



- ▶ 12+ Program Hours
- ▶ Networking
- ▶ Panel Discussions | Q & A
- ▶ Video Recording

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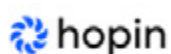


2nd Annual

# INHALED DRUG DELIVERY SUMMIT 2021

5-6 August 2021  
● VIRTUAL CONFERENCE

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



AGENDA

WEB

LinkedIn

HOPIN



**Dr. Andrew Feilden**, CSci CChem FRSC  
European E&L strategic Director  
Hall Analytical, UK



**Dr. John N Pritchard**  
Independent Business Owner  
Inspiring Strategies, UK



**Dr. Herbert Watchel**  
Senior Principal Scientist  
Boehringer Ingelheim  
Pharma GmbH & Co. KG, DE



**Dr. Felix Weiland**  
Head of Product & Process Technology  
Boehringer Ingelheim microParts  
GmbH, DE



**Thomas Sécher**  
Scientist  
INSERM, FR



**Dr. Carsten Ehrhardt**  
Professor in Pharmaceutics and  
Biopharmaceutics  
Trinity College  
Dublin, IE



**Nina Hobi**  
CEO & Scientific Director  
AlveoliX AG, CH



Univ.-Prof. **Dr. Sven Stegemann**  
Professor for Patient Centric Drug  
Development & Manufacturing  
Graz University of Technology,  
AT



**Mark Parry**  
Technical Director  
Intertek Pharmaceutical Services, UK



**Tom French**  
Device Industrialisation Engineer  
3P innovation, UK



**Dr. Orest Lastow**, PhD  
Chief Technology Officer & Founder  
Iconovo AB, SE



**Dr. Simon Moore**, BSc(Hons) PhD MRSC  
Global Lead of Inhalation Sciences and  
Engineering  
Covance Laboratories, UK



**James B Fink**, PhD, RRT, FAARC, FCCP  
Chief Scientific Officer  
Aerogen Pharma Corp., USA



**Khaudeja Bano**, MD  
Executive Medical Director  
Head of Combination and  
Device Product Safety  
Amgen, USA



## YOUR 'GO-TO' DPI AUTOMATION EXPERTS

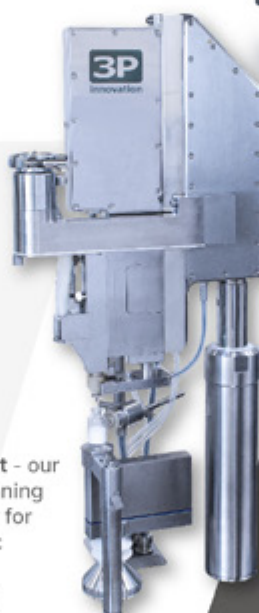
**DEVICE ASSEMBLY:** PLUS A RANGE  
OF POWDER DISPENSERS FOR  
RESERVOIR, BLISTER OR CAPSULE  
BASED DEVICES.



Micro-auger



**Fill2Weight** - our  
award-winning  
technology for  
gravimetric  
powder  
dispensing



**R500/R1000**  
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for devices and capsules

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Intertek is the industry leader with over 42,000 people in 1,000 locations in over 100 countries. Whether your business is local or global, we can ensure your products meet quality, health, environmental, safety, and social accountability standards for virtually any market around the world. We hold extensive global accreditations, recognitions, and agreements, and our knowledge of and expertise in overcoming regulatory, market, and supply chain hurdles is unrivaled.

Intertek (Schweiz) AG provides a comprehensive range of Good Laboratory Practice (GLP) and Good Manufacturing Practice (GMP) compliant analytical services including chemical trace analysis, reverse engineering, complex analyses, substance identification, method development, and a wide range of other applications in conjunction with consulting expertise and engineering support.

#### Intertek - WEBINARS:

- ▶ Webinar Recording: Repurposing Products for Inhaled Delivery - Rapid Response Strategies  
<https://www.intertek.com/knowledge-education/webinars/rapid-repurposing-for-inhaled-delivery/>
- ▶ Webinar: Formulation and Manufacturing Approaches for Nasal Drug Products  
<https://www.intertek.com/knowledge-education/webinars/webinar-formulation-nasal-drug-products/>
- ▶ Article: In Vitro Bioequivalence for Pulmonary and Nasal Delivery  
<https://www.intertek.com/knowledge-education/invitro-bioequivalence-generic-oindp-article/>

## SNAPSHOT OF ATTENDEES - VIRTUAL 2nd Annual Extractables & Leachables Conference 2020:

3P Biopharmaceuticals, ES - Abbott Healthcare Products B.V., NL - Abbvie Deutschland GmbH & Co. KG, DE - Accord-UK Ltd, UK - Advent Consulting Canada, CA - ALK, DK - Alkermes Pharma Ireland Limited, IE - Alphamed Formulations PVT LTD, IN - Apotex Research Pvt Ltd., IN - Aspen Holdings, ZA - Aspen Pharmacare, ZA - B.Braun medical SA, CH - Bavarian Nordic, DK - Becton Dickinson, CN - Becton Dickinson, FR - Biogen, USA - Boston Analytical, USA - Claudia Cusa, d.i., IT - CSL Behring AG, CH - Datwyler Pharma Packaging International NV, BE - DuPont, USA - DuPont-Asahi Flash Spun Products, JP - EirGen Pharma, IE - Eli Lilly and Company, USA - EMS SA, CH - Eurofins Analytical Science Laboratories, Inc., JP - Fujifilm Diosynth Biotechnologies, UK - GSK, US - GSK Vaccines, BE - Hall Analytical, UK - Hemofarm AD, RS - HTL-Strefa S.A., PL - Intertek (Schweiz) AG, CH - Janssen, USA - Kora Healthcare, IE - LEO Pharma, IE - Maven E&L Ltd, UK - Medline Industries, USA - Merck KGaA, DE - MilliporeSigma a business of Merck KGaA, USA - Novartis, CH - Novartis Pharma Stein AG, CH - NOVAVAX CZ a.s., CZ - Orexo AB, SE - Orion Corporation - FI, Philips, NL - Polifarma İlaç San. ve Tic. A.Ş., TR - PPD, IE - Rentschler Biopharma SE, DE - Safetree Consulting e.U., AT - Sandoz Manufacturing Inc., CA - Sanofi, FR - Sanofi, DE - Sanofi Pasteur, CA - Sartorius Stedim Biotech GmbH, DE - SCHOTT AG, DE - SCIEEX, UK - Selvita S.A., PL - Septodont, FR - SGS, CN-TW - SGS Institut Fresenius GmbH, DE - Solvias AG, CH - Sthree, BE - Swedish Biomimetics 3000 Ltd, UK - Takeda Pharmaceuticals, USA - Vet-Agro Sp. z o.o., PL - West Pharmaceutical Services, USA - Wockhardt Ltd, IN - and others.

Agenda: <https://qepler.com/agendas/agenda-2nd-extractables-and-leachables-20.pdf>

## 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

- |  |   |   |
|--|---|---|
| <ul style="list-style-type: none"><li>▶ Aerosol Science</li><li>▶ Asthma</li><li>▶ Combination Products</li><li>▶ Connective Health</li><li>▶ COPD</li><li>▶ Cystic Fibrosis</li><li>▶ Device Development &amp; Engineering</li><li>▶ Drug Development &amp; Delivery</li><li>▶ Dry Powder Inhalers</li><li>▶ E-Health</li><li>▶ Formulation Development</li></ul> | <ul style="list-style-type: none"><li>▶ Formulation Development</li><li>▶ Generics</li><li>▶ Inhalation Delivery</li><li>▶ Inhalation Product Development</li><li>▶ Inhalation Products</li><li>▶ Inhaled Dosage Forms</li><li>▶ Medical Devices</li><li>▶ Metered Dose Inhalers</li><li>▶ Nasal Delivery</li><li>▶ New Materials</li><li>▶ Particle Characterisation</li><li>▶ Process Development</li></ul> | <ul style="list-style-type: none"><li>▶ Pulmonary Delivery</li><li>▶ Pulmonary Diseases</li><li>▶ R&amp;D</li><li>▶ Regulatory Affairs</li><li>▶ Respiratory Delivery</li><li>▶ Respiratory Drug Delivery &amp; Development</li><li>▶ Respiratory Supply Chain</li><li>▶ Respiratory Therapeutics</li><li>▶ Respiratory Pharmacology</li><li>▶ Scientific Research</li><li>▶ Marketing &amp; Business Development</li><li>▶ Other</li></ul> |
|--|---|---|

## INDUSTRIES

- |  |   |
|--|---|
| <ul style="list-style-type: none"><li>▶ Pharmaceutical</li><li>▶ Biotechnology</li><li>▶ Chemical</li><li>▶ Medical Devices</li><li>▶ Plastics</li></ul> | <ul style="list-style-type: none"><li>▶ CMOs/CDMOs</li><li>▶ CROs</li><li>▶ NOPS</li><li>▶ Regulatory Agencies</li><li>▶ Training providers</li><li>▶ Other</li></ul> |
|--|---|



# INHALED DRUG DELIVERY

**qepler**  
INHALED  
DRUG DELIVERY  
VIRTUAL SUMMIT  
2021

**August 5 | 1<sup>st</sup> DAY**

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

12:00 - 12:20

**Registration**

12:20 - 12:30

**Opening Address from the Chairman**

12:30 - 13:00

**Understanding of regulations and requirements for OINDPs.**

Direct link to HOPIN session: <https://app.hopin.com/events/2nd-inhaled-drug-delivery-conference-2021/sessions/2cf6e546-f7cc-4251-9993-6cf091bd8ec7>

- Overview of E&L for OINDPs
- What are Extractables and leachables
- Why most important for OINDPs
- Brief overview of regulations
- Case studies

**Dr. Andrew Feilden**, CSci CChem FRSC | European E&L strategic Director | **Hall Analytical**, UK



13:00 - 13:10

**Q & A**

13:10 - 13:40

**Aerodynamics and Air Flow Resistance of DPIs.**

Direct link to HOPIN session: <https://app.hopin.com/events/2nd-inhaled-drug-delivery-conference-2021/sessions/6e3eee08-d568-4e43-98a3-4a8ec24dabc8>

- Introduction – The relevance of the air flow resistance
- The air flow inside of a DPI – An engineer's perspective
- Interaction with formulation – A completely different story
- Basic approach using a bypass – visualisation and modelling
- Summary

**Dr. Herbert Watchel** | Senior Principal Scientist | **Boehringer Ingelheim Pharma GmbH & Co. KG**, DE



13:40 - 13:50

**Q & A**

13:50 - 14:00

**Break**

14:00 - 14:30

**Using the inhalation route to delivery drugs to the systemic circulation.**

Direct link to HOPIN session: <https://app.hopin.com/events/2nd-inhaled-drug-delivery-conference-2021/sessions/9d642ace-420a-43ab-bc20-3e2c1c506133>

- Advantages and limitation of the pulmonary route to the systemic circulation
- Requirements for distal lung aerosol delivery
- Medicines for systemic inhalation therapy on the market and in the development pipeline
- Critical assessment of factors governing the success (or failure) of systemically inhaled products

**Dr. Carsten Ehrhardt** | Professor in Pharmaceutics and Biopharmaceutics | **Trinity College Dublin**, IE



14:30 - 14:40

**Q & A**

14:40 - 15:10

**Lung on chip applications in respiratory health.**

Direct link to HOPIN session: <https://app.hopin.com/events/2nd-inhaled-drug-delivery-conference-2021/sessions/4d3aad8b-a2a5-4d34-b9aa-bd846f4ddaed>

**Nina Hobi** | CEO & Scientific Director | **AlveoliX AG**, CH



15:10 - 15:20

**Q & A**



# INHALED DRUG DELIVERY

**August 5 | 1<sup>st</sup> DAY**

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

15:20 - 16:05



## Translating Inhaled and Nasal Technologies for the Delivery of Biologics.

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Direct link to HOPIN session: <https://app.hopin.com/events/2nd-inhaled-drug-delivery-conference-2021/sessions/ca077f2e-3834-4f98-961c-28ae9ec77eb3>

Inhaled and nasal delivery platforms have specific applications outside of their traditional uses for asthma/chronic obstructive pulmonary disease (COPD) and seasonal rhinitis/sinusitis: They can offer real advantages for the delivery of therapeutic biologics.

- Overview of currently available technologies and successfully marketed products.
- Review of the development challenges that might be encountered — and the solutions that are available — when formulating these delivery routes.
- A focus on analytical approaches for impurity identification and quantification.
- Key considerations when rapidly repurposing existing products for inhaled delivery.

Mark Parry | Technical Director | **Intertek Pharmaceutical Services, UK**



**Q & A**

**Break**

16:05 - 16:15

16:15 - 16:25

16:25 - 16:55



## Inhalation of therapeutics to fight respiratory tract infections.

Direct link to HOPIN session: <https://app.hopin.com/events/2nd-inhaled-drug-delivery-conference-2021/sessions/c5a836cb-09a4-411f-8c22-eb114ad432fa>

- Inhalation addresses drugs topically as an aerosol through the nose and/or mouth to its site of action in the respiratory tract. Actually, inhalation is the gold standard for the delivery of drugs with topical action to treat asthma, chronic obstructive respiratory disease (COPD) or cystic fibrosis (CF).
- Inhalation provides a better therapeutic index for some drugs, often requires reduced dose as compared to other routes and is non-invasive, improving patient compliance and comfort.
- Presently, most (topical) inhaled drugs are small molecules from different classes. Despite the obvious theoretical advantages of topical administration for therapeutics antibody (Ab) by inhalation, few of these benefits have yet materialized in the clinics.
- This paucity highlights the complexity of developing inhaled antibodies and points out the persisting hurdles to overcome. A detailed understanding of the biology and pharmacology of inhaled Ab is required to ensure the successful transition from pre-clinical to clinical assessment.

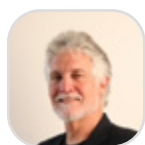
Thomas Sécher | Scientist | **INSERM, FR**



**Q & A**

16:55 - 17:05

17:05 - 17:35



## Transnasal Pulmonary Drug Delivery in Acute and Critical Care – Practice to Promise.

Direct link to HOPIN session: <https://app.hopin.com/events/2nd-inhaled-drug-delivery-conference-2021/sessions/8c43d6f6-04cf-4101-af93-7f1b4255056b>

- Administration of medical aerosols to the lung of our sickest patients has multiple challenges in the critical care environment including the need to not interrupt oxygen and ventilatory support.
- Aerosol delivery via High Flow Nasal Oxygen is used by >70% of intensivists worldwide for a variety of applications, with expanding knowledge of best practices of optimal delivery efficiency achieving double digit delivery efficiency in both preterm infants and adults.
- Knowable and controllable, transnasal pulmonary aerosol delivery has the promise of efficient and consistent administration of a wide range of formulations supporting development and approval of inhaled medications for management of the critically ill.

James B Fink, PhD, RRT, FAARC, FCCP | Chief Scientific Officer | **Aerogen Pharma Corp., USA**



**Q & A**

**Networking Hour**

17:35 - 17:45

17:45 - 18:45



# INHALED DRUG DELIVERY

**August 6 | 2<sup>nd</sup> DAY**

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

12:00 - 12:20

**Registration**

12:20 - 12:30

**Opening Address from the Chairman**

12:30 - 13:00

**The climate is changing for metered dose inhalers.**

Direct link to HOPIN session: <https://app.hopin.com/events/2nd-inhaled-drug-delivery-conference-2021/sessions/6eda48e1-6985-4282-bcdb-f1c83801d36e>

- Increases in global temperature are already having a significant impact on our climate. The hydrofluorocarbon (HFC) propellants used today in pressurized metered-dose inhalers (pMDIs) have global warming potential (GWP) many times that of carbon dioxide. This has prompted calls to switch patients to dry powder inhalers (DPIs)
- Dry powder inhalers are often more expensive than the equivalent pMDI. A wholesale switch of reliever medications would lead to significant increases in the cost of these life-saving medications
- At the same time, it is projected that there may be a 5-fold increase in the cost of pharmaceutical grade propellants in the next few years. This may lead to a price increase in reliever medication
- At least two companies are now working to develop pMDIs using propellants which are potentially cheaper in the long-term and have much lower GWP

**Dr. John N Pritchard** | Independent Business Owner | **Inspiring Strategies, UK**



13:00 - 13:10

**Q & A**

13:10 - 13:40

**Practical challenges with developing inhalation drugs during pre-clinical testing.**

Direct link to HOPIN session: <https://app.hopin.com/events/2nd-inhaled-drug-delivery-conference-2021/sessions/0f184786-aef5-4939-a48b-a65538dc25d6>

- Extrapolating from clinical to pre-clinical and regulatory expectations
- Study designs – what is different for inhalation studies – histo, animal numbers or not, dose calculation
- NCEs vs biologics – differences or not
- Aerosol generation, exposure systems, aerosol sampling, additional DFA/FIA support
- Animal welfare considerations – TK blood volumes, BAL collection, limitations of dosing wrt time, dosing large animals – animal compliance

**Dr. Simon Moore, BSc(Hons) PhD MRSC** | Global Lead of Inhalation Sciences and Engineering  
**Covance Laboratories, UK**



13:40 - 13:50

**Q & A**

13:50 - 14:00

**Break**

14:00 - 14:30

**From perception to use - the patient DPI product interface.**

Direct link to HOPIN session: <https://app.hopin.com/events/2nd-inhaled-drug-delivery-conference-2021/sessions/3a0a9a8a-e2c6-4222-b84a-e3ec2eefdafe>

- Patient characteristics and therapeutic complexity
- DPI product administration from a patient perspective
- The role of learning, intuition and standardization
- TDPI product design to improve therapeutic outcomes

**Univ.-Prof. Dr. Sven Stegemann** | Professor for Patient Centric Drug Development & Manufacturing  
**Graz University of Technology, AT**



14:30 - 14:40

**Q & A**

14:40 - 15:10

**Are sustainability, reusability and carbon neutrality major trends for devices in the future?**  
**A case study of RespiMat® re-usable.**

Direct link to HOPIN session: <https://app.hopin.com/events/2nd-inhaled-drug-delivery-conference-2021/sessions/521829cc-025f-42bf-ad91-c221e5919789>

- Historic and upcoming political initiatives
- Carbon footprint and neutrality
- RespiMat® re-usable - technology and performance
- Sustainability goes beyond design

**Dr. Felix Weiland** | Head of Product & Process Technology | **Boehringer Ingelheim microParts GmbH, DE**



15:10 - 15:20

**Q & A**



# INHALED DRUG DELIVERY

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**August 6 | 2<sup>nd</sup> DAY**

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

15:20 - 15:30

Break

15:30 - 16:10



## [The impact of filling technology selection for dry powder formulations on device performance, process consistency and commercial scale-up.](#)

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Direct link to HOPIN session: <https://app.hopin.com/events/2nd-inhaled-drug-delivery-conference-2021/sessions/2ecd49b6-f8c2-40ce-882b-7c81b4d67132>

- Consistent high efficiency aerosolisation performance is a critical quality attribute for all dry powder inhalers. There is a strong dependant relationship between the powder formulation, filling technology, device design and the device performance.
- The desire to deliver a wider range of molecular types of drug has promoted a large increase in the use of engineered particle technologies e.g. spray drying for DPIs which require careful consideration of process conditions.
- Highlight the impact of filling technology on device performance, process efficiency and manufacturing throughput. Could selection of the right filling technologies enable increased formulation and device design spaces.
- Assess the potential issues due to filling technology with process scale-up to achieve continuity of performance as you move from bench, through clinic to commercial; minimising risk in the development process.
- Affirm the importance of early stage filling trials on formulation selection and device design.

**Tom French** | Device Industrialisation Engineer | **3P innovation, UK**



16:10 - 16:20

Q & A

16:20 - 16:50



## [Postmarket Safety reporting for Combination products in the US](#)

Direct link to HOPIN session: <https://app.hopin.com/events/2nd-inhaled-drug-delivery-conference-2021/sessions/8f02555e-1bbc-442f-beed-c223c730d3b8>

- What are the regulatory requirements
- Discussion of key challenges
- Walk through a reportable event case scenario

**Khaudeja Bano, MD** | Executive Medical Director, Combination Product Safety Head  
Global Patient Safety & Pediatrics | **Amgen, USA**



16:50 - 17:00

Q & A

17:00 - 17:30



## [ICOpres - Development of a generic DPI platform for a global market.](#)

Direct link to HOPIN session: <https://app.hopin.com/events/2nd-inhaled-drug-delivery-conference-2021/sessions/fde73368-8fe6-47ce-863d-2399701faa43>

Generic versions of marketed dry powder inhaler (DPI) drug products represent an attractive market opportunity. In the coming years, GSK's Ellipta platform is the largest opportunity with several drug substance patents expiring. However, development of generic DPI drug products is a complicated process with many challenges. Complex drug-device interactions represent a major hurdle to achieve therapeutic equivalence. The very intricate patent landscape in combination with the requirement of similar user-handling and flow resistance limits the design options. The need for cost-efficient development and low manufacturing costs adds additional complexity. There is a great need to replace injections with safe and low cost inhaled drug delivery. Iconovo's unit-dose inhaler ICOone is currently used in two ongoing projects on inhaled oxytocin and inhaled covid-19 vaccine.

- Overview of market and patent situation.
- Regulatory requirements on generic inhalation products.
- Initial choice – copy original or develop new technology.
- Concurrent development of device and formulation.
- ICOone – inhalation instead of injection.

**Dr. Orest Lastow** | Chief Technology Officer & Founder | **Iconovo AB, SE**



17:30 - 17:40

Q & A

17:40 - 18:40

Networking Hour

18:40 - 18:50

Closing remarks and end of conference





# INHALED DRUG DELIVERY

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VIRTUAL SUMMIT  
2021

## SPEAKER'S BIOGRAPHIES



**Dr. Andrew Feilden**  
European E&L strategic Director  
Hall Analytical, UK

Dr. Andrew Feilden is the European E&L strategic Director at Hall Analytical. Prior to that he was the Chemistry Operations Director, for 6 years, where he led the chemistry group at the Shawbury site in the UK. The Shawbury site carries out extractable and leachable testing, GPC analysis and food contact testing. He has delivered numerous international podium presentations on Extractables and Leachables.

Andrew has been with Smithers for over 7 years, prior to that he worked for AstraZeneca, specialising in Extractables and Leachables. He has a degree and D Phil from the university of York, is a Fellow of the Royal Society of Chemistry and is a Scientific advisor to IPAC-RS.



**Dr. Felix Weiland**  
Head of Product & Process  
Technology  
Boehringer Ingelheim microParts  
GmbH, DE

Felix is a pharmacist by training with a PhD in pharmacology. In 2006, he joined Boehringer Ingelheim as a trainee, focusing on launch and transfer activities of inhalative products. He then took over different roles at BI microParts in Dortmund at the development site of inhalation devices as development QA manager, senior project manager, and lab head of device development. In 2010, he joined the Ger-resheimer Group at Bünde as a QC head and later as quality director. Buende is a large-scale manufacturing site of sterile primary packaging components, i.e. RTF<sup>®</sup>-syringes and insulin cartridges. In 2015, he returned to Boehringer Ingelheim to implement systems for systematic life cycle management of the RespiMat<sup>®</sup> Plat-form Technology, including ownership of the design history files. Currently he is the director of product- & process-technology including responsibilities for project management, design verification laboratories, clinical trial supply, and design & process technology of devices.



**Dr. Herbert Wachtel**  
Senior Principal Scientist  
Boehringer Ingelheim Pharma  
GmbH & Co. KG, DE

Dr. Herbert Wachtel is a Senior Principal Scientist at Boehringer Ingelheim, Germany. Boehringer Ingelheim is a global, research-driven pharmaceutical company embracing many cultures and diverse societies. Within its business unit Prescription Medicines, Respiratory is one of the major areas. Herbert has joined the company in 1998 and since then he has been involved in basics of inhalation therapy, e.g. formulation development, novel methods for particle sizing, design of aerodynamic components in inhalers and aerosol therapy in children. In his spare time Herbert serves as a lecturer on the subject of Pharmaceutical Technology at the Johannes Gutenberg-University in Mainz.

Herbert has studied Physics at the University of Stuttgart where he investigated conducting molecular solid films and surfaces before switching to the field of aerosolized drug delivery. Apart from CAD tools, Herbert regularly applies Computational Fluid Dynamics (CFD) and he advances up-to-date 'in vivo-in vitro correlations' (IV-IVC) for the optimization of devices in the industrial setting.



**Dr. Carsten Ehrhardt**  
Professor in Pharmaceutics and  
Biopharmaceutics  
Trinity College Dublin, IE

Carsten is Professor in Pharmaceutics and Biopharmaceutics and Fellow at Trinity College Dublin. He also holds an Adjunct Professorship at the University of Southern California. His research is focused on lung drug disposition and pulmonary epithelial transport. Moreover, he is interested in molecular origins of airways disease. Carsten has edited 1 book and (co-) authored 98 peer-reviewed publications and over 250 abstracts. He is the recipient of honours and awards from German Pharmaceutical Society (DPHG), American Physiological Society and Galenus Foundation.

Carsten serves as Section Editor of European Journal of Pharmaceutical Sciences and is a member of the Editorial Boards of American Journal of Physiology - Lung Cellular and Molecular Physiology, European Journal of Pharmaceutics and Biopharmaceutics, Journal of Aerosol Medicine and Pulmonary Drug Delivery, Journal of Pharmaceutical Sciences, Pharmaceutics, and Pharmaceutical Research.



**Dr John N Pritchard**  
Independent Business Owner  
Inspiring Strategies, UK

From January 2011 - September 2018, John was CTO for Philips Respironics Drug Delivery, with global accountability for the development of products for the treatment of respiratory diseases. He is now a private consultant specialising in strategic approaches to developing respiratory devices, drugs and digital health. At different stages in his career across 3 major pharmaceutical companies, he has been associated with the launch of 11 major products and at RDD in April 2018, John received the Charles Thiel award for outstanding research and discovery in respiratory drug delivery. John has published widely in the field, as well as having served as Board member on various scientific and industry bodies. He has sat on a number of Advisory Boards and is currently a member of the UN Committee that makes recommendations on the essential uses of propellants.



**Univ.-Prof. Dr. Sven Stegemann**  
Professor for Patient Centric  
Drug Development &  
Manufacturing  
Graz University of Technology,  
AT

Sven Stegemann is professor of patient centric drug design and manufacturing at the Graz University of Technology, Austria. Over the course of his 21-year career he has worked as an advisor to major pharmaceutical companies on ways to improve the design, development and manufacture of pharmaceutical products so they better address the individual needs of patients. In his academic role, he focuses his research on the rational development of patient centric drug products and their associated manufacturing technologies, as well as education and training of students and young scientists. He is the founder and chair of the AAPS Focus Group on Patient-Centric Drug Development, Product Design, and Manufacturing as well as the founder and President of the Geriatric Medicine Society e.V.. He recently started the industrial-academic collaboration partnership Patient Centric Medicine (PaCeMe) to suitable and meaningful guidance for patient centric drug product design. He is the editor of the book "Developing Drug Products in an Aging Society - From Concept to Prescribing", a multidisciplinary approach towards patient centric drug development for the older and multimorbid patient populations.



**Thomas Sécher**  
Scientist  
INSERM, FR

Thomas is a research scientist in the field of mucosal immunology and therapeutics. He is particularly concerned about infectious diseases and the way we can prevent them. Quickly realized the importance of the host-pathogen-environment triad in determining the outcome of infectious events and he was fascinated by the host-pathogen dualism and how their interactions dictate pathogenesis and subsequently modulate the efficacy of therapeutics. Studying this in more details has always been the driving force of my research.

Thomas owned a PhD in immunology/infectiology and have more than 10 years of experience in mucosal immunology and experimental disease models. After pursuing research projects at the CNRS (UMR 6218, Orléans, France) and INSERM (UMR1043, Toulouse, France), he joined the Research Center for Respiratory Diseases in Tours in 2016. His research interests are mainly focused on proof-of-concept for aerosol delivery of biotherapeutics and mainly therapeutic antibodies to treat respiratory tract infections.

Thomas (co-)authored more than 40 peer-reviewed publications, 1 patent and has given more than 20 oral presentations. He was a member of the scientific committee for the 7th (2019) and 9th (2021) AIS congress and actively serves as reviewer for Frontiers in Immunology, Frontiers in Microbiology, Gut and Plos One.

**SUMMIT NAME:** VIRTUAL - 2nd Annual Inhaled Drug Delivery Summit 2021

**REGISTRATION DATE:** \_\_\_\_\_

PACKAGE NAME			Standard price
Individual ticket - 1 <sup>st</sup> Day (5 <sup>th</sup> August 2021) - (*includes 1 <sup>st</sup> Day's post-event conference materials distribution)			€195
Individual ticket - 2 <sup>nd</sup> Day (6 <sup>th</sup> August 2021) - (*includes 2 <sup>nd</sup> Day's post-event conference materials distribution)			€195
Individual ticket - 2 Days - (*includes complete post-event conference materials distribution)			€295
Group ticket - 2 Days (*2-3 delegates) - (*includes complete post-event conference materials distribution)			€215
Group ticket - 2 Days (*4+ delegates) - (*includes complete post-event conference materials distribution)			€145
Documentation package - (*if you have no plans to join the live conference)			€395
Promotional materials distribution			€445
SPEAKER SPONSOR - €995		PARTNER SPONSOR - €1295	GOLD SPONSOR - €1695

**CONFERENCE MATERIALS:**

All participation tickets, already contains complete conference materials distribution package, including - slides, list of participants, stream and video recording. You don't need to order an additional «Documentation Packages». Documentation package will be sent to the attendees within 72 hours after the event. The presentation content is subject to speaker's companies approval for distribution.

ATTENDEE DETAILS	1 <sup>ST</sup> ATTENDEE	2 <sup>ND</sup> ATTENDEE	3 <sup>RD</sup> ATTENDEE	4 <sup>TH</sup> ATTENDEE	5 <sup>TH</sup> ATTENDEE	6 <sup>TH</sup> ATTENDEE
Title:						
Name:						
Surname:						
Company:						
Country:						
Job Title:						
Direct phone:						
Email:						
Special Requirements: (If you have any special dietary requirements or other needs that would enhance your enjoyment of this summit, please specify)						

## INVOICE DETAILS:

Title: \_\_\_\_\_ Name: \_\_\_\_\_ Surname: \_\_\_\_\_

Job Title: \_\_\_\_\_

Direct Phone: \_\_\_\_\_ Mobile: \_\_\_\_\_ Email: \_\_\_\_\_

Company: \_\_\_\_\_ Country: \_\_\_\_\_ City: \_\_\_\_\_ EU VAT #: \_\_\_\_\_

Address: \_\_\_\_\_ Postcode: \_\_\_\_\_

Payment Method: ☐ Bank Transfer ☐ Credit Card ☐ Pay Pall

## TERMS & CONDITIONS:

### REGISTRATION & PAYMENT

Upon receiving the signed registration form, we will process your application. The registration confirmation and the invoice will be sent to you within one (1) working day with the relevant payment instructions and terms. The registration fee includes access to all sessions and conference materials. Payment is due 14 working days from the invoice date. Payment should be made by Credit Card, Pay Pall or by Bank Transfer. The delegate is responsible for any bank charges/fees associated with the payment.

### CANCELLATION & SUBSTITUTION POLICY

You may substitute a delegate at any time and at no extra cost. Cancellations must be in a written notice. Cancellations made 30 days or more before the event start date will be refunded less than 50% of the registration fee. Cancellations made less than 30 days before the event start date will receive no refund. If you cannot attend an event due to illness or other unforeseen circumstances, you may transfer your delegate pass to another upcoming event within one year from original event start date.

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While all effort will be made to adhere to the advertised package, Qepler s.r.o. reserves the right to change event dates, sites or location, omit event features, or merge the event with another event as it deems necessary without penalty. In such situations no refunds, part refunds or alternative offers will be made. In the event that Qepler s.r.o. permanently cancels the event for any reason, and provided that the event is not postponed to a later date nor is merged with another event, you will receive a credit note or refund for 100% of the conference fee paid. Please note, Qepler s.r.o. will not be held liable for any accommodation or associated travel costs should the event be canceled or rescheduled.

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## ONLINE PACKAGES:

If you are unable to attend, you may purchase these packages

PACKAGE NAME	PRICE
<b>DOCUMENTATION</b> (*if you have no plans to join the live conference) Post-event presentations with video records, list of participants and other materials. The presentation content is subject to speaker's companies approval for distribution.	€395
<b>PROMOTIONAL MATERIALS DISTRIBUTION</b> Distribution of your company's promotional materials to all attendees	€445

## SPONSORSHIP PACKAGES:

BENEFITS	SPEAKER €995	PARTNER €1295	GOLD €1695
Number of passes included	1	2	3
Registration fee for additional company representatives	€195	€145	€95
Link to Landing Page/Video Presentation trough the live event translation.		•	•
Link to Virtual Exhibition Page trough the live event translation.			•
Opening keynote presentation			15 min
Speaking slot	20 min	30 min	30 min
Workshop slot			40 min
Recognition in chairman's opening address		•	•
Opening & closing speech			•
Chairman of Day 1			•
Chairman of Day 2		•	
Logo and URL on summit website, agenda and pre/post-summit communication activities	•	•	•
Recognition on Qepler social media channels (LinkedIn/Facebook/Twitter/Instagram)	•	•	•
Color advert placed on agenda		1/2 Page	1 Page
Online distribution of your company's promotional materials to all attendees		•	•

## MARKETING CAMPAIGN

► Website ► Email Marketing ► Digital Advertising ► Social Marketing ► Press ► Direct Sales

## PARTICIPATION FEE

Fees are inclusive of the complete summit materials, online post-event documentation/presentation package, list of participants, video records, and certificate of participation.

## TRANSLATION

The event translation link will be announced online and sent to the delegates within a reasonable period before the summit start date.

## POST-EVENT DOCUMENTATION

Presentations and other materials will be sent to the attendees within 72 hours after the event. The presentation content is subject to speaker's companies approval for distribution.

## DISCOUNTS

Early booking discounts are not valid in conjunction with any other offers.

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INHALATION - ASEPTIC PROCESSING - MDR - CMC - QRM - PFS - DDC - EM

**2<sup>nd</sup> Genotoxic Impurities in Pharmaceuticals Summit** ..... July 15-16, 2021  
• VIRTUAL CONFERENCE  
GTL strategies & new methodologies: analysis, in silico & regulations. Challenges & opportunities.  
<https://qepler.com/pdf/v2gti21.pdf>  
**REGISTRATION IS OPEN**

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**3<sup>rd</sup> Annual Pharmaceutical Lyophilization Summit** ..... July 29-30, 2021  
• VIRTUAL CONFERENCE  
Discuss best practices in tech & regulatory updates, process, formulation, testing, monitoring, new products development.  
<https://qepler.com/pdf/v3lyo21.pdf>  
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**2<sup>nd</sup> Annual Inhaled Drug Delivery Summit** ..... August 5-6, 2021  
• VIRTUAL CONFERENCE  
Assess and harness novel approaches to the development of inhaled drug products for enhanced patient care.  
<https://qepler.com/pdf/v2idd21.pdf>  
**REGISTRATION IS OPEN**

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**3<sup>rd</sup> Annual Highly Potent APIs Summit** ..... October 7-8, 2021  
• VIRTUAL CONFERENCE  
Assess and reduce manufacturing and handling challenges for highly potent active pharmaceutical ingredients.  
<https://qepler.com/pdf/v3hpapi21.pdf>  
**REGISTRATION IS OPEN**

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**3<sup>rd</sup> Annual Extractables & Leachables Summit** ..... October 20-21, 2021  
• VIRTUAL CONFERENCE  
Get the latest updates in regulation, analytical testing, risk & safety assessment, biocompatibility.  
<https://qepler.com/pdf/v3el21.pdf>  
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**3<sup>rd</sup> Annual Drug/Device Combination Products Summit** ..... December 2-3, 2021  
• VIRTUAL CONFERENCE  
Get up to date with the regulatory and quality compliance strategies for combination product development.  
<https://qepler.com/pdf/v3ddcp21.pdf>  
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## CONTACTS

Please send your session title and summit name to:



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