Program – Future Opportunities of Inhalation

DAY 1 – Wednesday the 3rd of October 2018

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

▶ New Drugs and Clinical

Chairman: MD Lars-Göran Carlsson

09.15–09.35	Future Opportunities for Inhaled Biomolecules	*Dr Gunilla Petersson, AstraZeneca*
09.35–09.55	Inhaled Oxytocine	*Peter Lambert, Monash University*
09.55–10.15	Experiences and Learnings from Pharmacokinetic Studies with Easyhaler Products	*Satu Lähelmä, Orion Pharma*
10.15–11.10	**Coffee and Mingle**	

▶ Formulation Development

Chairman: Dr Jessica Elversson

11.10–11.30	Parameters Influencing the Performance of Interactive Blends for Inhalation	*Nancy Rhein, Christian-Albrechts-Universität, Kiel*
11.30-11.50	Lactose for Inhalation: More than a Carrier	*Dr Mohit Mehta, DFE Pharma*
11.50–12.10	Development of Nasal Products	*Dr René Bommer, PharmAccel*
12.10–13.45	**Lunch and Mingle**	

▶ Device

Chairman: Dr Orest Lastow

13.45–14.10	Innovation Challenges in Inhalation Device Development	*Charlotte Harris, Team Consulting*
14.10–14.35	Cipla's Broad Respiratory Product Portfolio: Historical and Scientific Aspects	*Dr Gur Jai Pal Singh, Cipla*
14.35–15.00	Design of a Dual Inhaler System for Lung Delivery of API and Buccal Delivery of Excipients	*Wilbur de Kruijf, Medspray BV*
15.00–16.00	**Coffee and Mingle**	

Program – Future Opportunities of Inhalation

▶ Dissolution

Chairman: Dr Per Bäckman

16.00–16.25	Developing Alternative In Vitro Approaches for Bio-equivalence Testing of Orally Inhaled Drug Products	*Professor Rob Price, University of Bath*
16.25–16.50	Do We Understand Absorptive Clearance of Inhaled Drugs in Lung?	*Professor Ben Forbes, King's College London*
16.50–17.15	Applications of Computer Based Modelling in Support of OIP Design	*Dr Helena Thörn, AstraZeneca*
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 4th of October 2018

▶ Tox and Pre-Clinical

Chairman: Dr Karin Svens

09.00–09.25	Toxicology – Practical Considerations for Non-clinical Testing	*Dr Simon Moore, Envigo*
09.25–09.50	Predictive Respiratory Toxicology with the GARD In-Vitro Testing Platform,	*Dr Henrik Johansson, SenzaGen AB*
09.50–10.15	Evaluation of Genotoxicity of Impurities, Leachables and Extractables – ISO10993 Meets ICHM7	*Dr Stefan Czene, Toxicology Knowledge Team Sweden, TKT*
10.15–11.00	**Coffee and Mingle**	

▶ New Opportunities and Regulatory

Chairman: Dr Ingrid Lamberg

11.00–11.25	New Opportunity – 1nhaler	*Don Smith, 1nhaler*
11.25–11.50	Regulatory Aspects of Establishment of Therapeutic Equivalence with Focus on Pharmacodynamic Studies	*Dr Karolina Thörneke, Swedish MPA*
11.50–12.10	Missing Approvals for Abridge Products in EU+US: Why the Bottleneck is Not Regulatory	*Dr Anders Fuglsang, Fuglsang Pharma*
12.10–12.20	Closing Symposium	*MSc Lars Asking, MVIC*
12.20–13.00	**Lunch and Mingle**	

Speakers

René Bommer, PhD

Dr René Bommer is founder and owner of pharmAccel Consulting and has been active in academia and the pharmaceutical industry since 25 years. After various research positions in pharmaceutical chemistry and in molecular biology he joined the delivery device and dispenser industry. As a director of business development he concurrently focused on scientific and economic issues and learned to balance these sometimes controversial and conflicting interests. After long years of experience in the industry Dr René Bommer founded in 2007 its own company which is engaged in the drug delivery device industry. The company offers the relevant service corresponding to all activities for the design, the manufacture and the marketing of successful drug delivery dispensers and medical devices. Dr René Bommer published several articles in medical device and packaging journals, is regularly invited as a speaker at international drug delivery conferences and is chairing the annual Nasal Drug Delivery Conference in London.

Stefan Czene, PhD

Dr Stefan Czene has received his MsC in biochemistry in 1986, followed by a PhD in oncology in 1992. After about a decade of academic research within the field of radiobiology and genetic toxicology at Stockholm University, including supervision of several PhD and MSc students, he has joined AstraZeneca in 2003. During his years at AstraZeneca, Dr Stefan Czene has extensively supported AZ discovery and development projects with in vivo and in vitro Comet assay studies. As an AstraZeneca Principal Scientist, he also provided toxicological advice and guidance on risk assessment of impurities in drug substances and products including organic/inorganic impurities, solvents, metals, leechables/extractables and genotoxic impurities in order to meet regulatory demands. His additional roles included interpretation of SAR analyses (e.g. DEREK, CASE) and identification of potential risks associated with chemical structure(s) of lead series in early drug discovery as well as problem-solving activities within genetic toxicology including regulatory interactions. Together with a group of former AstraZeneca toxicologists, Dr Stefan Czene is a co-founder of the consultancy firm Toxicology Knowledge Team Sweden AB, which since 2012 provides highly specialized toxicological expertise to clients engaged in pharmaceutical development, chemical risk assessment and medical devices.

Ben Forbes, PhD

Ben Forbes is Professor of Pharmaceutics at King's College London. He has a BPharm from King's College London (1987) and a PhD in Drug Delivery from Strathclyde University (1996). Before doctoral studies, he worked in hospital pharmacy in London and Sydney, and for Inveresk Clinical Research in Edinburgh. He was appointed to the academic staff of King's College London in 1997 and is a registered pharmacist in the UK. Professor Ben Forbes has authored many publications in the topics of: (1) inhaled medicine formulation, (2) the development and application of techniques to study respiratory drug transport and metabolism, (3) inhalation toxicology. He chairs the Scientific Advisory Committee of the Aerosol Society's annual Drug Delivery to the Lung's (DDL) conference in UK.

Anders Fuglsang, PhD

Dr Anders Fuglsang graduated in 1998 from the Royal Danish School of Pharmacy, Copenhagen, spending part of his studies at Leiden University, in the Netherlands. He was awarded his PhD in 2002 specialising in cardiovascular pharmacology. Following work as an Assistant Professor, he worked as a consultant for a number of Originator Pharmaceutical companies at a brand optimisation company in Copenhagen. In 2005, he joined the Norwegian Medicines Agency as a Clinical Assessor and became Expert Advisor to the WHO and member of the Efficacy Working. Party at the EM(E)A. Dr Anders Fuglsang was Chair of the sub-group for Orally Inhaled Products which published the 2009 guideline on Therapeutic Equivalence for inhalation products (still in force), and was also a member of the PK-subgroup. Other duties included provision of Expert Scientific Advice, GLP/GCP-inspection and -training, and responsibility for Assessor Training for Inhaled Products at the EM(E)A. Through 2009 to September 2010, he was Clinical and Regulatory Strategy Manager at a world leading generic company. Dr Anders Fuglsang has now established his own pharmaceutical consultancy, Fuglsang Pharma. Present and former clients include the World Health Organization (WHO), regulatory agencies, United States Pharmacopeial Convention (USP) and private companies. Dr Anders Fuglsang has authored approximately 45 papers in the fields of Pharmacokinetics, Generics, Genetics and Pharmacology, and has served as reviewer for some 15+ international journals including Science, Trends in Genetics and Drug Discovery Today.

Charlotte Harris

Charlotte is a senior consultant at Team Consulting, a medical device product design and development consultancy. Her work is typically focused on managing the strategic and creative 'front-end' of the product development process. She utilises her design research, facilitation skills and knowledge of innovation techniques, to understand the needs of the market, determine strategic direction and plan and run creative and direction setting workshops – to ensure the creation of innovative but realistic solutions. Charlotte Harris has over 20 years' experience in the medical device industry and has worked in clinical, start-up and consultancy environments. Her experience spans a wide range of devices such as patient monitoring and cardiac assist devices, surgical instrumentation and parenteral and inhaled drug delivery devices. Charlotte studied medical engineering and has a BEng (Hons) from Cardiff University and an MSc (Hons) from King's College London.

Henrik Johansson, PhD

Dr Henrik Johansson is Senior Scientist at SenzaGen AB. Dr Henrik Johansson is scientific professional in the fields of immunology, toxicology and cell & molecular biology. He is specialized in in vitro assay development for predictive immunotoxicology. Dr Henrik Johansson has long experience with genomics applications and high-dimensional data analysis and he is passionate about bringing the latest advances in technology in practical use for the benefit of society.

Speakers

Wilbur de Kruijf

Wilbur de Kruijf is responsible for new business development at Medspray Pharma, the Netherlands. Medspray develops novel metered dose liquid inhalers, based on proprietary micro nano technology spray nozzles. Wilbur de Kruijf joined Medspray twelve 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 (MSc Design Engineering 1995, MSc 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 de Kruijf 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 de Kruijf is the co-chair of WG2 of Cost Action SimInhale (Inhalation Devices) and he is the secretary of the Dutch medical aerosol scientist network 'MAD Foundation'.

Pete Lambert

Pete Lambert is the Director, Program Management at Monash University where he manages an international collaboration to develop a heat stable inhaled oxytocin product to prevent postpartum haemorrhage in resource-poor settings. Pete Lambert originally qualified as a pharmacist from the Liverpool School of Pharmacy in the UK. He spent 7 years at Ciba Pharmaceuticals and Astra AB working in the formulation and manufacturing development of inhaled medicines before joining specialty pharma company, Britannia Pharmaceuticals. At Britannia, he worked on development programs targeting the reformulation of existing molecules for niche indications, most recently as Director of Development overseeing this development portfolio. In 2009, Pete Lambert switched his career focus to follow his passion for global health following seven months volunteering with HIV/AIDS-affected communities in rural South Africa. He completed a Master of Philosophy degree in HIV/AIDS Management from Stellenbosch University and worked as Development Director at Medicines Development for Global Health in Melbourne, Australia (2010-2012). Pete Lambert joined the inhaled oxytocin team at Monash University in 2012.

Satu Lähelmä

Satu Lähelmä works at Orion Corporation Orion Pharma in Kuopio, Finland. She started as a Research Scientist and has held various positions in the company and has gained experience on drug development and especially on development of inhaled products during the last 25 years. Currently, she works as Easyhaler Development Head being responsible for the clinical development of Easyhaler products. Satu Lähelmä has a Master of Science (Pharm.) degree from University of Eastern Finland.

Mohit Mehta, PhD

Dr Mohit Mehta obtained his Master of Pharmaceutical sciences from Mumbai University, India in 2009 and followed by PhD in the field of Pharmaceutical technology in 2013. Dr Mohit Mehta entered the inhalation field at Respiratory center of excellence Cipla, India working on respiratory API processing, particle engineering and formulation development of dry powder inhalers. He gained extensive experience working on formulation process optimization and scale-up of dry powder inhalers. Dr Mohit Mehta is presently working as Product developer Inhalation DFE Pharma, Germany. He joined Technology and Innovation team, DFE Pharma in Jan 2018 and since then working as technical lead and customer support for development of customized Inhalation grade lactose.

Simon Moore, PhD

Dr Simon Moore joined Envigo in 1999 as an inhalation study analyst and was promoted quickly within the Aerosol Technology and Analysis section. When the section expanded and divided in 2003 into inhalation chemistry and aerosol technology, Simon was promoted to the role of Head of Aerosol Technology with managerial responsibility for the aerosol technologists. In 2009, he took managerial responsibility for the inhalation engineering services group. In 2016, he was promoted to his current title Director of Inhalation Science and Engineering and Team Leader. In July 2017, Dr Simon Moore took on the additional responsibility of being part of the Toxicology Operations Management as a Team Leader of the inhalation study management team with line management responsibility for Study Managers and Trainee Study Managers in the Inhalation Studies Group. In this role, Simon is responsible for all aerosol technology aspects including of the overall interpretation and reporting of the inhalation studies including safety pharmacology and ADME at the Huntingdon site. The inhalation engineering services groups designs, prototypes and manufactures custom made inhalation equipment for all inhalation sites within the Envigo organisation. Dr Simon Moore obtained his degree from the University of Dundee in Chemistry (1996) and gained his PhD in Heterogeneous Catalysis from the University of Glasgow (2000) using high-pressure gas flow and chromatography. Simon lectures at the University of Surrey as part of the MSc Toxicology course on inhalation dosing, techniques and methodology, is the Vice Chairman of the Association of Inhalation Toxicologists, a committee member of the British Standard Institution on Nanotechnologies and has produced over 100 publications.

Gunilla Petersson, PhD

Dr Gunilla Petersson has a PhD from Lund University in Analytical Chemistry. Dr Gunilla Petersson has 25 years in AstraZeneca holding different line management and scientific expert roles linking formulations and devices, mainly for inhaled drug product development. Technology development and scouting, product development and registrations of new products, competitor landscape, CMC industry consortia boards and working teams (EPAG, IPAC-RS) for 10 years, drug project due diligences and scientific marketing of AZ products. Dr Gunilla Peterssons current role is Science & Innovation Director, inhaled drug delivery, affiliated to Innovation Strategies & External Liaison (IS&EL) in AZ.

Speakers

Robert Price, PhD

Dr Robert Price is a Professor of Pharmaceutics at the Department of Pharmacy and Pharmacology, University of Bath, UK, where he leads the pharmaceutical surface science research group. His research has been focused on developing an understanding of how the chemistry, manufacturing and controls of materials and processing conditions determine the microstructure of formulations that governs product functionality. With a background in pharmaceutical surface science, he has developed an array of technologies and techniques to engineer and measure the physical, chemical and interfacial properties of excipients and active pharmaceutical ingredients. Dr Robert Price research group has published over 100 scientific papers on the properties of crystals, particles and powders for orally inhaled drug products. He is also co-founder and chief scientific officer of Nanopharm Ltd., a leading provider of orally inhaled and nasal drug product design and development services.

Nancy Rhein

Nancy Rhein started pharmaceutical sciences studies at Kiel University 2013. She had her Pharmacist in training at Kiel university and at Anker Apotheke, Kiel during 2014. 2015 Nancy Rhein got her Licensure as pharmacist. Then she started as Research Associate at department of Pharmaceutics and Biopharmaceutics at Kiel University, and since 2015 she is a Doctoral Candidate at department of Pharmaceutics and Biopharmaceutics at Kiel University, the theme is *Mannitol as an alternative carrier for DPI*.

Gur Jai Pal Singh, PhD

Dr Singh is a Senior Vice President at Cipla Ltd. and heads its Respiratory Center of Excellence. He directs the development, clinical evaluation and regulatory filing of respiratory drug products. His Center provides end-to-end support for the Cipla Respiratory programs for a number of international markets. Before joining Cipla, Dr Singh headed Clinical and Regulatory Affairs at Axar Pharmaceuticals, in Corona, California. Before moving to Axar, Dr Singh was a Director of Biopharmaceutics at Watson Laboratories in Corona, California, where he established a program for development and evaluation of multisource respiratory drug products. In both positions he provided oversight for respiratory product development in several countries. Before joining Watson in 2006, Dr Singh worked for many years in the Division of Bioequivalence at the US FDA. He was Team Leader and the designated Division Expert for the locally acting drug products including inhalation aerosols, metered nasal sprays and dermatologic products containing corticosteroids. During his tenure at the Agency, Dr Singh maintained professional relationship with the relevant New Drug Divisions, and enthusiastically participated in several multidisciplinary committees to develop BE guidances for a variety of products. He played key roles in the development of BE methodologies for albuterol metered dose inhalers, nasal sprays and dermatologic corticosteroids. He actively participated in the Agency efforts to develop methods for evaluation of comparative in vitro performance of devices used in drug products intended for oral inhalation and nasal drug delivery. He chaired the CDER PD/BE Working Group and the Dry Powder Inhaler Working Group and was an active member of several committees which focused on resolution of complex issues to prepare the Agency guidances for documentation of in vivo BE and equivalent in vitro performance of locally acting drug products. He also participated in the Agency-sponsored clinical studies designed to gain insights for the development of novel BE methodologies, and represented the Agency by invitation at a number of international conferences and actively participated in scientific committees associated with PQRI, ISAM and AAPS deliberating on complex issues related to bioequivalence of respiratory drug products.

Don Smith

Don Smith is an inventor and has his own Invention and Disruption Practice called One Hundred Flowers. He is consult on innovation, invention, disruption and creative strategy and he has a business developing his respiratory invention, The 1nhaler. Until 2016, Don was an award winning Creative Director in the Advertising and Digital Marketing field. He left to begin a new career as an inventor, looking to bring his philosophy on innovation and invention into the fields of health, energy, environment and sustainability. His first invention, the 1nhaler is a revolutionary, single dose, dry powder inhaler. Don also consults on innovation, invention and disruption theory, helping businesses in a number of sectors to embrace the value of innovation. He has recently been involved with projects relating to Artificial Intelligence in life sciences, business modelling in financial services, blockchain technology in healthcare, and marine conservation in tidal energy.

Helena Thörn, PhD

Dr Helena Thörn works at AstraZeneca in Gothenburg, Sweden and holds a position as a Senior Scientist in Biopharmaceutics with main focus in the inhaled drug delivery area. Dr Helena Thörn has a Master of Science in Pharmacy and a PhD in Biopharmaceutics from Uppsala University. Her research has been focused on mechanistic understanding of drug absorption and she has many years' experience of PBPK modeling. The PhD thesis included *in vitro*, *in vivo* and simulation studies to investigate first-pass intestinal metabolism of drugs. At AstraZeneca Dr Helena Thörn has worked as a biopharm expert within product development in both the oral and inhaled area since 2013. Dr Helena Thörn has been involved in the Orbito (oral biopharmaceutics tool) project and is a member of the Siminhale COST action. Since 2016 Dr Helena Thörn is industrial supervisor to a PhD student at Uppsala University who studies the absorption of inhaled drugs using the isolated perfused lung model in combination with PBPK modeling.

Karolina Törneke, PhD

Dr Karolina Törneke is a pharmacologist, employed as a clinical assessor at the Medicinal Products Agency (MPA) since 2002. She is a senior expert with main focus on respiratory medicine including approval of orally inhaled products. She is chair of the Scientific Board at MPA and also involved in guideline work as chair of the Respiratory Drafting Group at the European Medicines Agency.