# RESCON -SUMMERSON -EUROPE UNE20-21



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## JOIN US .

207

World of Wine, Rua do Choupelo 39

Porto, Portugal

# Inhalation & Respiratory Drug Delivery | Connected Devices

- Digital trends in drug delivery for lungs
- Eco-friendly inhalers for a sustainable future
- Achieving sustainability goals in medical devices...







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Aerosol Medicine and Pulmonary Drug Delivery Mary Ann Lielert, Inc. & publishers













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**RESCON EUROPE** highlights innovations in the respiratory sector and connected devices. RESCON EUROPE will feature key case studies on the latest trends in Sustainable Inhalation devices, Inhaled mRNA Therapy, from inhaled insulin to gene therapy to overcome lung and pulmonary conditions, such as COPD, asthma and cystic fibrosis. Further discussion focusses at on-body device design and development for large volume delivery while engaging in the latest digital applications for wearable devices.

# LEARN THE KEY PRACTICAL POINTS

- Digital trends in lung drug delivery
- Green inhalers and sustainability in devices
- Plastic supplier insights on sustainability
- Combined nasal and pulmonary vaccine delivery
- User factors affecting dry powder inhalers
- Alternative pathway for generic respiratory products
- Biopharmaceutical modeling from in vitro to PK
- Preclinical studies on intranasal medication delivery
- Advances in nebulizer technology for respiratory drug delivery
- Novel approaches to treating asthma and COPD
- Regulatory considerations for inhaled drug products and connected devices.
- Optimizing drug delivery with high flow nasal cannula
- Liquid foams for high-dose pulmonary therapy

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- Risk of nebulizer treatment in infection transmission
- Aerosol delivery for interstitial lung disease
- Inhaled divalent salts for respiratory illness treatment
- Microbiota modulation for cough treatment
- Analytical tools for inhaled medicines
- Challenges and opportunities in developing inhaled biologics
- Impact of COVID-19 on inhalation drug delivery & respiratory care
- Post-market surveillance data and inhalation product development

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## **SPEAKERS**



Director, Medicinal Chemistry at *AstraZeneca* 



Associate Professor at the Food and Drug Department, University of Parma (IT)



Director Sales and Business Development at Global Inhalation & Medical Devices – Berry Healthcare



Director Core Facility Imaging, Center for Medical Research at *Medical University of Graz* 



Vice-president of Associação Nacional de Fibrose Quística (ANFQ)



Professor & Associate Dean for Research at Texas State University



CEO at VisionHealth GmbH



Senior Adviser -Inhalation Science at Emmace Consulting AB



Sr. Marketing Manager HealthCare Global at Avient Colorants Germany GmbH



Leader-Formulation and Drug Delivery at Research Center Pharmaceutical Engineering GmbH (RCPE)



Head of Analytical Development and Life Cycle Management at Nanopharm, an Aptar Pharma Company



Professor in Pharmaceutics and Biopharmaceutics at *Trinity College Dublin* 

## **SPEAKERS**.



Managing Human Factors Specialist at *Emergo by UL* 



Physician at Tel Aviv Medical Center



Medical Device Consultant at Beyond Conception



Inventor and independent researcher



CEO of Emmace Consulting



Professor Emerita at the Johns Hopkins School of Medicine



Professor at The University of Texas at Austin



Innovation Scout at Boehringer Ingelheim Pharma



Senior Sales Manager at Harro Höfliger



Senior Human Factors Engineer at *Roche* 



Commercial Director at Intertek Pharmaceutical Services



CTO & Founder at Iconovo AB



Founder at FEND



# SCIENTIFIC AGENDA.

## JUNE 19TH, MON

#### 18:00 - 19:00

Planet Cork Networking Experience

#### 19:00 - 21:00

Pre-Conference Cocktail reception at Angel's Share Bar



### JUNE 20TH, TUE

**Morning Sessions Moderator: Herbert Wachtel** 

#### 08:00 - 08:20

**Registration & Welcome Coffee** 

#### 08:20 - 08:30

RESCON Europe Opening Speech By **Joana Roque** Vice-president of Associação Nacional de Fibrose Quística (ANFQ)

Patients as Partners in Research & Development.

- » The value of integrating patient experience and perspective since early stages of R&D.
- » The Cystic Fibrosis experience in Europe.

**08:30 - 09:00** Emerging digital trends in drug delivery to the lungs By **Sabine Häussermann** CEO at VisionHealth GmbH

- » Enhanced drug delivery.
- » Market challenges in digitalisation strategies.

#### 09:00 - 09:30

Grey Soft Mist Inhalers for a green environment By **Herbert Wachtel** Innovation Scout at Boehringer Ingelheim Pharma

- » Design features of a re-usable Inhaler:
  - > Multi-Dose cartridge
  - > Multi-cartridge device
- » Performance characteristics:
  - > Slowly moving soft mist with long spray duration
  - > Delivered Dose
  - > Aerodynamic Particle Size Distribution
- » The carbon footprint of Respimat SMI:
  - > Investigation of the life cycle from cradle to grave.

# ORALLY INHALED & NASAL DRUG PRODUCT DEVELOPMENT AND CESTING Interfector Supporting global OINDP development for over 30 years Interfector 9 consultation development Interfector 9 consultation Interfector

#### 09:30 - 10:00

How to achieve your sustainability goals in Medical Devices. Insights from a plastic material suplier perspective.

By Volker Dickfeld Sr. Marketing Manager HealthCare Global at Avient Colorants Germany GmbH

- » In this presentation we will highlight, new material options to reduce the carbon footprint for healthcare application, while keeping the regulatory integrity.
- » Learn more, on how to reduce the carbon footprint using color and additive solutions formulated with bio-based polymers. You will get insides on the concrete PCF Product carbon footprint savings of these solutions, that are of cause specially designed for the use in regulated healthcare applications with regulatory compliance support and comprehensive documentation.
- » In addition, you will discover further option to save material, reducing weight of plastic article, using special Additive solutions.

#### 10:00 - 10:20

Speed Networking

#### 10:20 - 11:00

Morning Coffee Break & Sponsors Presentation

#### 11:00 - 11:30

Novel system for combined nasal and pulmonary drug delivery of vaccines By **Orest Lastow** CTO & Founder at Iconovo AB

- Future pandemics are expected to be caused by airborne virus infecting the respiratory tract. Several studies have shown that Mucosal IgA can provide immunity against respiratory viruses. A future vaccine, treatment or prophylactic drug could therefore be more efficacious using combined nasal and pulmonary delivery to give maximal mucosal absorption in the entire respiratory tract.
- » A non-invasive method to simultaneously administer drug or vaccine to both the nose and the lung could be an important first line of defense against the next pandemic. Several nasal spray vaccines are under development, but sprays have the inherent limitation in terms of short shelflife and coordination issues. A passive dry powder delivery system would address the limitation of wet sprays. A nasal DPI is driven by the inspiratory flow, eliminating all coordination issues.

A dry powder is stable in room temperature eliminating the need for expensive and complicated cold storage. The dry powder formulation can also be optimized to give a maximal pulmonary deposition.

» A platform for simple and cost-efficient delivery of vaccines and biomolecules via the nose has been developed and optimized. The dry powder inhalation platform includes a device and a family of dry powder formulations. The platform is developed to be ultra-low-cost and suitable for low-income countries and tropical conditions. The project is funded by Bill & Melinda Gates Foundation.

#### 11:30 - 12:00

#### Aiming to the balance point: thinking next generation DPIs

By **Marco Franza** Director Sales and Business Development at Global Inhalation & Medical Devices – Berry Healthcare

- » Digital empowerment;
- » Different approaches for sustainable development of generic DPI.

#### 12:00 - 12:30

Patient in-use factors decisive to the performance of dry powder inhalers

By **Amrit Paudel** Leader-Formulation and Drug Delivery at Research Center Pharmaceutical Engineering GmbH (RCPE)

#### 12:30 - 13:00

Challanges of powder dosing in inhalation product manufacturing By **Marian Asch** Senior Sales Manager at Harro Höfliger

- » Powder properties and its impact on manufacturing processes;
- » Considerations from lab to production during the development of Dry Powder Inhaler products;
- » Two-stage filling for pMDI manufacturing.



Filling trials • Powder blending • DPI analytic (emitted dose, fine particle dose) • Technical sample manufacturing • Stabilities

**13:00 - 14:00** Business Lunch

Afternoon Sessions Moderator: Carsten Ehrhardt

#### 14:00 - 14:30

Physiology Based Biopharmaceutical Modeling - Bridging from In Vitro to PK By **Per Bäckman** Senior Adviser - Inhalation Science at Emmace Consulting AB

- » The potential of PBBM modelling to understand and predict the pharmacokinetics of inhaled medicines will be discussed. This will include predictions of PK parameters such as AUC and Cmax based on critical product attributes such as dissolution, dose deposition and delivered dose in support of pivotal bioequvalence studies.
- » From a biopharmaceutical standpoint, critical product and drug attributes describe the extent to which the dose reaches the lung, dose penetration into the distal parts of the lung, dissolution rate in situ, permeation through lung epithelium and diffusion through lung tissue into the systemic circulation
- » PBBM models mechanistically describe the processes involved and allow for the prediction of systemic and local exposure following administration of an inhaled medicine. This provide opportunities to predict bioequivalence between products, define clinically relevant product design specifications, as well as the potential of novel and repurposed drugs for inhalation.

#### 14:30 - 15:00

Preclinical studies of factors that affect delivery of aerosolized medications within the intranasal airways using 3D models

By Beth Laube Professor Emerita at the Johns Hopkins School of Medicine

#### 15:00 - 15:30

Optimizing Aerosol Drug Delivery via High Flow Nasal Cannula By **Arzu Ari** Professor & Associate Dean for Research at Texas State University

- » Overview of transnasal aerosol delivery via high flow nasal cannula (HFNC) application and its safety.
- » Present the latest research on aerosol delivery via HFNC
- » Provide strategies to optimize aerosol delivery during HFNC based on the best evidence

**15:30 - 16:00** Inhaled Antimicrobials: Navigating The Barriers And Targeting Infections By **Hugh Smyth** Professor at The University of Texas at Austin

#### 16:00 - 16:30

Afternoon Coffee Break & Sponsors Presentation

#### 16:30 - 17:00

The risk of nebulizer treatments in the transmission of bacteria and viruses - A Systematic Review

By Israel Amirav Physician at Tel Aviv Medical Center

#### 17:00 - 17:30

Panel Discussion: "Advancements and Innovations in Inhalation Therapies: Enhancing Drug Delivery, Patient Experience, and Outcomes"

- » Next-generation Inhalation Technologies: Advancements in Drug Delivery Systems
- » Innovations in Inhaled Therapy for Respiratory Conditions: From Research to Clinical Translation
- » Human Factors Engineering in Inhalation Device Design: Enhancing User Experience and Adherence
- » Personalized Inhalation Medicine: Tailoring Treatments to Individual Patient Needs
- » Digital Solutions and Wearable Devices in Respiratory Health MonitoringThe role of digital health in improving inhalation therapy outcomes

**Moderator: Carsten Ehrhardt** Professor in Pharmaceutics and Biopharmaceutics at Trinity College Dublin

#### **Panelists:**

- . Søren Skov Senior Human Factors Engineer at Roche
- . Sabine Häussermann CEO at VisionHealth GmbH
- . Herbert Wachtel Innovation Scout at Boehringer Ingelheim Pharma
- . Per Bäckman Senior Adviser Inhalation Science at Emmace Consulting AB
- . David Edwards Founder at FEND

**17:30** RESCON Europe 1st Day Closing Remarks

**19:00 - 20:00** Networking Wine Experience

**20:00 - 22:00** Gala Dinner With Live Fado Concert at **1828** 



## JUNE 2IST, WED

#### **Morning Sessions Moderator: Sabine Haeussermann**

#### 08:00 - 08:20

Registration & Welcome Coffee

#### 08:30 - 09:00

Aerosol delivery in ILD - breakthrough or lost cause?

By Carsten Ehrhardt Professor in Pharmaceutics and Biopharmaceutics at Trinity College Dublin

- » Interstitial lung disease (ILD) is an umbrella term used for a large group of diseases that cause irreversible fibrosis of the lungs. In many cases, such as idiopathic pulmonary fibrosis (IPF), the causes may be unknown.
- » There is currently no cure for IPF. Pirfenidone and nintedanib are used with the aim of relieving the symptoms as much as possible and slowing down its progression. Bot drugs, however, cause significant unwanted side effects when given orally.
- » Inhalation therapy could potentially increase the local drug concentration while simultaneously decrease systemic exposure. This presentation will explore if it is possible and meaningful to deliver drug aerosols to fibrotic lungs.

#### 09:00 - 09:30

Replacement Strategies for Animal Studies in Inhalation Testing

By **Eleonore Fröhlich** Director Core Facility Imaging, Center for Medical Research at Medical University of Graz

#### 09:30 - 10:00

Nasally Inhaled Divalent Salts for Prophylaxis and Treatment of Upper Respiratory Illnesses such as Chronic Cough By **David Edwards** Founder at FEND

#### 10:00 - 10:30

Treatment for cough or lactobacilli powders for microbiota modulation By **Francesca Buttini** Associate Professor at the Food and Drug Department, University of Parma (IT)

#### 10:30 - 11:00

Morning Coffee Break & Sponsors Presentation

#### 11:00 - 11:30

Analytical tools for inhaled medicines By Mårten Svensson CEO at Emmace Consulting

- » Analytical insights into dry powder formulations for inhalation.
- » Characterizing aerosol dynamics
- » Tests according to ISO 18562-2,-3,-4

#### 11:30 - 12:00

SmartTrack: An Alternative Pathway to the Approval of Generic Respiratory Products By **Lucas Silva** Head of Analytical Development and Life Cycle Management at Nanopharm, an Aptar Pharma Company

- » Presentation of SmartTrack approach to derisk and accelerate generic product development as a biowaiver for clinical end point studies. Introduction of the in vitro and in silico tools comprising SmartTrack platform under the umbrella of bioequivalence studies for generic orally inhaled products.
- » Presentation of SmartTrack in silico tools by Fluidda: Functional Respiratory Imagining and Rapid Deposition Analysis. Opportunities versus limitations and how, if combined together into the SmartTrack platform, they can make clinical trials shorter, faster and thus, more cost effective.
- » Presentation of SmartTrack realistic in vitro tools by Nanopharm and their application in a regulatory submission of a dry powder inhaler bioequivalent product.

#### 12:00 - 12:30

Inhaled New Modalities - from preclinical research to the clinic By **Lena Ripa** Director, Medicinal Chemistry at AstraZeneca

#### 12:30 - 13:00

How to Build an Inhaler: Selecting the Right Device and Formulation Platform for Your Molecule By **Chris Vernall** Commercial Director at Intertek Pharmaceutical Services

#### 13:00 - 14:00

**Business Lunch** 

#### **Afternoon Sessions Moderator: Mark Sanders**

#### 14:00 - 14:30

**Clinical Evaluations & Repiratory Devices** 

By Ortzi Olasolo Medical Device Consultant at Beyond Conception

- » Overview of the regulatory landscape for respiratory devices
- » Which respiratory devices mandate a Clinical Evaluation according to Regulation 2017/74
- » Overview of the Clinical Evaluation Process
- » When are Post-market Clinical Follow-up activities necessary?

#### 14:30 - 15:00

Behavior design and connected devices. Simplifying the complex by identifying what matters

By Søren Skov Senior Human Factors Engineer at Roche

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#### 15:00 - 15:30

The uncovered treasure of Post-Market Surveillance data By **Yvonne Limpens** Managing Human Factors Specialist at Emergo by UL

» How to make the most of post-market data to develop safe and effective medical devices

#### 15:30 - 16:00

Inhaler technique errors impact the majority of patients - what strategies can change this?

By Mark Sanders Inventor and independent researcher

- » Since initial reports of inhaler technique difficulties in 1965 over 14,000 publication have explored the subject but the problems continue to exist.
- » Inhaler technique training is called for in GINA, GOLD and other reports and a plethora of tools exist to conduct inhaler training, and yet the problem persists...
- » This presentation reviews what has been done and the potential for new technologies in future.

#### 16:00 - 16:05

End of RESCON Europe & Chairperson Closing Remarks







#### Lena Ripa | Director, Medicinal Chemistry at AstraZeneca

Lena obtained her PhD at the Medicinal Chemistry Department at the Biomedical Centre at Uppsala University, Sweden. Following a postdoc in combinatorial chemistry at the University of Pittsburgh she joined AstraZeneca, Lund as a Senior Research Scientist in Medicinal Chemistry in 2000. Lena has experience from projects in all stages of preclinical research addressing a range of different targets classes in the discovery of new drugs for the treatment of chronic diseases such as asthma, chronic obstructive pulmonary disease (COPD) and idiopathic pulmonary fibrosis (IPF). Since 2019, she is Director in Medicinal Chemistry, in the Respiratory & Immunology unit at AstraZeneca in Gothenburg, Sweden. Her current role includes leading a team of medicinal chemists as well as leading projects aimed both at oral and inhaled delivery.



#### Arzu Ari | Professor & Associate Dean for Research at Texas State University

Dr. Arzu is a Professor and the Associate Dean for Research at Texas State University. Her primary area of research is aerosol medicine, which is closely tied to significant developments with a global impact on the practice of aerosol drug delivery to patients with pulmonary diseases. Dr. Ari's interest in research has manifested in 85 peer-reviewed articles, 84 conference proceedings, 17 book chapters, two clinical practice guidelines, and two books. She gave 318 presentations at conferences worldwide. She is the first author of the book entitled "A Guide to Aerosol Delivery Devices for Respiratory Therapists, 2nd ed." published by the American Association for Respiratory Care in 2009. Her book was downloaded by approximately 3 million people worldwide and translated into Spanish, Chinese, Italian, Turkish, and Arabic. Since October 2000, Dr. Ari has received 32 prestigious awards for her accomplishments in research and education. She is the only researcher who received the Monaghan/Trudell Fellowship for Aerosol Technique Development from the American Respiratory Care Foundation three times. Dr. Ari is also the recipient of the Presidential Award for Excellence in Scholarship and the Mitchell Baran Achievement Award for Clinical Excellence in Aerosol Therapies and the Hector L. Garza Achievement Award for Excellence in International Respiratory Care. scale. Her expertise is focused mainly on nps, Inps and EVs in the GT field.



#### Sabine Häussermann | CEO at VisionHealth GmbH

Sabine Häussermann, PhD, founded VisionHealth in 2017, after 25 years' experience in various position in research and healthcare industry. She is a leading expert in drug delivery to the lungs and digital health. She has gathered a skilled and diverse team of experts to tackle the challenge of enhancing the low therapy outcome for Asthma and COPD patients.



#### Per Bäckman | Senior Adviser - Inhalation Science at Emmace Consulting AB

Dr Bäckman is senior adviser at Emmace Consulting AB in Lund Sweden. He is currently focused on the development and application of computer based mechanistic models and in vivo predictive test methods to understand critical product attributes and their influence on the disposition of orally inhaled therapeutics. This includes the impact of dose, aerosol quality and drug dissolution on the rate and extent of drug absorption from the airways. Dr Bäckman holds a PhD from the University of Lund and has been actively engaged in research and development of inhaled therapeutics since 1995. He is also the current co-chair of the Product Quality Research Institute (PQRI) sponsored working group laying the foundation for an inhaled biopharmaceutical classification system.



#### Volker Dickfeld | Sr. Marketing Manager HealthCare Global at Avient Colorants Germany GmbH

35 Year in the company. Various Sales, and Marketing Positions. Over 12 years abroad in Italy, France, China, and New Zealand. In the last 3-year Marketing responsible for Avient´s Mevopur Healthcare solutions. And always passioned about supporting customers to find solutions for their challenges in the plastics industry.



#### Amrit Paudel | Leader-Formulation and Drug Delivery at Research Center Pharmaceutical Engineering GmbH (RCPE)

Dr. Amrit Paudel is an associate professor at Graz University of technology and scientific leader of formulation drug delivery at Research Center Pharmaceutical Engineering (RCPE), Graz, Austria. Amrit worked for some years in the discovery pharmaceutics team of Bristol-Myers Squibb. He completed his Ph.D. in 2013 in the drug delivery and disposition group at the University of Leuven, Belgium. He is the recipient of the Young Investigator Award of 2014, issued by the APGI. Dr. Paudel has a broad interest in the physical chemistry of formulations, drug delivery, and pharmaceutical material engineering. His current work involves predictive knowledge/model development for the stability of pharmaceutical products. In addition, particle design and engineering of oral as well as pulmonary drug delivery, are of his key interests.



#### Lucas Silva | Head of Analytical Development and Life Cycle Management at Nanopharm, an Aptar Pharma Company

Lucas Silva is Head of Analytical Development and Life Cycle Management at Nanopharm. He has over 7 years of experience in the pharmaceutical industry, from analytical services to formulation technology to drug delivery devices, mostly in the research and development space focused on orally inhaled and nasal drug products. His key research areas are the development of clinically relevant analytical methods, the application of specialized in vitro performance data to de-risk and accelerate drug product development.

#### Søren Skov | Senior Human Factors Engineer at Roche

Søren is a senior Human Factors and user experience engineer at Roche, where he uses his passion for collaborative product innovation in the development of connected smart devices and behavior design applications in digital health. Previously he has led the HFE and UX development for connected autoinjectors and their companion ecosystems at Novartis. His background in psychology informs his interest in the improvement of physical and digital products across the patient journey. He holds a Master of Science in Psychology from the University of Aarhus.



#### Marco Franza | Director Sales and Business Development at Global Inhalation & Medical Devices – Berry Healthcare

Marco covered different roles in Sales, Business Development and Marketing. As Inhalation devices have constantly been identified as the key growth factor for the company, Marco always had a particular focus on them, driven also by personal interest. 1997 to 2019: Sales, Marketing and Key Accounts Director at Plastiape Since 2020: Director Sales and Business Development – Global Inhalation & Medical Devices – Berry Healthcare



#### Marian Asch | Senior Sales Manager at Harro Höfliger

Marian Asch has a BSc. degree in business and engineering from University of Stuttgart. He started his career as Project Manager in Harro Hoefligers Business Unit Inhalation in 2017. In this role he managed DPI projects of multinational pharma clients worldwide. Since summer 2021, Marian Asch works as a Sales Manager for Inhalation Technologies focusing on business development and sales for dry powder inhaler pharma industry.



#### Ortzi Olasolo | Medical Device Consultant at Beyond Conception

Ortzi Olasolo is a regulatory expert with a solid background in biomedical engineering. He holds a MsC on Medical Devices from University of Navarra. He has been working as a consultant for Beyond Conception since 2021, supporting a variety of companies in several areas (Quality Management Systems, Risk Management, Technical File reviews, Notify Body Opinion submission process and Clinical Evaluations). Before starting to work as a consultant for Beyond Conception, he gained extensive experience in Quality Management Systems, Design Controls and Risk Management in the field of Pharmacy Compounding Devices as Development and Quality Engineer. He has authored several clinical evaluations for drug device combination products.



#### Joana Roque | Vice-president of Associação Nacional de Fibrose Quística (ANFQ)

Joana Roque MD is the vice-president of Associação Nacional de Fibrose Quística (ANFQ), one of the Cystic Fibrosis (CF) Patient Associations that exist in Portugal. She finished her Medical Degree in 2011 and started her Pediatric Surgery Residency in Lisbon in 2013. In 2016, after being a mom to a CF baby, she decided to change the route of her career and started her residency in Public Health. She´s an active Cystic Fibrosis Patient Advocate at national and European level. She joined ANFQ in 2016 and has been it´s vice-president since 2018. She´s a member of CF Europe´s Community Advisory Board and has participated in the PO group on Access to Medicines. She´s interested in integrating the patient voice and perspective in the Research & Development process, raising awareness to Cystic Fibrosis and improving health literacy within the CF community.



# *Eleonore Fröhlich | Director Core Facility Imaging, Center for Medical Research at Medical University of Graz*

Eleonore Fröhlich is a biochemist and a Medical Doctor with specialization in Anatomy, Histology and Embryology. Her current appointments include Director of the Core Facility Imaging at the Center for Medical Research of the Medical University of Graz, extraordinary professor at the Institute of Anatomy of the University Tübingen, Key researcher at the Research Center Pharmaceutical Engineering and President of the Animal Welfare Body of the Medical University of Graz.



#### Hugh Smyth | Professor at The University of Texas at Austin

Hugh D. C. Smyth is the Alcon Centennial Professor, College of Pharmacy, The University of Texas at Austin. Dr Smyth oversees and multidisciplinary laboratory funded through NIH, FDA, and industry that focuses on engineering new drug delivery systems with an emphasis on drug delivery to the airways. He has over 300 published works which have been cited over 6500 times. Dr Smyth is editor of 3 books, and an inventor on numerous patents or patent applications. He has a Pharmacy and a Ph.D. degree from the University of Otago, New Zealand. He has been faculty at The University of North Carolina at Chapel Hill, and The University of New Mexico. He was the American Association of Pharmaceutical Scientists (AAPS) New Investigator award winner for Pharmaceutics and Pharmaceutical Technologies in 2007. He also received the PhRMA Foundation New Investigator Award in pharmaceutics in 2007. He was the Editor in Chief of Drug Development and Industrial Pharmacy from 2014-2022. Dr. Smyth has started several companies resulting from technologies discovered in his laboratory including Respira Therapeutics, Nob Hill Therapeutics, Via Therapeutics, and Cloxero Therapeutics which are now advancing these technologies for clinical use.



#### Israel Amirav | Physician at Tel Aviv Medical Center

I have been a Pediatric Pulmonologist and clinician-researcher for almost 40 years. Over the years, I have built my reputation as a world leader in various pediatric respiratory fields, including >150 publications, worldwide presentations, and various patented innovations to help infants and young children with asthma better receive their necessary respiratory medications. These innovations have found their way to hospitals, clinics, and homes worldwide.



# Carsten Ehrhardt | Professor in Pharmaceutics and Biopharmaceutics at Trinity College Dublin

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 > 100 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.



#### Mark Sanders | Inventor and independent researcher

Mark Sanders has held senior positions in Pharmaceutical and Medical Device industries, during the course of which he registered 11 patents (including formulations and inhaler training tools) and published over 90 pieces of work including an expert review of the history of inhalation devices. Now retired from industry, he continues to innovate and conducts research (through the University of Hertfordshire) into the development of inhaler training.



#### Mårten Svensson | CEO at Emmace Consulting

Dr. Mårten Svensson is currently holding a position as CEO at Emmace Consulting which he founded in 2011. Prior to this position, he worked at AstraZeneca for thirteen years as Associate Principal Scientist within Inhalation Technology and has during this time worked with particle sizing using different approaches such as lung dose prediction models, impaction methodology, fast screening methods, various automation projects and device development of dry powder inhalers. For several years, he has been a member in industry-wide organizations such as the EPAG as well as the Cascade Impactor Working Group of IPAC-RS.

Mårten has a PhD in surface and colloid science and has published several articles, posters, and book chapters in the inhalation field.



# Beth Laube | Professor Emerita at the Johns Hopkins School of Medicine

Beth L. Laube received her Ph.D. from the Johns Hopkins Bloomberg School of Public Health and is currently Professor Emerita at the Johns Hopkins School of Medicine. Dr. Laube's research is translational in nature and is centered on in vivo and in vitro quantification of the deposition and removal of particles in healthy and diseased lungs and noses, using radiolabeled aerosols and scintigraphic imaging assessments. This approach has been very useful in the development of aerosol therapies for asthma, cystic fibrosis and diabetes and for answering basic physiologic questions about mucociliary clearance. She has been a member of the Editorial Board of the Journal of Aerosol Medicine (now the Journal of Aerosol Medicine and Pulmonary Drug Delivery) since 1998. From 2003-2007, she participated in the World Health Organization's Product Development Group for Aerosolized Measles Vaccine.

From 2005-2007, she served as President of the International Society for Aerosols in Medicine (ISAM). In 2021, she was given ISAM's Willi Stahlhofen Award for outstanding experimental research in aerosols in medicine. She is a frequent advisor to pre-doctoral students and post-doctoral fellows and has published over 60 peer-reviewed articles.



#### Herbert Wachtel | Innovation Scout at Boehringer Ingelheim Pharma

Dr. Herbert Wachtel's current focus is Drug Delivery based on Medical Devices. Working as a Senior Principal Scientist at Boehringer Ingelheim he has gained experience in the design and testing of complex drug delivery systems, e.g. inhalers and autoinjectors. He is interested in the interface between devices and the respective parts of the body, be it for humans or animals. His aim is basic modelling of drug delivery processes and in doing so he relies on structural and functional modelling e.g. computer aided design, CAD, finite element modelling, FMEA, and computational fluid dynamics, CFD. By training, Dr. Wachtel is a physicist. Connecting industry and university, Dr. Wachtel is also affiliated to the Department of Biopharmaceutics and Pharmaceutical Technology at the University of Mainz.



# Yvonne Limpens | Managing Human Factors Specialist at Emergo by UL

Yvonne Limpens is a Managing Human Factors Specialist with Emergo by UL's Human Factors Research & Design (HFR&D) team based in Utrecht, The Netherlands. She has been with the team since 2013 and has experience delivering HFE services to the medical device, and pharmaceutical industries. Yvonne leads and oversees research activities and helps clients develop key HFE documents for their design history files. Furthermore, she advises and trains clients on how to apply HFE during product development to meet regulators' expectations. Yvonne holds a B.S. in Industrial Design and an M.S. in Human Technology Interaction, both from Eindhoven University of Technology (NL)



#### Francesca Buttini | Associate Professor at the Food and Drug Department, University of Parma (IT)

Francesca Buttini is currently holding an Associate Professor position at the Food and Drug Department, University of Parma (IT) and where now she is leading the unit dedicated to design of pharmaceutical products for inhalation. In 2014, she was appointed as Visiting Lecturer at the Institute of Pharmaceutical Science of King's College London (UK). Combining her background in pharmaceutical technology, regulatory aspects, and device design, she is executing research programs aimed to deliver medicinal products that take into consideration the patient, industrial and regulatory requirements. Up to date, she has published more than 80 original papers and as a result of her research achievement she obtained in 2017 the DDL Emerging Scientist Awards from the UK Aerosol Society. Francesca Buttini is a founder of PlumeStars, an innovative SME, dedicated to development of orphan drug products to treat lung and systemic disease by inhalation therapy.



#### Chris Vernall | Commercial Director at Intertek Pharmaceutical Services

Chris is currently the Commercial Director at Intertek Pharmaceutical Services, where his responsibilities include leading the business development team at their inhaled and nasal drug product centre of excellence near Cambridge, UK, and establishing partnerships and collaborations across the respiratory industry.

He started his career at Nanopharm in 2010, as an Inhalation Scientist, working on formulation development and analytical testing projects, before moving to Intertek in 2013, as a Senior Scientist. Then progressed into a business development role at Intertek in 2014 and has also worked in commercial roles at Aptar Pharma and Vectura, before re-joining Intertek in 2022 in his current position.



#### Orest Lastow | CTO & Founder at Iconovo AB

Dr Orest Lastow is the founder and CTO of Iconovo AB. He was the first CEO of Iconovo and is also the inventor of Iconovo's five inhalation device platforms. He is the founder and previous CEO of Medicon Valley Inhalation Consortium, MVIC AB and was with AstraZeneca for over 15 years and is the principal inventor of AstraZeneca's new dry powder inhalation platform. Orest is the inventor behind over 40 patents and patent applications.

Orest received a M.Sc. in Engineering Physics and a Licentiate of Engineering degree in Aerosol Science from Lund University. He has also a Ph.D. in electrohydrodynamic atomization from Brunel University. His expertise is device development, electrostatics, Computational Fluid Dynamics (CFD), aerosol science and inhalation technology. He is the author behind a textbook on EHD atomization, several journal publications and book contributions. He is frequently invited to speak at conferences and teaches aerosol drug delivery at Lund University and Copenhagen University. Orest is a co-author of the Aerosol drug delivery device design verification standard (ISO 20072).



#### David Edwards | Founder at FEND

David A. Edwards PhD is a pioneer of inhaled aerosols, long-standing faculty member at Harvard University (2001-2019), and founder of multiple respiratory healthcare startups including his most recent company, Sensory Cloud, pioneering upper airway hydration for respiratory health (hellofend. com). A member of the national academes of engineering in the US and France, member of the National Academy of Inventors, and Chevalier of Arts & Sciences by the French Ministry of Culture, David is a prolific inventor, writer and speaker internationally.



# WORLD OF WINE

This cultural district in the Gaia neighborhood on the opposite side of the Douro River from the Old Town is perfectly positioned for postcard-worthy views of Porto. From this vantage point, Porto's iconic building facades unfurl like a Madras patchwork of colors.

World of Wine is the perfect place to begin any visit to and through Portugal. Part museum, part dining, part shopping and part entertainment districts, this is a microcosm of all things Portuguese when it comes to food, drinks, art and history. Opened in mid-2020, but finally getting the global attention it deserves, World of Wine is a WOW experience. It actually goes by that acronym, and it's easy to see why.



# 1828

The best meat in the world is in Portugal, at 1828.

The El Capricho is known as the "best meat in the world". The cattle is carefully selected and fed. The meat is then prepared with respect, slowly matured and taken care of.



# **PLANET CORK**

Portugal is by far the world's largest cork producing country, accounting for over 50% of global production, harvested from more than 730 hectares of forest.

Explaining and demonstrating how this natural product has changed our lives for the better, Planet Cork brings to life the incredible world of cork, from the ancient exploration of the cork oak to the most varied and avant-garde applications.



# ANGEL'S SHARE

In the Port wine city of Gaia, and housed in a refurbished wine warehouse, we're a short walk from the Douro River and several Port wine cellars. Enjoy our bar, with a view of Porto, a UNESCO World Heritage site, and 2,195 square meters of event space. Our Wellness Center offers treatments, an indoor pool, steam bath, sauna, and fitness facilities.

# NOTES

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