"Global Regulatory Trends"

at 6th Symposium on

Nasal and Pulmonary Drug Delivery

Hotel Novotel, Juhu, Mumbai, India (24th - 25th October, 2013)

The Indian Pharmaceutical Industry is showing increasing interest in developing orally inhaled and nasal drug products (OINDP) compared to conventional dosage forms as they provide significant benefits to patients, including minimal systemic exposure, faster onset of action, and broader options for disease management. These developments represent significant opportunities for pharmaceutical companies, provided they choose delivery systems that adequately "partner" each drug during its development. Nasal and pulmonary drug delivery systems are used for local and systemic treatment of diseases such as asthma, chronic obstructive pulmonary disease (COPD), rhinitis, migraine and many more. New inhalation products are being developed for non-respiratory disease indications, e.g., diabetes, which would allow patients to avoid more intrusive medical treatments. Drug delivery device used in these products is far more than an instrument for the administration of the formulation. The device is part of the primary packaging, is part of the container closure, and is the vehicle to transport successfully the active medicine to the target. During the dispensing act the responsibility of the effect of the therapy switches to the device. Delivery devices for nasal and pulmonary applications require additional particular attention during development and production as their performance characteristic and reliability has a crucial impact on the efficiency of the nasal or pulmonary delivery to the target site.

Regulatory Challenges

Inhalation science and technology is a rapidly developing field. In the U.S., for many years, industry had no formal FDA guidance for OINDP. This situation started to change in the late 1990s. Between October 1998 and June 1999, the FDA issued three draft Guidances for Industry: (i) Metered Dose Inhaler (MDI) and Dry Powder Inhaler (DPI) Drug Products Chemistry, Manufacturing, and Controls Documentation, (ii) Nasal Spray and Inhalation Solution, Suspension, and Spray Drug Products Chemistry, Manufacturing, and Controls Documentation and (iii) Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action. The industry widely recognized the need for guidance and commended the FDA's effort in preparing the drafts. However, numerous and substantial public comments were filed in response to these drafts. Many of the industry comments contended that certain aspects of the draft Guidances were not scientifically justified.

The regulatory hurdles facing inhaler developers have become more stringent as the global market place has extended the impact of the U.S.A.'s Food and Drug Administration. FDA is probably the strictest of the world's regulatory authorities. OINDPs must now be shown to deliver individual doses reproducibly throughout their shelf-life, in temperatures and humidities that represent commonly experienced environmental conditions. Not only must doses be reproducible, but the particle or droplet size distributions from each device must also be shown to be "stable" over the product's lifetime, and the product proven to be manufactured reproducibly. This must be done to show that the clinical results that are presented to the regulators at the time of product submission are "representative"of the "to be marketed" product.

Well known international experts shall share their knowledge to help the Indian Pharmaceutical Industry understand the Regulatory Challenges for OINDPs.

Introduction of Speakers

Dr. Steven Nichols - Consultant

Steve Nichols is a Consultant to the Pharma Industry for OINDPs and devices and has 27 years of industry experience in inhaled product development. He has a Ph.D in physical chemistry from the University of London. Joining Fisons Pharmaceuticals in 1980 working on developing a range of drug products, including respiratory products, ophthalmic product tablets and sustained release capsules. In 1998 (Rhone-Poulenc Rorer) he was responsible for MDI Analytical Development and Respiratory Physics, then became head of Drug Delivery Research, focusing on the appraisal and the development of new inhalation systems. In 2000, within Aventis, he was appointed manager of Materials Science which focused on API characterisation and selection. In 2001 he took up the role of New Technology Co-ordination Manager, assessing new inhalation delivery technologies and focusing on inward and outward licensing opportunities of inhalation delivery platforms. Finally, at Sanofi-Aventis, he was leading a team working on late phase DPI product development and regulatory strategy. He has been a consultant for 5 years specifically focussed on OIPs with particular emphasis on CMC product development and regulatory strategy aspects

Dr. Tim Noakes - Mexichem Fluor

Tim Noakes gained his Ph.D in Organic Fluorine chemistry in Manchester in 1975. Since then he has worked for ICI, transferring with the sale of the ICI refrigerants business to INEOS in 2000, and then to Mexichem in 2010. Over the years he has worked on atomisation science, electrostatics, and for the last 23 yrs has specialised in HFA MDI propellants. He has become an acknowledged expert on the technical use, handling and regulatory aspects (both in the developed world and in the developing world) of these specialised medical propellants. At present he spends much of his time providing advice to both MDI companies and regulators around the world who are either in the process of converting their existing products from CFCs to HFA, or developing new ones.

Mr. Richard Turner - Presspart

Mr Richard Turner has spent the past over 12 years with Presspart Manufacturing Ltd, part of the Heitkamp and Thumann Group, currently as the Pharmaceutical Business Development Director. He has been instrumental in the company's global growth strategy, combining his commercial experience with his technical skills in maintaining Presspart's market leadership in the supply of MDI canisters and actuators. Prior to joining Presspart, Mr. Turner held positions with Steritech and the AptarGroup in both a commercial and technical capacity. Mr Turner originally trained as an accountant. In 1996, he received his business and science honours degree from the University of Bristol, with additional emphasis in biomedical instrumentation.

Mr. Paul Sullivan - DH Industries Ltd.

Mr. Paul Sullivan is the Managing Director of DH Industries Ltd in the UK, part of the Pamasol organisation. Pamasol are the worlds' leading manufacturer of aerosol filling and test equipment and as part of the group, DH Industries specialise in the design and supply of equipment for the manufacture of Pharmaceutical Aerosols, especially pMDIs. DH provides equipment from Research and Development installations to full scale production and has established DH/Pamasol equipment as the industry standard. Paul has great experience in this subject having worked for DH Industries since 1988 building, installing, commissioning and validating the equipment worldwide. He has spoken at many national and international symposiums and meetings related to aerosol filling and technology as well as ISPE (International Society for Pharmaceutical Engineering) and ECEC (European Continuing Education College) training courses. He is also an active member of BAMA (British Aerosol Manufacturers Association) where he sits on the Operational Safety Committee and prepares and presents training material at their Technical and Safety courses.

Mr. Harry Peters - DFE Pharma

Harry Peters is a technical support specialist in the use of lactose in pharmaceutical applications for more than 10 years. In the last 3 years at DFE Pharma he has further specialized in the dry powder inhalation field, where he started working as R&D manager for inhalation grade lactose. He advices formulators of dry powder inhalers about the use of inhalation grade lactose. Together with customers, special lactose grades are developed to optimize the filling and the performance of the inhalation formulations. Together with Universities and industry new characterization techniques are explored to further understand lactose in dry power formulations.

Dr. Kapileswar Swain - Wockhardt

Kapileswar Swain currently serves a Vice President of Wockhardt Research Centre in the department of Formulation development. Major Area of research includes development and registration of Dry powder Inhalers, Metered Dose Inhalers and Nasal sprays. He has developed more than 50 products in this delivery system which are commercially available in India and outside India as well.

Many patents and publications on this subject matter go to his credit. He also served as Vice president Macleods research centre, responsible for development and registration of various dosage forms like DPIs, MDIS, Nasal sprays, Solid orals, Liquid formulation, Semisolids to the global market. He also served as General Manager at Pharmaceutical technology centre of Zydus Cadila, Group leader at Ranbaxy research centre and senior research fellow at Sun Pharma advanced research centre. Kapileswar has been the recipient of numerous honors and awards including Suresh Khare Indico foundation award scholarship and Best Research Scientist Award at Ranbaxy research center. He has also received the Distinguished Alumni Award from Manipal College of Pharmaceutical Sciences in appreciation of the high distinction achieved by him in the profession and service to the community.

Mr. Mark Copley - Copley Scientific

Mark Copley graduated from the University of Bath, UK in 2000 with a Master's Degree in Aerospace Engineering. For 8 years he was Technical Sales Manager and product specialist for Copley Scientific's range of inhaler testing equipment and is now Sales Director for the company. An invited member of the European Pharmaceutical Aerosol Group (EPAG) impactor sub-team, Mark has also made recommendations to the Inhalanda working group, leading to subsequent revisions to Ph. Eur. and USP monographs.

Dr. Paul Kippax - Malvern Instruments Ltd.

Paul Kippax has a degree in Chemistry and a Ph.D in Physical Chemistry, both obtained at the University of Nottingham in the UK. He joined Malvern Instruments in 1997 as an applications scientist. In 2002 became laser diffraction Product Manager, and has recently become the Product Group Manager responsible for the development strategy for Malvern's laser diffraction and image analysis product ranges. He has worked closely with the pharmaceutical industry to understanding how particle characterisation techniques can be best applied to characterizing the performance of pharmaceutical devices and formulations, and has been involved in the development of new analytical systems specifically for the analysis of inhalation products. As part of this he has published research, in cooperation with others, relating to the operation of dry powder inhalers and nasal sprays.

Mr. Henrik Krarup - Innova Systems

Henrik G Krarup has a Master of Science in Materials Science from University of Florida/USA and a Master of Science in Geology from the Univ. of Aarhus/Denmark. Over the past 15 years he has worked as Director of the Particle Characterization Lab/Pennstate University and as Product Manager for Malvern's US based Laser Diffraction Products. Currently he is Vice President at InnovaSystems Inc. USA. He has authored and co-authored several articles and conference proceedings on the issue of spray characterization.

Mr. Chris Baron - Aptar Pharma, Prescription Division

Chris Baron is currently the Associate Director for Business Development at Aptar Pharma (formally Valois). Chris is based at Aptar Pharma's manufacturing facility in Le Vaudreuil, Normandy, where he oversees the global business development activities for inhalation drug delivery devices pertaining to the application fields of Asthma & COPD. Chris has an Honours degree in Mechanical Engineering and has spent the last 22 years working in the field of Inhalation Drug Delivery (IDD) with specific focus on metering valves for pMDIs and their accessory device technologies, including dose indicators / counters. Chris spent 18 years working for 3M Health Care (Drug Delivery Systems Division - UK), holding various positions and responsibilities within 3M R&D (Valve Development Specialist), Manufacturing (Manufacturing Technology Leader), Six-Sigma (Site Coach), Technical Sales and New Business Development functions. During this period Chris was closely involved in the development, commercialization and sale of IDD componentry (valves, canisters and accessory devices) for several pMDI products.

Mr. Herve Pacaud - Aptar Pharma, Prescription Division

Herve Pacaud has an experience of more than 20 years in drug delivery devices. After joining Valois, now Aptar Pharma, Herve occupied several sales positions in Europe and Asia and is now Director Business Development. In the new Aptar Pharma organisation Herve has the global responsibility for the development of the sales of Aptar Pharma's for Allergic rhinitis, CNS and Vaccine applications. Herve is graduated in Sales and Marketing by the University of Amiens France.

Mr. Tamal Mukherjee - Malvern Instruments Ltd.

Tamal Mukherjee is the technical specialist for Malvern's laser diffraction and imaging range of products which includes Mastersizer range, Spraytec and Morphologi G3, G3-ID. He is responsible for supporting Malvern diffraction and vision product line in India, Bangladesh, Sri Lanka, Nepal and Bhutan through applications, technical, sales/marketing support. Previous to this role he was working as an Applications Specialist and during that tenure has handled Malvern's different product ranges and has hands on knowledge on Malvern Spraytec and Morphologi G3 including participation in technical and scientific publications.

Mr. David Harris - Team Consulting

David joined as principal consultant in 2011 to further strengthen Team's technical and scientific capabilities in drug delivery. He now heads up the Respiratory Drug Delivery sector and enjoys the challenge of balancing commercial and technical activities. He has been working in the field of respiratory drug delivery since 1994, when he began his career in the Respiratory Physics group at Fisons. He is a qualified physicist who specialises in fluid mechanics, aerosol science and their application to inhaler devices. His current interests focus around the characterisation of lung function; and the future of inhaled medicine.

Dr. Amit Misra - CDRI

Amit did his B. Pharm. from the University of Saugor and M. Pharm. in Pharmaceutics from Delhi University's Hamdard College of Pharmacy. He worked at Trends Pharma, Bombay and then at the National Institute of Immunology (NII), New Delhi. Amit's Ph.D was awarded by the Jawaharlal Nehru University, New Delhi, for a thesis on pulsatile transdermal delivery of testosterone. He got a post-doctoral Young Scientist award from the Department of Science & Technology, and worked on transdermal immunization by electroporation at NII. He has been working at the Pharmaceutics Division of the Central Drug Research Institute, CSIR, Lucknow in various capacities since 1998. He has published 43 research articles as first or corresponding author, 6 reviews, and 8 book chapters. His research interests include pulmonary delivery in tuberculosis, nanoparticles targeting infected erythrocytes in malaria, a delivery system for use in Leishmaniasis in an outpatient setting, and non-invasive contraception for men and women.

Dr. Geralllt Williams - Aptar Pharma, Prescription Division

After obtaining his Ph.D from the University of Wales, UK in 1985, he has held various industrial positions at Monsanto Inc. (UK), Fisons Ltd (UK), Valois (France) and Inhale/Nektar Therapeutics (USA). He is now in charge of scientific affairs for the Aptar Pharma Prescription division, Le Vaudreuil, France and is engaged in the development of new devices for nasal and inhaled drug products.

Dr. Julie Suman - Nextbreath LLC.

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 co-organizer of the Management Forum's Nasal Drug Delivery Annual Meeting. Dr. Suman is 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 has served as the Chair of the AAPS Inhalation Technology Focus Group. She is also a licensed Maryland pharmacist. Her research is published in peer-reviewed journals and has been presented during podium sessions at international meetings and the FDA Visiting Professor Lecture Series. 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. Suman received an award from the Greater Baltimore Committee for Entrepreneurial Spirit.

Dr. Susanne Keitel – EDQM

Susanne Keitel is a licensed pharmacist with a Ph.D in pharmaceutical technology. Her work experience includes 10 years in pharmaceutical development in industry. From 1997 to 2005, she held the position of Division Head Pharmaceutical Quality at the Federal Institute for Drugs and Medical Devices (BfArM), Germany. She additionally served as Acting Head of the Division European Procedures from November 2003. From July 2005 to October 2007, Susanne was Head of EU, International Affairs at BfArM. During her time with BfArM, she represented the agency in a number of EU committees and was actively involved in the International Conference on Harmonization (ICH), where she represented the EU as topic leader and rapporteur. On a national level, she was, from 2001 to 2007, Chair of the German Pharmacopoeia and the German Homeopathic Pharmacopoeia. Since October 2007, Susanne is Director of the European Directorate for the Quality of Medicines & HealthCare (EDQM) of the Council of Europe in Strasbourg. Susann Keitel also lectures in the postgraduate course “Master of Drug Regulatory Affairs” at Bonn University, where she is responsible for the module on the quality dossier. In 2009, she was elected as corresponding Foreign Member at the French AcadémieNationale de Pharmacie.

AGENDA : DAY 1 (October 24, 2013)

8.45 am - 9.15 am	**Registration**	
9.15 am - 9.30 am	**Welcome Address**	**Hon. Secretary - IPA**
Time	**Subject**	**Speaker**
9.30 am - 10.15 am	Overview of the Ph. Eur	Dr. Steven Nichols
10.15 am - 10.45 am	Poster session Time for exhibitions	
10.45 am - 11.00 am	**TEA / COFFEE BREAK**	
11.00 am - 11.45 am	Medical Propellants: Regulatory Update and Other News	Dr. Tim Noakes (Mexichem)
11.45 am - 12.30 pm	The HFA Challenge: The Safe, Effective Containment and Delivery of pMDI Respiratory Medicines	Mr. Richard Turner (Presspart)
12.30 pm - 1.15 pm	pMDI Filling and Control Equipment Solutions to Meet the Ever Increasing Demands of the Global Regulatory Authorities	Mr. Paul Sullivan (DH Industries)
1.15 pm - 2.00 pm	**LUNCH BREAK**	
2.00 pm - 2.45pm	Optimizing Lactose to Enhance Formulation Performance of Dry Powder Inhaler	Mr. Harry Peters (DFE Pharma)
2.45 pm - 3.15 pm	QbD Approach in the development of Dry Powder Inhaler	Dr. Kapileswar Swain (Wockhardt)
3.15 pm - 3.30 pm	**TEA / COFFEE BREAK**	
3.30 pm - 4.15 pm	Methodologies for In Vitro Bioequivalence Testing of Generic Inhaled Products in the Emerging Markets	Mr. Mark Copley (Copley Scientific)
4.15 pm - 4.45 pm	Utilizing QbD Analytical Method Development in Nasal Spray Droplet Size Characterization Size, Shape & Raman Microscopy in Nasal Spray Development	Dr. Paul Kippax (Malvern)
4.45 pm - 5.15 pm	Automated Testing of Nasal Sprays and Metered Dose Inhalers and FDA Regulatory Requirements	Mr. Henrik Krarup (Innova Systems)
5.15 pm - 5.45 pm	Panel Discussion Dr. Steven Nichols, Dr. Tim Noakes, Mr. Richard Turner, Mr. Paul Sullivan, Mr. Harry Peters, Dr. Kapileswar Swain, Mr. Mark Copley, Dr. Paul Kippax, Mr. Henrik Krarup	Chairperson
7.00 pm onwards	Gala Dinner for Delegates and Speakers	

AGENDA : DAY 2 (October 25, 2013)

Time	Subject	Speaker
9.00 am - 9.50 am	**Three Parallel Workshops** **Malvern:** Characterizing Oral Inhalation Droplet Size - A Practical Approach **Innova:** Automated Actuators Facilitating Compendial Testing of Nasal Sprays and Metered Dose Inhaler Products **Aptar:** Emerging Trends in Inhalation Drug Delivery Devices: A Respiratory Focus **Aptar:** Systemic Nasal and Buccal Delivery	 Mr. Tamal Mukherjee Mr. Henrik Krarup Mr. Chris Baron Mr. Herve Pacaud
10.00 am - 10.50 am	**Malvern:** Characterizing Oral Inhalation Droplet Size - A Practical Approach **Innova:** Automated Actuators Facilitating Compendial Testing of Nasal Sprays and Metered Dose Inhaler Products **Aptar:** Emerging Trends in Inhalation Drug Delivery Devices: A RespiratoryFocus **Aptar:** Systemic Nasal and Buccal Delivery	Mr. Tamal Mukherjee Mr. Henrik Krarup Mr. Chris Baron Mr. Herve Pacaud
11.00 am - 11.50 am	**Malvern:** Characterizing Oral Inhalation Droplet Size - A Practical Approach **Innova:** Automated Actuators Facilitating Compendial Testing of Nasal Sprays and Metered Dose Inhaler Products **Aptar:** Emerging Trends in Inhalation Drug Delivery Devices: A RespiratoryFocus **Aptar:** Systemic Nasal and Buccal Delivery	Mr. Tamal Mukherjee Mr. Henrik Krarup Mr. Chris Baron Mr. Herve Pacaud
11.50 am - 12.30 pm	Time for Posters & Exhibitions	
12.30 pm - 1.30 pm	**LUNCH BREAK**	
1.30 pm - 2.15 pm	Time for Change: Patient Choice and Improving Compliance	Mr. David Harris (Team Consulting)
2.15 pm - 2.45 pm	Inhaled Therapies for Tuberculosis in the Russian Regulatory Landscape	Dr. Amit Misra (CDRI)
2.45 pm - 3.15 pm	Nasal and Pulmonary Devices - Regulatory Aspects Including Leachable and Extractable Trends	Dr. Geralt Williams (Aptar)
3.15 pm - 3.30 pm	**TEA / COFFEE BREAK**	
3.30 pm - 4.00 pm	Global Bioequivalence Expectations for Orally Inhaled and Nasal Drug Products	Dr. Julie Suman (NextBreath)
4.00 pm - 4.30 pm		Dr. Susanne Keitel (EDQM)
4.30 pm - 5.00 pm	Panel Discussion Mr. Henrik Krarup, Mr. Tamal Mukherjee, Mr. Chris Baron Mr. Herve Pacaud, Mr. David Harris, Dr. Amit Misra, Dr. Geralt Williams, Dr. Julie Suman, Dr. Susanne Keitel	Chairperson

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6th symposium on

Nasal and Pulmonary Drug Delivery

Organized by

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Novotel, Juhu, Mumbai

(24th - 25th October, 2013)

REGISTRATION FORM

Name of the Delegate Dr. / Mr. / Ms. .....

Company / Institute : .....

Designation : .....

Address for Correspondence : .....

.....

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