5th Medicon Valley Inhalation Symposium 2016

Program – Future Opportunities of Inhalation

DAY 1 – Wednesday the 12th of October

08.30 – 09.00	Registration	
09.00 – 09.10	Welcome to MVICs Symposium	*Dr Ola Nerbrink, MVIC*

Generic Value Chain

Chairman: Dr Orest Lastow

09.10 – 09.30	Things Shaping Generic Product Development	*Dr Walter Cook, Mylan*
09.30 – 09.50	Challenges in Generic pMDI Development	*Dr Nayna Govind, Dr. Reddy*
09.50 – 10.10	Regulatory Hurdles to Overcome in the Process of Registering a Generic Inhalation Product	*Dr Hans Keegstra, Sandoz*
10.10 – 10.30	Keeping It in the Family – Devices and Formulations for Generic Dry Powder Inhaler Products	*Dr Sandy Munro, Vectura*
10.30 – 11.20	Coffee and Mingle	

Human Factors Aspects on Inhalation Device Development

Chairman: Dr Hans Lundbäck

11.20 – 11.45	Human Factors Studies – Design, Planning and Implementation	*Rob Fernall, Team Consulting*
11.45 – 12.10	Human Factors in the Regulatory World	*Dr Stefan Leiner, Boehringer Ingelheim*
12.10 – 12.30	Usability Aspects of Multi-Dose Liquid Inhalers	*Wilbur de Kruijf, MedSpray BV*
12.30 – 13.45	Lunch and Mingle	

Powder Generation

Chairman: Dr Mårten Svensson

13.45 – 14.15	Supercritical Fluid (SCF) Particle Engineering for Optimised Inhaled Delivery	*Prof Peter York, CrystecPharma*
14.15 – 14.35	Particle Engineering of Inhalable Drugs with Supercritical Fluids – Opportunities and Limitations	*Dr Magnus Brisander, XSpray Microparticles*
14.35 – 14.55	Importance of Coating for Powder Aerosolization	*Dr Janne Raula, Teicos Pharma*
14.55 – 15.15	iSPERSE: A Novel Particle Engineering Platform Enabling Inhaled Therapies	*Dr David Hava, Pulmatrix Inc.*
15.15 – 16.00	Coffee and Mingle	

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Clinical Trials and BE-studies

Chairman: Dr Lars Asking

16.00 – 16.25	Strategies and Challenges in Inhaled Clinical Studies	*Miguel Nilsson, TFS, Trial Form Support AB*
16.25 – 16.50	Regulatory Aspects of Establishment of Therapeutic Equivalence with Focus on Pharmacokinetic Studies	*Erika Fredriksson, Swedish Medical Product Agency MPA*
16.50 – 17.15	On Therapeutic Equivalence Testing for Dronchodilators	*Thomas Bengtsson, Statmind AB, MVIC*
17.15 – 17.30	Close and Summary Day 1	*Dr Ola Nerbrink, MVIC*
17.45 – 18.30	Drink Reception	
18.30	Dinner	

DAY 2 – Thursday the 13th of October

New Opportunities

Chairman: Dr Karin von Wachenfeldt

09.00 – 09.20	Development Challenges Associated with Inhaled and Intranasal Anti-virals	*Dr Staffan Edsbäcker, AstraZeneca*
09.20 – 09.40	Transforming the Teatment of Lung Fibrosis – Development of an Inhaled Galectin Inhibitor	*Dr Hans Schambye, Galecto Biotech*
09.40 – 10.00	Development of Innovative Inhalation Drugs for Orphan Lung Diseases in a Transatlantic Company	*Cecilia Ganslandt, Savara ApS.*
10.00 – 10.45	Coffee and Mingle	

Trends in Inhaled Delivery

Chairman: Prof Stefan Ulvenlund

10.45 – 11.10	How the Patient's Breathing Pattern Determines the Delivered Dose of Inhaled Drugs	*Dr Gerhard Scheuch, Ventaleon GmbH*
11.10 – 11.35	Trends in Nasal Drug Delivery	*Dr Julie Suman, NextBreath*
11.35 – 12.00	Generic Products on Emerging Markets	*David Howlett, PharmaDelivery Solutions Ltd*
12.00 – 12.10	Closing Symposium	*Dr Ola Nerbrink, MVIC*
12.10 – 13.10	Lunch and Mingle	

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Speakers

Thomas Bengtsson

Thomas Bengtsson, StatMind AB, has 22 years of experience as a statistician within the pharmaceutical sector. Prior to co-founding StatMind AB in 2011, Thomas Bengtsson was an employee of AstraZeneca Lund including roles as Global Product Statistician for both early and late phase respiratory products, further working with device development, biomarkers and pharmacokinetics. Thomas Bengtsson has a M.Sc. from Lund University in 1986 and has been a co-author of 25 scientific articles.

Magnus Brisander

Dr Magnus Brisander, XSpray Microparticles AB, has 15 years of preclinical and early clinical drug development experience with enfaces on drug delivery, materials science and physical chemistry. Before joining XSpray as Director, Solid State Sciences in 2008, Dr Magnus Brisander worked as a senior scientist, pharmaceutics at Pharmacia and Biovitrum. He received a Ph.D. in Structural Chemistry from Stockholm University in 1998 and has been a postdoctoral fellow in medicinal chemistry at Tromsø, University. Dr Magnus Brisander has published 13 scientific articles and is the inventor of 5 patent applications.

Walter Cook

Dr Walter Cook is Head of Global Respiratory Scientific Affairs at Mylan Global Respiratory Group in Sandwich, UK. He leads Mylan's integrated Respiratory Product Development activities, where Respiratory Pharmaceutical Sciences, Clinical and Regulatory groups work together on development of innovative and generic inhalation products in dry powder inhaler, pressurised metered dose inhaler, and nebuliser presentations. Dr Walter Cook is a Pharmaceutical Scientist, with a first degree in Pharmacy from the University of Strathclyde, and a PhD in Pharmaceutical Sciences from the University of Nottingham.

Staffan Edsbäcker

Dr Staffan Edsbäcker has 35+ years of pharma experience at AstraZeneca within pharmacology, clinical pharmacology and pharmacokinetics – responsible for regulatory agency interactions, project management, in-licensing opportunities and due diligence. His work has been focused on locally acting drugs for asthma, COPD and IBD. Dr Staffan Edsbäcker has been invited lecturer at many international conferences and is author of 50+ original research papers and book chapters within the metabolism, pharmacokinetics, inhalation and intestinal research areas. Dr Staffan Edsbäcker is an Associate Professor in Experimental Clinical Pharmacology at Lund University. As a senior inhalation consultant at Emmace, he assists clients with the planning, evaluation and documentation of drug and device opportunities, primarily within the inhalation field of research.

Rob Fernall

Rob Fernall works as a Human Factors (HF) specialist for Team Consulting, a medical device development company based near Cambridge in the UK. He took his first step into the world of HF thirty years ago when he started his BSc in Ergonomics at Loughborough University. Since graduating, Rob Fernall has applied his HF knowledge to several sectors including software, transport, defence, and medical. He is now responsible for all things HF throughout the medical device development process, including running HF studies and applying analytical techniques in order to optimise device usability and manage risk. Rob Fernall also has an MSc in Psychology from the University of London and is a Chartered Psychologist.

Erika Fredriksson

Erika Fredriksson is a pharmacist graduated from Uppsala University. Since 2010 she works as a Pharmacokinetic assessor at the Medical Products Agency, Sweden, mainly focusing on assessment of bioequivalence for generic products, hybrids, line extensions, fixed dose combinations etc. Erika Fredriksson has a special focus on pharmacokinetic studies with orally inhaled products and is a member of the MPA internal expert group for inhaled products as well as a member of the EMA Respiratory Drafting Group.

Cecilia Ganslandt

Cecilia Ganslandt, MD, MSc Pharmaceutical Medicine, serves as Head of Medical Affairs at Savara ApS., and has more than 19 years of experience from positions within global clinical development and medical affairs in small, mid-size and large pharma companies. Cecilia Ganslandt has supported a number of clinical development programs from early clinical phase up to and beyond marketing authorizations in Europe, US and Asia. Prior to joining Savara, Cecilia Ganslandt was CMO for Serendex Pharmaceuticals, assuming overall responsibility for nonclinical and clinical development.

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Nayna Govind

Dr Nayna Govind graduated from Bradford University as a Pharmacist in 1991. Following completion of her PhD at Aston University in 1994, Nayna entered the inhalation field at 3M Healthcare working on pMDI formulation development before moving to AstraZeneca in 1997. As Team Manager at AstraZeneca, Dr Nayna Govind worked on a number of inhalation development programmes and played a significant role in the development and NDA approval of Symbicort pMDI. Following closure of the AstraZeneca site in 2011, as Director of NG Pharma Consulting Ltd, Dr Nayna Govind provided inhalation product development expertise to a range of pharma and healthcare companies, which included significant contributions to the development of Voke Nicotine Inhaler for Kind Consumer Ltd leading to successful MHRA approval. In 2013, Dr Nayna Govind moved to Dr Reddy's Laboratories Ltd where she currently holds the position of Director and is responsible for development of generic inhalation products for the EU and US markets.

David Hava

Dr Hava is the Chief Scientific Officer at Pulmatrix Inc. As CSO, Dr Hava leads the Research and Development organization in the development of inhalation products in the iSPERSE dry powder delivery platform. In addition, Dr Hava directs and manages the company's therapeutic strategy to identify and prioritize drug targets and drugs that are enabled by the iSPERSE dry powder delivery platform. Dr Hava joined Pulmatrix in 2006 as one of the first Senior Scientists and has been involved in the early stage research and development programs that identified and characterized several of the key aspects of the Pulmatrix technology. Dr Hava earned his PhD. in Molecular Biology and Microbiology at Tufts University and completed his post-doctoral training studying immunology and host-pathogen interactions at Harvard Medical School.

David Howlett

In 2003 David established PharmaDelivery Solutions Ltd as a highly specialised consultancy service in the field of drug delivery (especially respiratory) device technology. This has led to involvement in projects with focus in pulmonary, nasal and other delivery routes, with an international client base. David has over 30 years experience in the development, industrialization and approval of inhalation drug delivery systems, combination products and medical devices. In addition to activities supporting commercial organizations, David has been involved in the following roles; Honorary Teaching Fellow in the School of Pharmacy and Pharmaceutical Sciences at the University of Manchester and is author/ tutor for the Pharmaceutical Industry Advanced Training (PIAT) MSc module on Inhalation dosage forms. A UK national expert representing the British Standards Institute on ISO TC84 developing new international standards for pulmonary and nasal delivery devices syringes and catheters. David has also worked with the United Nations and various national governments to develop and establish transition strategies from the use of CFC in Metered Dose Inhalers and to secure appropriate budgets from the Multi-lateral fun for the implementation of the Montreal Protocol in emerging markets around the world.

Hans Keegstra

Dr Hans Keegstra is a Registered Industrial Pharmacist. He is currently Head of Sandoz Development Centre Rudolstadt, responsible for the development of respiratory products for Sandoz GmbH. During 2006 – 2015 he worked at Respiratory Products for the TEVA Global Branded Product Division, first as Director Respiratory Drug Development responsible for the analytical and pharmaceutical development and from 2013 as Senior Director Global Respiratory R&D. Before that he worked for Pharmachemie BV in various positions. Dr Hans Keegstra has been an expert of group 10A of the European Pharmacopoeia committee, WME (Working group of the Dutch health authorities for evaluation of monographs of the European Pharmacopoeia), and is a member of EPAG, European Pharmaceutical Aerosol Group and the Aerosol Society.

Wilbur de Kruijf

Wilbur de Kruijf is responsible for new business development at Medspray, the Netherlands. Medspray develops novel metered dose liquid inhalers and eye spray devices, based on their proprietary micro nano technology spray nozzles. Wilbur joined Medspray ten years ago to start up device development in collaboration with Medspray's device partners. Wilbur (born in 1971) has a background in Industrial Design Engineering, M.Sc. Design Engineering 1995, M.Sc. Advanced Industrial Design Engineering 1997, Delft University of Technology, with further specialisation in medical device development (acc. ISO 13485), design for six sigma and user centred design. Before joining Medspray, Wilbur worked almost 10 years for a Dutch design consultancy firm, Indes, winning several international design and usability awards for homecare & rehab products and hospital equipment. Wilbur is active in the IPAC-RS consortium's device work group and he is the secretary of the Dutch medical aerosol scientist network 'MAD Foundation', organising two lecture and discussion events yearly on aerosols in medicine.

Stefan Leiner

Dr Stefan Leiner is a pharmacist by training and joined Boehringer Ingelheim in Germany in 1987. After a couple of years in manufacture, galenical and analytical development, he focussed on inhalation forms. He is responsible for the scientific standard of the Quality / CMC part of MAAs and NDAs. He wrote the Quality Overall Summaries for some of Boehringer Ingelheim's new inhalation developments. Dr Stefan Leiner represents Boehringer Ingelheim in the International Pharmaceutical Aerosol Consortium – Regulation and Science (IPAC-RS) and was chair of this organization. He participated in the development of the ISO 20072 Standard on "Aerosol Drug Delivery Devices". He is active in the German Pharmacopeia.

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Speakers

Sandy Munro

Dr Sandy Munro, Director of Pharmaceutical Sciences, has worked in inhaled product development for over 25 years and has been at Vectura since 2008 in a variety roles relating to the leadership of the company's pharmaceutical development activities. Prior to joining Vectura, Dr Sandy Munro worked at GSK for 20 years and latterly in the role of Global Director of Inhaled Science and Technology. Dr Sandy Munro has a chemistry degree from the University of Edinburgh and a PhD in synthetic organic chemistry from UEA the University of East Anglia, UK.

Miguel Nilsson

Miguel Nilsson joined TFS in 2012 and as Executive Director, Project Management is responsible for the oversight of all key client projects conducted by TFS. He has more than 22 years' clinical research experience and has previously worked at AstraZeneca for 18 years, across a range of positions and therapeutic areas, but primarily within Respiratory.

Janne Raula

Dr Janne Raula is Co-founder and Chief technology officer at Teicos Pharma and Senior scientist at Aalto University School of Science. Janne Raulas previous work experience is Research fellow, Aalto University School of Science, 2010-2015, Post-doc, Helsinki University of Technology, 2003-2010 and Post-doc, University of Helsinki, Laboratory of Polymer chemistry, 2002-2003. Dr Janne Raula has total 61 scientific publications and one patent "Surface modified aerosol particles, a method and apparatus for production thereof and powders and dispersions containing said particles, US 8,349,295, and CA 2688288 A1".

Gerhard Scheuch

Dr Gerhard Scheuch is recently chief executive officer (CEO) of Ventaleon GmbH, a pulmonary drug development company and GS-Bio-Inhalation GmbH which is a pulmonary consulting company. He was founder and chief executive officer (CEO) of Activaero GmbH from1998 and President of Activaero America Inc. until the acquisition of Activaero by Vectura in 2014. Dr Gerhard Scheuch was also founder and CEO (1998–2004) of Inamed Research GmbH, a respiratory CRO. He has worked as a senior scientist at Helmholtz Centre Munich Research Centre for Environment and Health (1992–1998) and as an engineer at GSF National Research Centre for Environment and Health in Frankfurt, Germany (1980–1992). Dr Gerhard Scheuch has published over 150 scientific articles on aerosol and lung research. He is also a member of the expert panel of the European Medical Agency (EMA) and more recently, Dr Gerhard Scheuch was involved in developing the guidelines on orally inhaled products (OIP-Guideline). From 1999 until 2013 he was member of the Board of the International Society for Aerosols in Medicine (ISAM) and served as President from 2007 until 2013.

Hans Schambye

Dr Hans Schambye is a seasoned biotech entrepreneur with extensive experience in drug discovery and development. Previously, Hans served as the Chief Executive Officer of ReceptIcon from 2006 to 2009 and as the CEO of Gastrotech Pharma A/S from 2004 to 2006. Before joining Gastrotech, he was Director of Biology and Pharmacology and Head of Portfolio Management at Maxygen, a US biotech company. Dr Hans Schambye has co-founded several biotech companies, including ProFound Pharma A/S, a Danish biotech company, which was acquired by Maxygen in 2000. Prior to this he had a successful research career at Stanford University and Copenhagen University within the field of receptor biology. Dr Hans Schambye holds an MD from Odense University and a PhD in Medical Sciences from Copenhagen University.

Julie D. Suman

Dr Julie D. Suman is co-founder and President of Next Breath, LLC, a contract research organization dedicated to the development and analytical testing of nasal and inhalation delivery systems. Dr Suman directs the research division that supports product development and regulatory submissions for North American and International Clients in the pharmaceutical, biotechnology and medical device markets. Dr Suman holds a B.S. in Pharmacy from Duquesne University (1996) and a Ph.D. in Pharmaceutical Sciences from the University of Maryland, Baltimore (2002). She is a co-editor for Respiratory Drug Delivery Proceedings, an international symposium, and an adjunct assistant professor at the University of Maryland, School of Pharmacy in Baltimore, Maryland. She is also an Affiliate Assistant Professor in the Department of Pharmaceutics, School of Pharmacy, Virginia Commonwealth University. Dr Suman is the Past-Chair of the AAPS Inhalation Technology Focus Group. She is also a licensed Maryland pharmacist. Dr Julie D. Suman has published her research in peer-reviewed journals and has been presented during podium sessions at international meetings, the FDA Visiting Professor Lecture Series and has been an invited speaker at ANVISA in Brazil. Dr Suman's doctoral research, which focused on the relationship between in vitro tests for nasal sprays and in vivo deposition, has been recognized for excellence by a research award presented at the International Society for Aerosols in Medicine, 2001. In 2008, Dr Julie D. Suman received an award from the Greater Baltimore Committee for Entrepreneurial Spirit.

Peter York

Professor Peter York is a co-founder, Chairman and Chief Scientist at CrystecPharma, and has overall responsibility for guiding the science and innovation strategy at Crystec. As an expert in pharmaceutical materials science, Professor Peter York has published over 300 scientific articles, holds numerous patents and has received several research awards. Prior to Crystec, Professor Peter York was a former co-founder of Bradford Particle Design, which was acquired by Inhale Therapeutic Systems (now Nektar Therapeutics) for $200m in 2001. Peter York is currently an Emeritus Professor of Physical Pharmaceutics at the University of Bradford and an Honorary Visiting Professor of the Shanghai Institute of Materia Medica, Chinese Academy of Sciences, as well as a member of the MHRA Chemistry and Pharmacy Standards committee. He holds Fellowships at the Royal Pharmaceutical Society of Great Britain, the Royal Society of Chemistry, and the American Association of Pharmaceutical Scientists.