
Rameez completed his Bachelor studies in Metallurgical and Materials Engineering from one of the best engineering universities of the country i.e. "University of Engineering and Technology, Lahore, Pakistan". As an outstanding student, he secured fully funded scholarship to continue the higher studies in Germany at the Europe's second most innovative university "Friedrich-Alexander-Universität Erlangen-Nürnberg (FAU)". His master courses were highly interdisciplinary and focused on four main areas, namely, Chemical, Materials & Bio Engineering, and Computational science. He published his first scientific paper during his Masters, while working on ZnO nanorods for solar cells.
Because of his academic excellence and exceptional grades, he was offered Ph.D. positions from several Universities across Europe. He decided to take the employment at FAU Erlangen as a Scientific Staff and continued exploring the nanoparticles' applications in optoelectronics. He presented his work in several international conferences, supervised master and bachelor students, and published multiple scientific papers. It was the time when he was interacting with a range of different nationalities and cultures around the world. This enabled him to acquire a very high interdisciplinary and intercultural competence. As a result, he decided to put his social and scientific skills at work and acquired a position as a sales manager for scientific instruments.
He spends his free time volunteering for foreigners' integration projects in Germany, maintaining his aquarium, playing badminton and making YouTube videos.

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PHARMACEUTICAL LYOPHILIZATION SUMMIT 2020

BIOGRAPHIES

Martin Frei
Process expert, Sterile DP Stein
Lonza AG, CH

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, built and qualified our facility more than 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. Cleaning strategies and risk assessment regarding product residues in drug products

Dr. 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.

Dr. Bettine Boltres
Principal Scientific Affairs, Packaging & Delivery Systems
West Pharmaceutical Services Deutschland GmbH & Co KG, DE

As Principal Scientific Affairs, she is supporting the scientific exchange between West and the pharmaceutical industry. This is complementing her 7 years' work as Product Manager for Schott Pharmaceutical Tubing, where she provided scientific consulting for glass primary packaging.
She has held numerous trainings at pharmaceutical companies, glass converters and universities. She is a frequent speaker at industry conferences and has chaired and moderated several conferences and technical training events for the PDA and other formats.
A number of articles for several global magazines have been penned by her. In 2015 she published the book «When Glass Meets Pharma», which builds the bridge between glass for pharmaceutical primary packaging and drug substances.
Bettine is an active member of the USP Packaging and Distribution Expert Committee as well as the ISO TC76/WG 4 on elastomers, the European Pharmacopoeia Commission Group of Experts 16 (elastomers and plastics) and the GLS Working Party (glass).
Since January 2019 she is also a member of the PDA Board of Directors.
Dr. Boltres is a (bio)chemist by training, receiving a diploma in chemistry from the university of Frankfurt, Germany and a PhD in biochemistry from the university of Cologne, Germany.

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.

Salvatore Carmisciano, Msc.
Head Project and Process Sciences
Novartis Global Drug Development / Technical Research & Development, AT

Salvatore Carmisciano graduated from the Faculty of Chemical Engineering in Roma.
He joined Novartis vaccines in 2010 working as formulation expert in the fields of Drug Product process and formulation development.
In 2013, Salvatore joined Sandoz Austria working as Drug Product Leader being responsible on project process characterization and down scale model concepts.
In 2017, he joined the Novartis Drug Product Development Slovenia as Senior Scientist leading technical transfer/validation activities and supporting projects submission. He advised drug product leaders and Scientists inside Novartis Drug Product Development organization for studies, concepts and procedures regarding liquid and freeze-dried sterile products.
In 2018, he moved to the position of Head Project and Process Sciences in the Novartis Drug Product Development organization by managing pharmaceutical (drug product) development projects and leading late phase development team of scientists.

Michael Dekner
Head of Process Sciences Formulation, Fill and Finish
Baxter AG
now part of Takeda, AT

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

EVENTS CALENDAR 2020

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2ND ANNUAL PHARMACEUTICAL LYOPHILIZATION SUMMIT.....February 12-13, 2020
Berlin, Germany
Overviewing regulatory updates and advanced technologies, developing lyophilization process that ensure quality at all stages.
http://qepler.com/pdf/2lyo.pdf

2ND ANNUAL HIGHLY POTENT APIs SUMMIT.....February 19-21, 2020
Prague, Czech Republic
Enhancing HPAPIs manufacturing and handling via new technologies, engineering improvement and successful contamination control strategies.
https://qepler.com/pdf/2hpapi.pdf

3RD ANNUAL PRE-FILLED SYRINGES SUMMIT.....May 28-29, 2020
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MEDICAL DEVICE REGULATIONS SUMMIT.....September 22-23, 2020
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REGISTRATION IS OPEN NOW!

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