4th Medicon Valley Inhalation Symposium 2015

Program – Future Opportunities of Inhalation

DAY 1 – 7th of October

08.30 – 09.00	Registration	
09.00 – 09.05	Welcome to MVICs Symposium	*Dr Ola Nerbrink, MVIC*
09.05 – 09.10	Welcome to Medicon Village	*Kerstin Jacobsson, Medicon VIllage*

New Businesses – Challenges, Opportunities

Chairman: Dr Karin von Wachenfeldt

09.10 – 09.30	Providing Technology for Correlating Aerosol Exposures *In Vitro* and *In Vivo*	*Dr Per Gerde, Inhalation Sciences*
09.30 – 09.50	Transforming the treatment of Pulmonary Alveolar Proteinosis (PAP) – Development of Inhaled GM-CSF	*Kim Arvid Nielsen, Serendex Pharmaceuticals*

PK/PD

Chairman: Dr Karin von Wachenfeldt

09.50 – 10.10	Lung Receptor Occupancy Measurements Following Inhalation – a Glimpse of Light in the Black of Box	*Dr Pär Ewing, AstraZeneca*
10.10 – 10.30	Air Liquid Interface Exposure in Bioavailability and Toxicity Testing	*Dr Frédérique van Acker, TNO Triskelion*
10.30 – 11.20	Coffee and Mingle	

Dissolution

Chairman: Dr Karin von Wachenfeldt

11.20 – 11.40	Clinical Performance of Inhaled Products: How can We Link Dose, Deposition and Dissolution to Exposure?	*Dr Per Bäckman, AstraZeneca*
11.40 – 12.00	In-vitro Dissolution of Inhalation Formulations	*Hans Gredeby, Adroit Science*
12.00 – 13.30	Lunch and Mingle	

Filling and Manufacturing

Chairman: Dr Ola Nerbrink

13.30 – 13.55	Technology of Filling Low Dosage Inhalation Powders with a Dosator Nozzle Into Capsules	*Dr Eva Faulhammer, MG2*
13.55 – 14.20	Inhalation Drug Delivery Solutions Through Spray Dried Engineered Particles	*Dr Jeffrey Breit, Capsugel*

Device

Chairman: Dr Ola Nerbrink

14.20 – 14.40	Development of Inhalation Devices for the Generic Market	*Dr Orest Lastow, Iconovo*
14.40 – 15.00	Device Design	*Jonas Svennberg, Zenit Design*
15.00 – 16.00	Coffee and Mingle	

to be continued at page 2.

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Program – Future Opportunities of Inhalation

Inhalation Devices and Human Factors

Chairman: Dr Orest Lastow

16.00 – 16.30	Utility of FeNO in Measuring Adherence to Inhaled Corticosteroids	*Dr Ulla Seppälä, Aerocrine*
16.30 – 17.00	Clinical Research in the Development of Facemasks for Valved Holding Chambers	*Kurt Nikander, InDevCo*
17.00 – 17.30	Varying Particle Size and Excipient Levels for Three MDIs: Effects on On-Vitro Performance	*Dennis Sandell, S5 Consulting*
17.30 – 17.40	Close and Summary Day 1	*Dr Ola Nerbrink, MVIC*
18.00 – 19.00	Drink Reception sponsored by Micro-Sphere SA	
19.00	Dinner	

DAY 2 – 8th of October

Generic Strategies

Chairman: Dr Orest Lastow

09.00 – 09.30	Making Generics Better	*Danny Brinkley, Actavis*
09.30 – 09.50	Inhaled Vaccine	*Dr Orest Lastow, Iconovo*
09.50 – 10.45	Coffee and Mingle	

Performance Testing and New Opportunities

Chairman: Dr Mårten Svensson

10.45 – 11.10	Abbreviated Impactor Measurements – Overview of Available Methods	*Dr Patrik Andersson, AstraZeneca*
11.10 – 11.35	Dispersion, Deagglomeration and Aerosolisation – a Particle's Perspective	*David Harris, Team Consulting*
11.35 – 12.00	Breathing Life Back into Inhaled Drug Delivery – New Molecules, Formulations and Devices	*Dr Joanne Peart, Revenio*
12.00 – 12.10	Closing Symposium	*Dr Ola Nerbrink, MVIC*
12.15 – 13.15	Lunch	

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4th Medicon Valley Inhalation Symposium 2015

Speakers

Frédérique van Acker, Ph. D.

Dr Frédérique van Acker is a toxicologist with a Ph. D. in oncology and with 15 years experience in the field of genetic and in vitro toxicology. In 2009 she joined TNO as a scientist and since the foundation of the CRO TNO Triskelion BV in 2011, she is working as a project manager/study director in the field of genetic and in vitro toxicology at the Toxicology and Risk Assessment Department of that company. In this position, she performed many in vitro and in vivo genotoxicity studies both GLP and non-GLP and is involved in various innovation programs. She functions as an expert in genetic and in vitro toxicology supporting the other study directors within this group. From 2001 – 2009, she worked in the pharmaceutical industry at Organon and Schering-Plough, first as a Study Director and later also as Group Leader Genetic Toxicology. Dr Frédérique van Acker is the secretary of the section Genetic Toxicology of The Netherlands Society of Toxicology (NVT), member of the European Environmental Mutagen Society and the Dutch-Belgian Society for In Vitro Methods.

Patrik Andersson, Ph. D.

1999 Patrik Andersson got a Ph.D. at the Dept of Chemistry, University of Gothenburg (GU), and between 1999–2001 he was an Assistant researcher at the Dept of Chemistry, GU. 2000–2001 he had a postdoc at the Max-Planck-Institut für Strömungsforschung, Göttingen. 20001–2005 Dr Patrik Andersson was an Assistant project leader at the Dept of Chemistry, Atmospheric Science, GU and between 2005–2009 he was an Assistant professor at the Dept of Chemistry, GU. During 2009–2011 Dr Andersson was a Researcher at the Dept of Chemistry, GU. In 2011 Dr Patrik Andersson came to AstraZeneca R&D Mölndal, and started as a Senior Scientist (Inhalation specialist) at Product Development, and today Dr Patrik Andersson is a Associate Principal Scientist in Aerosol Physics at Product Development.

Jeffrey Breit, Ph. D.

Dr Jeffrey Breit is a Director at Bend Research Inc., where he works in the fields of biotherapeutic drug development, inhalation drug delivery and formulation technologies. He has worked at Bend Research for 7 years. Dr Breit earned his Ph. D. in Pharmacology from the University of South Alabama, while working in the Center for Lung Biology. His doctoral work focused on defining genetic and molecular signaling processes involved in pulmonary disease. Dr Breit performed his postdoctoral work at Roche Pharmaceuticals in Palo Alto, California, where he researched the genetics of complex disease states.

Danny Brinkley

Danny Brinkley is a manager at Actavis leading the generic DPI development programs. His educational background is BSc in Pharmaceutical Sciences from London Metropolitan University. He joined Actavis in 2012 from a branded development background, previously working at GSK and Novartis on products including Advair® Diskus®, Brio® Ellipta® and Onbrez® Breezehaler®. Since joining Actavis, he has strived to take a branded approach to product design and merge it with a flexible, lean mentality required for generic development.

Per Bäckman, Ph. D

Per Bäckman is a Principal Scientist at AstraZeneca R&D in Mölndal Sweden. He earned his Ph. D. in Thermochemistry from the University of Lund in 1991. In 1995 he joined Astra Draco in Lund following post-doctoral positions at University of Virginia and University of Lund. From 1995 to 2006, Dr Bäckman held several positions within Astra Draco/AstraZeneca in Lund, mainly focusing on the interface between preclinical and clinical development of inhaled medicines. In 2006, he joined Novo Nordisk A/S in Denmark as head of department for inhalation product characterization. Since 2011, Dr Bäckman has been active as Principal Scientist at AstraZeneca in Mölndal, Sweden, mainly focused on research activities related to developing and implementing models that integrate deposition, clearance, dissolution, uptake and systemic disposition of orally inhaled products.

Pär Ewing, Ph. D.

Under supervision of Dr Gerde and Prof Ryrfeldt, Pär Ewing earned a Ph. D. in toxicology at Karolinska in 2008. He continued as a post-doc at DMPK department AstraZeneca Lund. Following, the closure of AZ Lund Pär moved on to Mölndal in 2011 to continue to study the fate of inhaled particles with emphasis on the link between pulmonary absorption and pharmacodynamic effects.

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4th Medicon Valley Inhalation Symposium 2015

Speakers

Eva Faulhammer, Ph. D.

Dr Eva Faulhammer held her diploma in Pharmacy (University of Graz) and Masters in Chemical and Pharmaceutical Engineering (Technical University of Graz). She obtained Ph. D. from the institute of Particle and Process Engineering (Technical University of Graz). Her Ph. D. research was in the field of QbD driven process development and optimization for low-dose capsule filling using advanced material characterization and statistical methods conducted in cooperation with MG2, Italy and GlaxoSmithKline, UK. She currently holds the position of Senior Scientist at the Research Center Pharmaceutical Engineering (RCPE) in Graz. Trained in pharmaceutical material science and particle engineering, she harbors a broad interest in pharmaceutical particle technology and solid dosage form processing with a special focus into oral and inhalation capsules. She also has a long standing activities and interest in screening, engineering, stabilization and characterization of pharmaceutical particulate formulations intended for oral and inhalation routes. Also, she is working towards advancing the predictive knowledge of pharmaceutical capsule filling process via elucidation of multi-factorial physical and chemical properties of drug substances and excipients governing the success of capsule filling.

Per Gerde, Ph. D.

Dr Per Gerde is Associate Professor in inhalation toxicology at Institute of Environmental Medicine, Karoliska Institutet , Stockholm. Dr. Gerde's main research interest is to better understand the pharmacokinetics of inhaled pharmaceutical aerosols and air pollution aerosols. An important part of this effort is to design and develop methods suitable for allowing small-scale inhalation exposures with respirable aerosols in recipients from cell cultures to animals. In this latter role he is also co-founder and CSO at Inhalation Sciences Sweden AB.

Hans Gredeby

Hans Gredeby is the CEO of Adroit Science AB. He has spent more than 30 years in the pharmaceutical industry as scientist, manager and project leader. Hans has a long and wide experience from a multitude of pharmaceutical development projects and marketed products. With a background in analytical chemistry, Hans is skilled in separation and dissolution techniques.

David Harris

David has been working in the field of respiratory drug delivery since 1994, when he began his career in the Respiratory Physics group at Fisons. Since 2002 he has worked for Cambridge based medical device consultancies, and now leads Respiratory Drug Delivery at Team Consulting. He has been the technical lead on several inhaler development programmes and is widely published in the field. David also sits on the organising committee of the Drug Delivery to the Lungs conference, one of the largest respiratory events in the world.

Orest Lastow, Ph. D.

Dr Orest Lastow is the co-founder and CEO of Iconovo AB. He is responsible for the development of Iconovo's inhalation device platform. He is also the founder and previous CEO of Medicon Valley Inhalation Consortium, MVIC AB. Orest 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 50 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 atomisation 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 atomisation, several journal publications and book contributions. He is frequently invited to speak at conferences and teaches aerosol drug delivery at Lund University. Orest is a co-author of the Aerosol drug delivery device design verification standard (ISO 20072).

Kurt Nikander

Kurt Nikander has been working in the field of respiratory drug delivery and inhalation devices since 1976. Between 1976–1982 he worked for Astra Pharmaceuticals Finland, in sales and marketing and between 1982–1986 for Draco Läkemedel, Lund, Sweden (subsidiary of Astra Pharmaceuticals), in product management. He worked for AB Draco, Sweden (subsidiary of Astra Pharmaceuticals, international) 1986–1999 in clinical research and development, and 1999–2001 for Astra and AstraZeneca R&D, Lund, Sweden, in medical communication. He left AstraZeneca in 2001 for Profile Therapeutics Inc., Boston, MA, USA (subsidiary of Profile Therapeutics plc, Bognor Regis, West Sussex, UK) to work in product development and clinical research (nebulizers, spacers). Product development and clinical research was the focus of the work even after the acquisitions 2004 by Respironics Inc., NJ, USA, and 2008 by Royal Dutch Philips at Philips Respironics, NJ, USA (2008-2013). Kurt started the InDevCo AB consulting company in 2013 in Nyköping, Sweden focusing on inhalers and related in vitro and clinical research.

Kim Nielsen

Kim Arvid Nielsen is CEO of Serendex Pharmaceuticals A/S. Serendex is repositioning drugs for inhalation focusing on orphan indications. Kim Arvid Nielsen graduated as MD from the University of Copenhagen in 1988 and has worked in medical and commercial positions in several biotech and international pharma companies for the past 25 years. Dr. Nielsen was appointed CEO for Serendex in 2013.

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4th Medicon Valley Inhalation Symposium 2015

Speakers

Joanne Peart, Ph. D.

Dr Joanne Peart is an independent pharmaceutical consultant specializing in the field of respiratory drug delivery formulation and device technology (Revenio Consulting Ltd). Dr Peart also serves as an Affiliate Associate Professor at Virginia Commonwealth University School of Pharmacy, Richmond, Virginia. Dr 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 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 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 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.

Dennis Sandell, Ph. Lic.

Dennis Sandell holds a Ph. Lic. in Mathematical Statistics. He has worked for AstraZeneca, Amgen and Siegfried Pharma Development GmbH in both specialist and management roles. Dr Sandell is a world leading expert in the area of CMC statistics, especially related to development, registration and commercial manufacture of inhalation products and on in-vitro bioequivalence evaluations as well as IVIVC. He has deep experiences from of several innovator and generic DPIs, MDIs, nasal sprays and nebulization products, as well as different add-on devices. Dr Sandell has 62 publications and frequently presents at international conferences. He has participated in different industry collaborations such as IPAC-RS, EPAG, PQRI and PhRMA and is a member of USP Statistics Expert Committee and chair of the USP Large N Expert Panel. He is an Adjunct Professor at the Department of Pharmaceutics, University of Florida. In May 2010 Dennis started the consulting firm S5 Consulting, providing CMC statistical support, general inhalation development advice, regulatory writing, and due diligence support.

Ulla Seppälä, Ph. D.

Dr Ulla Seppälä performed her doctoral studies at the National Public Health Institute and Institute of Biotechnology at the University of Helsinki and received her Ph. D. in the field of biochemistry, allergy and immunology at the University of Helsinki, Finland 2001. She joined Medical Affairs at Aerocrine AB 2014 after working over ten years at ALK-Abelló A/S in Denmark were she held number of positions within R&D and Intellectual Property and Licensing.
Dr Ulla Seppälä has published patents, original research and presented internationally in the field of allergy, immunology and proteomics. She is a reviewer of major scientific journals in the field of allergy and a reviewer board member of Journal of Allergy and Clinical Immunology. In addition, she is a member of European Academy of Allergy and Clinical Immunology and American Academy of Allergy, Asthma and Immunology. Dr Ulla Seppälä has contributed to a number of research projects and managed cross functional project teams. In her current role in the Medical Affairs she focuses on medical communication, stakeholder relationships and clinical studies.

Jonas Svennberg

Jonas Svennberg, CEO of Zenit Design is an industrial designer with education from Umeå Institute of Design and Konstfack in Stockholm. He has a 20+ year experience from various design projects for products and services covering consumer goods via advanced medical devices to heavy industrial systems. Jonas will talk about his experiences from medical device projects and general trends in healthcare and medical devices.
Zenit Design is a strategic design agency that creates insight in for whom, why, what and how. Among the clients you find companies as: Sony Mobile, Astra Zeneca, Axis Communications, Assa Abloy Entrance Systems, Schneider Electric, SCA and Mölnlycke Healthcare.

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