6th Medicon Valley Inhalation Symposium 2017

Program – Future Opportunities of Inhalation

DAY 1 – Wednesday the 11th of October

08.30 – 09.00	Registration	
09.00 – 09.15	Welcome to MVICs Symposium	*MSc. Lars Asking, MVIC*

Connected Health

Chairman: Dr. Orest Lastow

09.15–09.35	Making Sense of Inhaler Monitoring Technologies: Can they Improve Respiratory Outcomes?	*Dr. Joanne Peart, Revenio Consulting Ltd*
09.35–09.55	Opportunities and Challenges with Connected Devices	*Chris Nother and Conor Mulcahy, Nypro Healthcare*

Formulation Development

Chairman: Dr. Jessica Elversson

09.55–10.25	Modelling of Dry Powders for Inhalation	*Dr. Kyrre Thalberg, AstraZeneca*
10.25–11.10	**Coffee and Mingle**	

Formulation Development *cont.*

11.10–11.30	A New Carrier for DPI on Basis of Mannitol	*Dr. Hans-Leonhard Ohrem, Merck*
11.30–11.50	Assessment of in vitro Similarity for Tiotropium Dry Powder Inhalable Formulations by Advanced Techniques	*Dr. Oliver Croad, Circassia Ltd*
11.50–12.10	Process Development and Scale up of Pressurized Metered Dose Inhaler (pMDI) Production Processes	*Dr. Mikael Bisrat, Recipharm AB*
12.10–13.45	**Lunch and Mingle**	

Pre-clinical and Tox

Chairman: Dr. Karin Svens

13.45–14.10	Controlled Aerosol Exposures	*Dr. Per Gerde, Inhalation Science*
14.10–14.35	Lung Tissue Responses to Inhaled Particulate Substances	*Dr. Hui Zhang, AstraZeneca*
14.35–15.00	Mini-pigs Instead of Dogs in Inhaled Tox Studies	*BSc. Vanessa Ross, Envigo*
15.00–16.00	**Coffee and Mingle**	

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Clinical Assessments and Trials

Chairman: Dr. Bengt Särnstrand

16.00–16.25	Characterisation of Patients with COPD beyond FEV1	*Professor Per Wollmer, Skåne University Hospital*
16.25–16.50	Questionnaire Assessment of Symptoms in Airway Diseases – an Overview	*M.D. Lars-Göran Carlsson, AB Kamsaco/ Skåne University Hospital*
16.50–17.15	Regulatory Considerations on the Application of Objective Physiological Assessments	*Bob Clay, Consultant, Drug Development and Regulatory Strategy*
17.15–17.30	Close and Summary Day 1	*MSc. Lars Asking, MVIC*
17.45–18.30	**Drink Reception**	
18.30	**Conference Dinner**	

DAY 2 – Thursday the 12th of October

Trends in Inhaled Delivery

Chairman: Dr. Anna Stenstam

09.00–09.25	Advanced Approaches to Traditional APIs: DPI Particle Engineering, Formulation and Characterization	*Dr. Eunice Costa, Hovione*
09.25–09.50	Trends in the Inhalation Space	*Martin Ohrt and Henrik Harboe, Liita Care*
09.50–10.15	SEM-EDS and Raman Spectroscopy to Accelerate Generic Drug Applications	*Dr. Julie Suman, Next Breath, a division of AptarGroup Inc.*
10.15–11.00	**Coffee and Mingle**	

New Opportunities and Regulatory

Chairman: Dr. Bo Olsson

11.00–11.20	Modelled Deposition in Human Throat Models	*Professor Stavros Kassinos, University of Cyprus*
11.20–11.45	In vitro Regulatory Aspects on Inhaled Drug Delivery	*Dr. Cornelia Nopitsch-Mai, German Medical Products Agency, MPA*
11.45–12.10	In vitro Regulatory Aspects on Inhalation products with focus on Inhaled Drug Delivery	*Dr. Anna Hillgren, Swedish Medical Products Agency, MPA*
12.10–12.20	Closing Symposium	*MSc. Lars Asking, MVIC*
12.20–13.10	**Lunch and Mingle**	

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Speakers

Mikael Bisrat

Dr. Mikael Bisrat is a Sales Director in the Development Sales team at Recipharm, involved in business development with a focus on the Nordic market. Dr. Mikael Bisrat, who has a Ph.D. in Pharmaceutics from Uppsala University and an EMBA from Stockholm School of Economics, has a wealth of experience in the pharmaceutical industry. He has extensive knowledge about late stage discovery, formulation development and the production of clinical trial materials.

Lars-Göran Carlsson

MD Lars-Göran Carlsson was until 2012 Medical Science Director in early and later in established respiratory product teams at AstraZeneca. Presently working as an independent clinical consultant to AstraZeneca and other national and international pharmaceutical companies. MD Lars-Göran Carlsson is still in clinical practice at Skåne University Hospital and is by training a specialist in pulmonary medicine and internal medicine. MD Lars-Göran Carlsson has also an association to Medicon Valley Inhalation Consortium and is a regular speaker at the Symposium Workshop.

Bob Clay

Bob Clay established his own regulatory consultancy practice through Highbury Regulatory Science in 2014 which supports small/medium size companies and their investors to develop regulatory/business strategies across multiple therapeutic and geographic areas. Prior to this he was a VP Global Regulatory Affairs at AstraZeneca with responsibility for oncology, infection and personalised healthcare. Bob has been a board member of TOPRA (The Organisation of Professional Regulatory Affairs) since 2014 and is President during 2017. He is a member of the Expert Scientific Advisory Committee for Medicines for Malaria Venture (MMV) and several working groups at CPTR (Critical Path to TB Regimens). Bob is a pharmacist with more than 30 years' experience in drug development, leading the global regulatory approval of many products across a range of therapy areas including metabolic diseases, neuroscience, cancer and infection, including more than 15 new active substances. Bob has led a full range of regulatory meetings, including IND/Scientific Advice during development and NDA/MAA reviews, with regulators in both Europe and North America. He has also been involved in "portfolio" meetings with several regulators; regulatory workshops and participated in trade association (PhRMA/EFPIA) working parties on topics including adaptive trial
designs, personalised medicines. Bob has held significant leadership roles in regulatory affairs in regional and global functions at several companies including AstraZeneca and Pfizer. Bob was also Chief Regulatory Officer at Kinapse, consulting to life sciences sector on capability building and operational services, from 2014 to 2017. Earlier in his career who worked as a formulation scientist and pharmaceutical assessor in the UK regulatory authority.

Eunice Costa

Dr. Eunice Costa is Group Leader Inhalation, R&D Drug Product Development at Hovione. Dr. Eunice Costa joined the R&D Drug Product Development group at Hovione in 2011 and has been since then working on particle design and formulation development, particularly for Inhalation drug products. At Hovione, she has also been the scientific advisor for PhD programs in process and formulation development for optimizing pulmonary drug delivery and for biopharmaceuticals. Dr. Eunice Costa holds a PhD in Bioengineering Systems from the MIT-Portugal Program that integrated polymer chemistry, materials characterization and tissue engineering. Before pursuing her PhD, Eunice worked as an undergraduate researcher in different institutions such as the Early Stage Pharmaceutical development group at Genentech, USA, as well as on the Human Physiology department at TNO, The Netherlands.

Oliver Croad

Dr. Oliver Croad is part of the Respiratory Product Development team at Circassia, a specialty pharmaceutical company focused on respiratory disease. During his 2 years at Circassia he has worked on a range of MDI, DPI and nebulised products at various stages of development from early feasibility assessment to commercial launch preparation. Prior to Circassia, Dr. Oliver Croad worked at Monash University (Melbourne, Australia) as the lead formulation scientist on the "Inhaled Oxytocin Project" an initiative aiming to produce a single-use dry powder inhaler formulation of oxytocin for use in resource poor locations. Dr. Oliver Croad obtained his PhD in Pharmacy from the University of Nottingham where he was developing a novel nanoscale screening method for the rapid optimisation of biopharmaceutical formulations.

Per Gerde

Dr. Per Gerde serves as Chief Scientific Officer at Inhalation Sciences Sweden AB. He is also an Associate Professor of Inhalation Toxicology and Scientist at the Institute of Environmental Medicine at Karolinska Institutet. Dr. Per Gerde is a Chemical Engineer and has a PhD in Chemical Engineering from the Royal Institute of Technology, Sweden. Dr. Per Gerde has previously served as a scientist at the Swedish National Institute of Occupational Health and the Lovelace Respiratory Research Institute in New Mexico, USA. He has published some 40 peer reviewed scientific papers. He is also the main inventor of six patent families. The main research interest of Dr. Per Gerde is to develop new inhalation exposure methods for studying the fate of toxic or therapeutic aerosols in the lungs after inhalation.

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Speakers

Henrik Harboe

Henrik Harboe is the Head of Medical Affairs at Liita Care. Henrik Harboe is Graduated Medical Doctor from University of Copenhagen 1978. Authorisation to work independently as a doctor 1980. Work experience includes ten years of clinical work followed by thirty years of entrepreneurship and advisory work within the medical device industry. Hernik Harboe is Co-founder of PNN Medical (pnnmedical.com) and several other start-up medical device companies. Multiple board positions. Holds profound insight in the process of developing profitable medical device business – from scratch to exit. Henrik Harboe is generalist by heart with both cerebral and cordial affinity to device development and clinical documentation including transcription of scientific facts into clinically relevant product positioning, marketing and sales. Henrik Harboe is driven by good ideas – which don't have to be his own – and enthusiastic people.

Anna Hillgren

Dr. Anna Hillgren is a pharmacist and has a PhD from Uppsala University. Since 2004 she works as a Quality assessor at the Medical Products Agency, Sweden mainly with assessment of the CMC documentation (Module 3) for various types of applications, but with a special focus on orally inhaled products. She is a member of the MPA internal expert group for inhaled products as well as a member of the EMA drafting group responsible for revision of the guideline on Pharmaceutical Quality of Inhalation and Nasal Products.

Stavros Kassinos

Professor Stavros Kassinos is Professor in the Department of Mechanical and Manufacturing Engineering at the University of Cyprus and the Head of the Computational Sciences Laboratory at the University of Cyprus (UCY-CompSci). He serves on the Editorial Board of the International Journal of Heat and Fluid Flow and is the Chair of COST Action MP1404 – Simulation and pharmaceutical technologies for advanced patient-tailored inhaled medicines (SimInhale). He completed his undergraduate studies at the University of Texas at Austin while on a CASP/USIA scholarship (1987) followed by graduate studies in Mechanical Engineering at Stanford University in California (M.Sc. 1989, Ph.D. 1995). His research interests center on the numerical simulation and modeling of complex physical systems including turbulent fluid-particle flows in connection with environmental, biomedical and technological applications. In particular, he is interested in the further development of in silico methods in support of inhaled drug development.

Chris Nother

Chris Nother heads up Business Development at the Pharma Delivery Solutions (PDS) division of Nypro Healthcare. Chris Nother is a Business and Economics graduate of Trinity College, Dublin and has almost thirty years' business experience in investment banking, print & packaging, plastics and in medical devices – in business development, CEO, M&A and entrepreneurial roles. Chris Nother has been with Nypro for 14 years.

Conor Mulcahy

Conor Mulcahy is Senior Director, Strategic Projects, Pharmaceutical Delivery Systems, at Nypro, a Jabil company. In that role, Mr. Mulcahy established a medical device development capability to guide customers through a highly optimised end-to-end product discovery, design, development and delivery process to speed innovation and time to market while lowering cost and risk. A 26-year veteran of product development and new product introductions, Conor brings deep expertise and broad experience to Nypro from a successful tenure in the medical, consumer electronics and military industries.

Cornelia Nopitsch-Mai

Dr. Cornelia Nopitsch-Mai studied pharmacy at the Free University Berlin and graduated in pharmaceutical biology. She is scientist at the Federal Institute for Drugs and Medical Devices in the assessment of the quality of the dossier since 1991. Dr. Cornelia Nopitsch-Mai is experienced in the assessment of pharmaceutical dossiers for marketing authorisation applications of medicinal products. She has broad knowledge of the national and EU regulations medicinal products as well as for the corresponding EU guidelines and the European Pharmacopoeia. Since 2000 she is assessor for the Certification Procedure (EDQM) in Strasbourg. Dr. Cornelia Nopitsch-Mai was member of the Technical Advisory Board (TAB) from 2001 to 2010. She was chairperson of the TAB from 2005 to 2010. Dr. Cornelia Nopitsch-Mai was member of the Quality Working Party from October 2007 to February 2011.Dr. Cornelia Nopitsch-Mai is member of the Inhalanda Working Party, EDQM, Strabourg since 2013.

Martin Ohrt

Martin Ohrt is founder and CEO at Liita Care. Martin Ohrt holds an AP Degree in Marketing from Copenhagen Business School and is currently attending The Pasteur Program at Harvard Business School, Executive Education on a scholarship from Innovation Fund Denmark. Work experience includes 20+ years of launching, promoting, distributing, advertising and communicating in the FMCG sector. In addition, Martin Ohrt worked as communication strategist to leading Danish politician and former EU commissioner and as advisor to numerous startup companies. Prior to founding Liita, Martin worked in STOIC (now LOOP Consulting) as business consultant alongside a former IDEO director. This collaboration further developed Martin's skills in consumer-centered innovation. Martin Ohrt is driven by establishing collaborations across geographical, cultural and academic borders to define a better, brighter future.

Hans-Leonhard Ohrem

Dr. Hans-Leonhard Ohrem is Technical Marketing Manager at Merck. He has expertise in solid dose excipients and formulation technologies.
Dr. Hans-Leonard Ohrem has more than 10 years experience as Marketing Manager, and he has experience from coordination of customer projects, development of production process in functional particle engineering, regulatory support and audits and complaint management. He has more than five years experience of leading of development group and pilot plant unit in central process development with focus on preparative chromatography and continuous reaction design. Dr. Hans-Leonard Ohrem has a master of Chemical Engineering at RWTH Aachen, Germany a master of Chemical Engineering at Cornell University, Ithaca and a PhD in Biochemical Engineering RWTH Aachen (Dr. Ing.).

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Speakers

Joanne Peart

Dr. Joanne Peart is an independent pharmaceutical consultant specializing in the field of respiratory drug delivery formulation and device technology (Revenio Consulting Ltd). Dr. Joanne Peart also serves as an Affiliate Associate Professor at Virginia Commonwealth University School of Pharmacy, Richmond, Virginia. Dr. Joanne Peart co-organizes and co-edits the Proceedings of the international conference series Respiratory Drug Delivery. She has a degree in Pharmacy (1991) and Ph. D. in Pharmaceutics (1996) from the University of Bath, UK. Dr. Joanne Peart was previously an Associate Professor in the Aerosol Research Group at VCU from 1996–2013, where her research focused upon the formulation and electrostatic characterization of pharmaceutical aerosols. Dr. Joanne Peart has published a series of original research articles and abstracts related to inhalation aerosol technology, been awarded extramural funding, spoken at national and international meetings, been awarded two U.S. Patents, and has also served as a consultant to pharmaceutical companies. Dr. Joanne Peart is a registered pharmacist in Great Britain, a member of AAPS, the Aerosol Society, the Institute of Physics, and the Electrostatics Society of America.

Vanessa Ross

BSc. Vanessa Ross joined the Large Animal and Avian department of Envigo (based at Huntingdon) as a Study Supervisor in October 1985, dealing mainly with Veterinary Medicinal Products safety/toxicology and residue studies. Vanessa Ross was promoted to Study Director in July 1988. As Study Director, she is responsible for the overall design, conduct, interpretation and reporting of non-clinical toxicology studies in rodents, dogs, minipigs, domestic livestock, avian and Old World primates. Vanessa has a BSc (Hons) in Pathobiology from the University of Reading (1982) and has study directed an extensive range of toxicology studies for the pharmaceutical, chemical, food and agrochemical industries and has a publication. BSc. Vanessa Ross is a UK Home Office Deputy Project Licence Holder for domestic livestock non-clinical studies.

Julie D. Suman

Dr. Julie D. Suman is co-founder and President of Next Breath, a division of AptarGroup Inc., 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.

Kyrre Thalberg

Dr. Kyrre Thalberg obtained his Master of Chemical Engineering from Lund University, Sweden, 1982, and a Ph. D. in the field of Physical Chemistry from the same university 1990. Since 1991, Dr. Kyrre Thalberg has been working with AstraZeneca, first in Lund, now in Gothenburg, both Sweden. Within AstraZeneca, Dr. Kyrre Thalberg has held a number of positions and has provided key contributions to several products on the market. His research interests has been directed to dry powder formulation, material science and processing. Dr. Kyrre Thalberg has authored or co-authored more than 25 publications in international journals. Aside from inhalation science, Kyrre Thalberg writes children's books about the dragon Kjetil and little Prince Pralin.

Per Wollmer

Professor Per Wollmer, MD, PhD is Professor of Clinical Physiology and Nuclear Medicine at Lund University since 1992. Main research interests are pulmonary physiology and pathophysiology, pulmonary function testing, functional imaging of the lung and deposition and absorption of inhaled pharmaceuticals. Scientific publications: 273 original articles in international, peer-reviewed journals.

Hui Zhang

Dr. Hui Zhang is an experimental and toxicological pathologist working at AstraZeneca. Dr. Hui Zhang was a clinical physician (MD from China) and academic scientist (PhD from Lund) before joining Novo Nordisk and then AstraZeneca (Södertälje, Lund and Mölndal). Her broad experience in drug R&D covers drug efficacy evaluation, drug toxicity assessment, tissue biomarker development and issue driving mechanistic investigation. She has evaluated different types of preclinical studies (species, routes and durations) for dozens of compounds, particularly inhaled compounds in dry powder formulations. The pathological evaluations supplied critical measures for candidate drug selection and milestone transition. Dr. Hui Zhang is a diplomate of American board toxicology, a member of Association of Inhalation Toxicologists, Society of Toxicological Pathologists (US), and European Society of Toxicological Pathologists (EU).