3rd Medicon Valley Inhalation Symposium 2014
Program – Future Opportunities of Inhalation

09.00 – 09.20  Welcome
Ola Nerbrink, MVIC AB

Development of Generic Inhalation Products

09.20 – 09.40  Essential Points to Consider when Ramping up an Inhaler from Concept to Mass Production
Johan Lindqvist, Phillips-Medisize

09.40 – 10.00  Important Patient Aspects in Inhaler Product Development
Hans Lundbäck, Emmace Consulting AB

10.00 – 10.40  Coffee

10.40 – 11.00  How to Develop a Generic Product – Device and Formulation
Jussi Haikarainen, Orion

11.00 – 11.20  Statistics of In-vitro Equivalence
Dennis Sandell, S5 Consulting

11.20 – 12.00  Panel Discussion – Innovative vs. me to

12.00 – 13.30  Lunch

Innovative Nebulization Technology

13.30 – 13.45  OptiLung® – Preservative Free Liquid Nebulizer
Horst Zimmer, URSATEC Verpackung-GmbH

13.45 – 14.00  Novel Nebulization Technology – Alphazer
Miron Hazani, Omega Life Science

14.00 – 14.20  Novel Liquid Formulations
Stefan Ulvenlund, CR Competence

Product Development

14.20 – 14.40  Spray Drying for Inhaled Drug Delivery
Michele Müller, Micro-Sphere SA

14.40 – 15.00  The Necessity and Opportunity of Moisture Control in DPI
Valère Logel, Clariant Healthcare Packaging

15.00 – 15.40  Coffee

What is Coming in the Future

15.40 – 16.00  Modern Patient Support Solutions to Address Adherence and Treatment Outcome in Respiratory Diseases
Magnus Jörnten-Karlsson, AstraZeneca

16.00 – 16.20  Taking a Holistic Approach to Patient Management
John Pritchard, Philips Home Healthcare Solutions

16.20 – 16.40  Inhaled Nicotine – Commercially Available e-Cigarettes
Mikael Sundahl, McNeil AB

16.40 – 17.00  Nano Particles as a Diagnostic Tool
Jakob Löndahl, Lund University

17.00 – 17.10  Closing Remarks and End of Symposium

17.10 – 18.00  Pre Dinner Reception sponsored by Micro-Sphere SA

18.00  Dinner
Jussi Haikarainen, MSc

Jussi Haikarainen is senior development manager in Orion Pharma’s Pharmaceutical Sciences platform. His educational background is MSc in materials science (Tampere University of Technology). Initially, Mr. Haikarainen joined Orion 1997 as a development engineer working extensively on Easyhaler dry powder inhaler. Field of work since then included product development, industrialisation, technology transfers and project management, mainly for the OIPs. On 2004 he joined sanofi-aventis and worked as project manager for the SoloStar insulin pen program for Lantus and Apidra insulins leading the pen project from the design freeze through industrialisation and first regulatory approvals. Since 2007 Mr. Haikarainen has been back at Orion and has lead the device and pharmaceutical development activities for the generic combination OIP products.

Miron Hazani, Ph D

Dr. Hazani holds a Ph D in Biochemistry from Tel Aviv University and conducted post doctoral studies in nanotechnology and surface science at the Weizmann Institute of Science. He held R&D positions in start-up companies in the fields of material science and nanotechnology and now serves as CTO at Omega Life Science.

Magnus Jörntén-Karlsson

Magnus Jörntén-Karlsson currently works as Project Director in Pharmaceutical Innovations team at AstraZeneca R&D specializing on digital support tools to optimize the treatment provided to patients in some of the key disease areas of AstraZeneca. This focus on understanding potential and real barriers for patients to adhere to the treatment plan and to understand how novel technology can actually improve standard of care through a better understanding of the patient journey and data. After more than 25 years in the Pharmaceutical Industry he has worked as a Specialist, Line Manager and Project Manager for developing and characterizing new pharmaceutical products, including Inhalation products, from early development to launch and post market support.

Johan Lindqvist, MSc

Is Business Manager for Drug Delivery Devices at Phillips-Medisize. He has worked for several companies, mainly in the business of manufacturing of sub contracted plastic products for the medical and automotive industry. His areas of responsibility have been in the field of general management, production and R & D. For over 20 years he has been working in sales and marketing. He has a MSc degree in chemical engineering with polymer chemistry as a specialty.

Valère Logel, MSc

Since 2005 Valère Logel has been the Head of Development for Clariant Healthcare Packaging, a globally active manufacturer of controlled atmosphere packaging. He holds master’s degrees in engineering and polymer science and has over 15 years of experience in research, development, production and market introduction of innovative products and related production technologies. His expertise includes material engineering, product design, and process validation, with specific focus on healthcare packaging systems that protect drugs from moisture degradation.

Hans Lundbäck, Ph D

Finished his doctoral studies in analytical chemistry, Flow Injection Analysis (FIA), with a Ph D 1984. From 1985 and up to July 2014, he has been dedicated to research and development of inhaled medicins at AstraZeneca in Lund/Mölndal Sweden, former Draco and Astra Draco in Lund, Sweden. Focus has been on developing inhaled products, both formulation an device. Except a few years with pressurised metered dose inhalers (pMDIs) his main focus has been Dry Powder Inhalers (DPI), not least the interest in patient related topics as given by the concerns related to the device as an interface between the drug formulation and the patient. During his work at AZ he has been an active member in e.g., PhEur Inhalanda Working Party, Swedish Pharmacopoeia commission and the industrial consortiums IPAC-RS and EPAG. He has recently joined Emmace Consulting AB as Scientific Advisor in Inhalation.

Jakob Lönldahl, MSc, Ph D

Is a senior researcher in aerosol technology at the Department of Design sciences at Lund University and CEO of JP Respiratory Technology. He has an MSc in engineering physics and in 2009 he received a Ph D on experimental analyses of inhaled aerosols. For this work he was awarded with the Färö&Frost prize for outstanding doctoral thesis. In 2010–2011 he carried out postdoctoral studies on biological aerosol particles at McGill University, Canada, and Aarhus University, Denmark. Since 2012 his research is mainly focused on health related aspects of aerosol particles, such as exposure to airborne contamination and medical applications of inhaled nanoparticles. Together with Prof. Per Wollmer he is inventor of the Airspace Dimension Test (ADT), which is a novel instrument for diagnosis of pulmonary emphysema.

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Speakers
Speakers

**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. 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 56 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 in the Department of Pharmaceutics, University of Florida. In May 2010 he started the consulting firm SS Consulting, providing CMC statistical support, general inhalation development advice, and regulatory writing.

**Michele Müller, Ph D**
Michele Müller has studies in biology and holds a Ph.D. in biochemistry at the Division of Natural Sciences at the Swiss Federal Institute of Technology (ETH), Zürich. Between 1984–1995 Michele Müller did academic research work and worked as a teacher University of Bern, Université de Nice, Inselspital Bern, 50+ paper, book and proceeding articles. Between 1995–1998 he was a Project leader at Cerbios Pharma SA, Barzengo, Switzerland. Michele Müller became Founder and General Manager of Micro-Sphere SA, Ponte Cremenaga, 1998. During 2002–2003 Michele Müller was R&D director of Sintetica SA, production of anesthetics and between 2005–2008 he was a Deputy General Manager of Micro-Macinazione SA, Monteggio, a jet-milling micronization company. Since 2008, he has been Co-Founder and Member of the Board of Industrie Biomediche Insubri, Mezzovico, a medical device company (Bone substitute class 3).

**John N. Pritchard, Ph D**
A graduate in physics from Birmingham University, John joined the UK Atomic Energy Authority, leading research into the deposition and clearance of particles in the respiratory tract, gaining a Ph D from Essex University on lung deposition of cigarette smoke. John moved to Glaxo in 1991, then 3M and AstraZeneca, during which, he was directly associated with the launch of 11 different inhaled marketed products. Since January 2011, John has been Chief Technology Officer for Philips Respironics Drug Delivery, with global accountability for the development of advanced delivery systems for the monitoring and treatment of respiratory diseases. John has published widely, been editor to several journals, as well as having served as President of The Aerosol Society and Board Member for ISAM. He is currently a member of the UN Medical Technical Options Committee, which recommends essential uses of CFC propellants and sits on the Scientific Advisory Board of Prosonix.

**Mikael Sundahl, MSc, Ph D**
Mikael Sundahl holds a Ph D in Organic Chemistry, 1990, Chalmers University of Technology and is a Docent “Associate Professor” in Organic Chemistry, 1995, Chalmers University of Technology. He has a Master of Science and Technology in Chemical Engineering, 1985, Chalmers University of Technology. Mikael Sundahl has been Principal Scientist, Novo Nordisk (Inhaled Insulin) 2006-2008, and he has been Manager Analytical Development, AstraZeneca Lund, (Inhaled products for Asthma and COPD) 2001-2006. During 1998–2001, he was Manager – Organic Analytical Chemistry, Swedish National Testing and Research Institute (Indoor Air Quality, Environmental and Workplace Environment, Materials analysis). During 1990–1996, he was a Researcher at Chalmers University of Technology, including post doc at Tsukuba University. Since 2008, Mikael Sundahl has been Director Analytical Development, McNeil AB Helsingborg (Nicorette, Digestive health and Cough&Cold products).

**Stefan Ulvenlund, Ph D**
Stefan Ulvenlund has more than 17 years of experience of pharmaceutical product development, 13 of which at AstraZeneca. Since 2010 he holds the position as CSO at the contract research company CR Competence AB in Lund. Stefan specializes in formulation strategies for poorly soluble compounds, and in liquid formulations for nasal and pulmonary administration. He has a keen interest in novel excipients and non-conventional formulation concepts.

**Horst Zimmer, Dipl. med. Phys.**
Horst Zimmer has a degree in Medical Physics, he has an education as Safety officer for medical products (German Medical Device Act) and Pharma Referent (§ 75 German Pharmaceutical Act). Between 1997-2005 Horst Zimmer was Product Manager for Medical Device Implants and during 2005-2013 he was the Head of Development & Sales at Ursatec GmbH. Since January 2014, Horst Zimmer has been General Manager of Ursatec GmbH.