



Day 1 – Development And Formulation Of Inhaled Therapies

- Combination product design
- Achieving an inhaled insulin product
- Developing a generic inhaled product
- Regulatory considerations for inhaled therapies
- Alternative therapeutic fields: inhaled antibiotics
- Future directions in inhalation and respiratory drug delivery research

Day 2 – Inhalation Devices And Analytics

- Novel technologies for pulmonary and nasal delivery
- The challenge of developing inhalation devices
 - Dry-powder inhalers (DPIs)
 - Metered-dose inhalers (MDIs)
 - Nebulisers
- Improving patient adherence with product design
- Establishing clear relationships between in vitro and in vivo data
- Analytical tools for inhaled medicines

Benefits to Attending

- ✓ **Hear from and meet with the key innovators in inhalation and respiratory drug delivery.** Attendees include: Vice President and Head, Respiratory Drug Delivery, Boehringer Ingelheim; Director, Clinical Pharmacology, GlaxoSmithKline; Global Device Director, AstraZeneca
- ✓ **Discover collaborative solutions to development and formulation of inhaled therapies.** The congress brings together key opinion leaders to discuss future directions in inhalation and respiratory drug delivery research, inhaled antibiotics and achieving inhaled insulin products
- ✓ **Discuss the latest innovations to inhalation devices and analytics.** Case studies include: novel technologies for pulmonary and nasal drug delivery, challenges of developing inhalation devices and analytical tools for inhaled medicines
- ✓ **Unparalleled networking opportunities.** The two-day congress offers dedicated networking breaks creating an interactive platform for scientific discussions and 1–1 meetings. The exhibition hall and poster presentation spaces offer a relaxed and professional environment for discussion
- ✓ **A high quality programme devised with the help of our esteemed advisory board.** Presentations will cover areas including regulatory updates for inhaled therapies, combination product design and improving patient adherence with product design
- ✓ Co-located with the **2nd Annual Formulation & Drug Delivery Congress**

2016 Speakers Include...



Ben Forbes
King's College London



Frank Thielmann
Novartis



Claudia Vincenzi
Mylan Pharma

Meet Senior Decision Makers

150 VPs, Directors & Senior Managers from leading pharmaceutical organisations, biotech companies and academic institutions will attend the event. Delegate job titles include:

Inhaled Drug Delivery
Inhaled Medicines
Drug Delivery Devices

Respiratory Drug Delivery
Respiratory Products
Product Development

Respiratory Pharmacology
Respiratory Therapeutics
Inhalation Devices

Particle Characterisation
Inhaled Dosage Forms
Drug Delivery Technology

Discover New Solutions

Formal and informal meeting opportunities offer delegates the chance to discuss key solutions with leading service providers. Services to be discussed include:

Particle Engineering
Particle Size Testing
Inhaler Components

Metered-Dose Inhalers
Respiratory Imaging
Nebulisers

Dry-Powder Inhalers
Inhaler Testing
Respiratory Drug Delivery

Dose Counters
Analytical Services
Formulation Development

For booking details & registration fees please refer to the last page or visit:

<http://www.drugdelivery-congress.com/marketing>

2016 Inhalation & Respiratory Drug Delivery Congress Confirmed Speakers:

- Peter Daley-Yates, Director, Clinical Pharmacology, GlaxoSmithKline
- Louise Sheridan, Global Device Director, AstraZeneca
- Frank Thielmann, Operational Lead, Inhalation New Solids, Novartis
- Andy West, Head Ex vivo Bioimaging UK, GlaxoSmithKline
- Holger Memmesheimer, Head of Quality Unit Chemical Production, Boehringer Ingelheim
- Jan Olof Svensson, Principal Scientist Inhalation, AstraZeneca
- Mike Tobyn, Research Fellow, Bristol-Myers Squibb
- Yuji Kasuya, Senior Scientist, Daiichi Sankyo
- John Patton, CEO and Chairman, Dance Pharmaceuticals
- Claudia Vincenzi, Director, Respiratory Regulatory CMC, Mylan Pharma
- Beverley Patterson, Inhalation Clinical Associate Director, Actavis
- Robert Price, Professor of Pharmaceutics, University of Bath
- Ben Forbes, Professor of Pharmaceutics, King's College London
- Janis Shute, Professor of Respiratory Pharmacology, University of Portsmouth and Scientific Director, Ockham Biotech
- Joy Conway, Professor of Respiratory Sciences and Lung Imaging, Southampton University
- Jonathan Reid, Professor of Physical Chemistry, University of Bristol
- Thys van der Molen, Professor of Primary Care Respiratory Medicine, University of Groningen
- Per Gerde, Associate Professor, Inhalation Toxicology, Karolinska Institutet

2016 Co-located Formulation & Drug Delivery Congress Confirmed Speakers:

- Menashe Levy, Vice President and Chief Technology Officer, Global R&D, Teva
- Matthew James Clemente, Chief Technology Officer, Connected Product Systems Engineering, Eli Lilly and Company
- Joel Richard, Senior Vice President, Peptides – Head of CMCS Dreux Site, Ipsen
- Justin M Wright, Vice President, Drug Delivery Innovation, DDR&D Technology, Eli Lilly and Company
- Anand Subramony, Vice President, Drug Delivery & Device Development, MedImmune
- Allen C. Templeton, Associate Vice President, Formulation Sciences, Merck & Co. (MSD)
- René Holm, Senior Director, Pharmaceutical Science, H. Lundbeck A/S
- Advait Badkar, Senior Director - Novel Delivery Technologies, Pfizer Inc
- Boris Shekunov, Director and Senior Principal Scientist, Shire
- Vijay Naringrekar, Director, Pharmaceutical Development, Biologics, Celgene
- Anthony Leone, Director, Preformulation, Merck & Co. (MSD)
- Ahmad Sheikh, Director, Solid State Chemistry, AbbVie
- Carol Thomson, Dose Form Quality Director, GlaxoSmithKline
- Nausheen Rahman, Director, Bioprocess Research and Development, Sanofi Pasteur
- Andy Lewis, Director, Novel Drug Delivery Technologies, Ipsen
- Marian Gindy, Director, Sterile Products Development, Merck & Co. (MSD)
- Christoph Saal, Director, Bioanalytical Chemistry, Merck
- David Elder, Director, Product Development, GlaxoSmithKline
- Patrick Garidel, Associate Director, Protein Science, Boehringer Ingelheim
- Brian Lobo, Associate Director and Group Leader, MedImmune
- Cédric Yernaux, Head, Drug Product Belgium, GlaxoSmithKline
- Herbert Wachtel, Senior Principal Scientist, Boehringer Ingelheim
- Karsten Petersson, Principal Scientist and Project Lead, LEO Pharma
- Carsten Worsøe, Principal Scientist, Novo Nordisk
- Martinus Capelle, Principal Scientist and Scientific Lead, Janssen
- Robert Kelley, Principal Scientist, Genentech
- Vijay Sethuraman, Fellow, Novartis
- Frank Bamberg, Senior Group Leader Pre-Fillable Syringe Engineering, F. Hoffmann-La Roche AG
- Clare Rawlinson-Malone, Senior Research Investigator, Bristol-Myers Squibb
- Stephen Buckley, Team Leader, Novo Nordisk
- Michael Keller, Project Leader, Biologics Technical & Manufacturing Development, Novartis
- Avinash Nangia, Vice President, R&D, Lupin Pharmaceuticals, Inc.
- Ijeoma Uchegbu, Professor in Pharmaceutical Nanoscience, University College London
- Kamalinder Singh, Professor of Pharmaceutical Technology and Drug Delivery, University of Central Lancashire
- David Needham, Niels Bohr Visiting Professor, University of Southern Denmark; and Professor, Duke University, USA



If you're on Twitter, make sure to follow us [@FDDCongress](https://twitter.com/FDDCongress) and join the Congress conversation on [#FDDC16](https://twitter.com/FDDC16)

For more information please contact marketing@oxfordglobal.co.uk

Inhalation & Respiratory Drug Delivery & Formulation & Drug Delivery Confirmed Sponsors 2016:



Inhalation & Respiratory Drug Delivery Congress
Day One – 18th May 2016

07.30 – 08.20	Registration
08.20 – 08.25	Oxford Global's Welcome Address
08.25 – 08.30	Chairperson's Opening Address
08.30 – 09.00	<p>Co-located Keynote Address: Developing Drug Delivery Devices For Large Molecules</p> <p>Matthew James Clemente, Chief Technology Officer, Connected Product Systems Engineering, Eli Lilly and Company</p>
	Development And Formulation Of Inhaled Therapies
09.00 – 09.30	<p>Stream Keynote Address: Inhaled Corticosteroids: Discovery, Development And Therapeutic Use</p> <ul style="list-style-type: none"> • Discovery and historical perspective • The quest to improve the efficacy and safety profile • New thinking on dose equivalence and therapeutic index <p>Peter Daley-Yates, Director, Clinical Pharmacology, GlaxoSmithKline</p>
09.30 – 10.00	<p>Solution Provider Presentation</p> <p>For sponsorship opportunities please contact sponsorship@oxfordglobal.co.uk</p>
10.00 – 11.20	Morning Coffee & Refreshments: Poster Presentation Sessions: One to One Meetings x3
11.20 – 11.50	<p>Dry Powders – Challenges On The Journey From Development To Manufacturing</p> <ul style="list-style-type: none"> • Obstacles and challenges during development and manufacturing of DPI formulations • Key properties affecting the performance and process-ability of dry powders • Manufacturing processes and selection of the right equipment and parameters <p>Frank Thielmann, Operational Lead, Inhalation New Solids, Novartis</p>
11.50 – 12.20	<p>Inhaled Insulin: History, Benefits, Risks, Status And Promise</p> <ul style="list-style-type: none"> • History of Exubera and early efforts • Afrezza: the only approved product • Development of Dance 501 <p>John Patton, CEO and Chairman, Dance Pharmaceuticals</p>
12.20 – 12.50	<p>Solution Provider Presentation</p> <p>For sponsorship opportunities please contact sponsorship@oxfordglobal.co.uk</p>
12.50 – 13.50	Lunch

**Inhalation & Respiratory Drug Delivery Congress
Day One – 18th May 2016**

13.50 – 14.20	<p>Comparison Of EU And US CMC Regulatory Requirements For Inhalation Products</p> <ul style="list-style-type: none"> • Comparison between the FDA and EMA CMC guidance documents: key similarities and differences • Filing in USA and EU: <ul style="list-style-type: none"> ○ Different CMC requirements ○ Additional considerations for generic products • Examples on on-going developments in CMC for inhaled products <p>Claudia Vincenzi, Director, Respiratory Regulatory CMC, Mylan Pharma</p>
14.20 – 14.50	<p>Role Of Pharmacokinetics And Pharmacodynamics In The Development And Registration Of Orally Inhaled Products</p> <p>Beverley Patterson, Inhalation Clinical Associate Director, Actavis</p>
14.50 – 15.20	<p>Solution Provider Presentation</p> <p>For sponsorship opportunities please contact sponsorship@oxfordglobal.co.uk</p>
15.20 – 16.20	<p>Afternoon Refreshments: Poster Presentation Sessions: One to One Meetings x2</p>
16.20 – 16.50	<p>Modulating The Pharmacokinetics Of Inhaled Drugs</p> <ul style="list-style-type: none"> • Current approaches in industry and academia • Scientific developments underpinning PK modification strategies • Product development challenges <p>Ben Forbes, Professor of Pharmaceutics, King's College London</p>
16.50 – 17.20	<p>Novel Strategies To Improve Inhaled Drug Delivery In Lung Inflammation Patients With Cystic Fibrosis</p> <p>Janis Shute, Professor of Respiratory Pharmacology, University of Portsmouth and Scientific Director, Ockham Biotech</p>
17.20 – 17.50	<p>Inhaled Heparin And The Formulation Of Active Agents For Inhalation</p> <p>Joy Conway, Professor of Respiratory Sciences and Lung Imaging, Southampton University</p>
17.50 – 18.20	<p>Patient Related Factors To Inhalation Therapy In Real Life</p> <ul style="list-style-type: none"> • How do patients inhale their drugs what is the influence on asthma control: Results of the IHARP inhalation technique study with 5000 patients • How can we teach patients a better inhalation technique: preliminary results of a qualitative study regarding appreciation of how patients were taught to inhale <p>Thys van der Molen, Professor of Primary Care Respiratory Medicine, University of Groningen</p>
18.20 – 18.50	<p>Developing Generic Products – Regulatory And Scientific Aspects</p> <p>Robert Price, Professor of Pharmaceutics, University of Bath</p>
18.50	<p>Networking Drinks End of Day One</p>

**Inhalation & Respiratory Drug Delivery Congress
Day Two – 19th May 2016**

	<p>Conference Room: Stream Chair:</p>
08.30 – 09.00	<p>Keynote Address: Analytical Techniques To Determine Key Performance Parameters Of Inhalation Products – Challenges And Perspectives</p> <ul style="list-style-type: none"> • Overview on inhalation products, guidelines and testing parameters • Aerodynamic performance characteristics – Requirements and Challenges during development, transfer and routine testing • New trends and perspectives <p>Holger Memmesheimer, Head of Quality Unit Chemical Production, Boehringer Ingelheim</p>
	<p>Inhalation Devices & Analytics</p>
09.00 – 09.30	<p>Stream Keynote Address: Challenges Of Implementing New Regulations For Legacy Products, Including Challenges In Management Of Complaints And Introducing Enhanced Processes For Post Market Surveillance</p> <p>Louise Sheridan, Global Device Director, AstraZeneca</p>

Inhalation & Respiratory Drug Delivery Congress
Day Two – 19th May 2016

09.30 – 10.00	Solution Provider Presentation For sponsorship opportunities please contact sponsorship@oxfordglobal.co.uk
10.00 – 11.00	Morning Coffee & Refreshments: Poster Presentation Sessions: One to One Meetings x2
11.00 – 11.30	Imaging The Distribution Of Unlabelled Drugs In The Lung Using Mass Spectrometry – From Tissues To Cells <p>Understanding the distribution of a dosed drug within the body is a key part of the drug development process, both in terms of drug efficacy (does the drug reach the target area and at sufficient concentration to have a pharmacological effect?) and potential side effects (where else does the drug go and what does it do there?). Mass spectrometry imaging (MSI) provides a powerful route for label-free observation of the spatial distribution (including depth) of key chemical entities in tissue.</p> <ul style="list-style-type: none"> • This talk will discuss our work using mass spectrometry to image the distribution of unlabelled dosed molecules in lung • Examples will include the use of Matrix Assisted Laser Desorption Ionisation (MALDI) MSI to image the tissue distribution of unlabelled small molecules and to study the distribution of a domain antibody following inhaled administration in the lung • Data will also been shown from our recent work investigating the use Secondary Ion Mass Spectrometry (SIMS) to image the 3 dimensional spatial distribution of unlabelled drugs at cellular resolutions in rat alveolar macrophages <p>Andy West, Head Ex vivo Bioimaging UK, GlaxoSmithKline</p>
11.30 – 12.00	Solution Provider Presentation For sponsorship opportunities please contact sponsorship@oxfordglobal.co.uk
12.00 – 12.30	Analytical Tools For Inhaled Medicines <ul style="list-style-type: none"> • Performance characterisation • Different types of delivery systems – different challenges • Patient relevant testing <p>Jan Olof Svensson, Principal Scientist Inhalation, AstraZeneca</p>
12.30 – 13.30	Lunch
13.30 – 14.00	Capturing And Understanding Excipient Variability In Dry Powder Inhalers <ul style="list-style-type: none"> • Methods for measuring variability of excipients • Implications for robust design of DPI products <p>Mike Tobyn, Research Fellow, Bristol-Myers Squibb</p>
14.00 – 14.30	Strategic Consideration For Application Of Inhalation Drug Delivery Technology In The Process Of Pharmaceutical Development <ul style="list-style-type: none"> • Choosing the right NCE candidate with reduced lead optimisation • Creating R&D projects with advanced inhalation technology • The possibility to switch the inhaler in the process of clinical development <p>Yuji Kasuya, Senior Scientist, Daiichi Sankyo</p>
14.30 – 15.00	A Novel Method To Aerosolize Powder For Short Inhalation Exposures At High Concentrations Per Gerde, Associate Professor, Inhalation Toxicology, Karolinska Institutet
15.00 – 15.30	Afternoon Refreshments: Poster Presentation Sessions
15.30 – 16.00	Aerosol Dynamics During Inhalation: Hygroscopic Growth, Coagulation And Deposition <ul style="list-style-type: none"> • Aerosol particle size and composition is extremely dynamic, changing on sub-second timescales due to hygroscopic growth during inhalation into the highly humid environment of the lungs • Control of hygroscopic growth facilitates control over evolving aerosol size distribution and properties (e.g. hydrophobicity, particle viscosity), with the potential to influence deposition patterns and the microphysical properties of the aerosol on deposition • We will describe new experimental tools that can provide unparalleled insights into the dynamics of aerosols during inhalation <p>Jonathan Reid, Professor, University of Bristol</p>
16.00	End of Conference

Inhalation & Respiratory Drug Delivery Congress
Conference: 18-19 May 2016, Kensington Close Hotel, London, UK

HOW TO REGISTER:
FAX your booking form to +44(0)1865 250985 | PHONE on +44(0)1865 248455 | EMAIL: marketing@oxfordglobal.co.uk

Delegate Details

Please complete fully and clearly. Please photocopy for additional delegates

Title: _____ Forename: _____ Surname: _____

Job Title: _____

Company/Organisation: _____

Email: _____

Address: _____

Postcode: _____

Country: _____

Direct Telephone _____ Direct Fax: _____

Mobile: _____ Switchboard: _____

Signature: _____

Date: _____

Registration Fees

I would like to attend: (Please tick as appropriate)

Industry Delegates (Biopharma, Pharma or Biotech Companies)

- Congress £799 plus VAT
 1 day pass £400 plus VAT
 Day 1
 Day 2

Academic Delegates

- Congress £499 plus VAT
 1 day pass £250 plus VAT
 Day 1
 Day 2

Vendor Delegates

(CROs, Consultants, Technology and Service Providers)

- Congress Only £1350 plus VAT
 1 day pass £799 plus VAT
 Day 1
 Day 2

- Poster Presentation £250 plus VAT

PROMOTIONAL LITERATURE DISTRIBUTION

- Distribution of your company's promotional literature to all conference attendees £999 plus VAT

Terms & Conditions of Booking

Agreed Terms between the Organiser (Oxford Global Marketing Ltd) and the Delegate:

Delegate Booking Fee

The Delegate Booking Fee includes: lunches and refreshments throughout the Congress event, conference presentations, workshop and panel sessions, scheduled one-to-one meetings and networking/social events, conference and speaker notes. Delegates may attend, free of charge, all sessions arranged by the Organiser. An admin surcharge of £50 + VAT will be applied to payments settled following the receipt of an invoice. This charge will not be applied to payments settled online.

Vendor Delegates will not be eligible for one to one meetings unless they purchase a sponsorship meetings package. These can only be purchased directly from Oxford Global Marketing Ltd and not via the online booking facility.

Poster Presentations

Those who have booked a poster presentation at the event must provide the poster title, abstract (200 words or less), principal author, organisation, mailing address, email, telephone, fax and additional authors, within a month of registration. All poster spaces will be for A0 (841mm x 1189mm) portrait size.

Cancellation and Curtailment

Delegates and vendor delegates are subject to the following charges and refunds upon withdrawal or cancellation.

More than 6 months prior 35% cancellation fee / 65% refund
Between 6 and 3 months prior 75% cancellation fee/ 25% refund
Less than 3 months prior to the event Full cancellation fee / No refund

Data Protection

The data controller is the Organiser. The Organiser may disclose such personal information to Registered Event Sellers (Solution Providers) and other Delegates but solely for the purposes of the Event. The Delegate consents to the use of his/her personal and company information on the terms set out herein.

Miscellaneous

This Agreement may not be transferred or assigned by either the Delegate or the Delegate's Company. The Organiser will determine the scope and content of Congress conference events, seminars, workshops and activities throughout the Event. The Organiser reserves the right to cancel the Event without liability to Delegate's Company or individual Delegate. If for any reason the Organiser has to cancel or postpone this Event, the Organiser reserves the right to transfer this Booking to another Congress within the same sector to be held within twelve months. Should another Congress in the same sector not be available within this period, the Booking Fee will be refunded.

I agree to the above Terms and Conditions

Documentation

I cannot attend but would like to purchase access to the following:

- Access to the online conference presentations £499 plus VAT
 Conference presentations - paper copy £499 plus VAT

VAT is charged at 20% on the attendance fees for all delegates. VAT is also charged on online and paper copy documentation and promotional literature distribution for all UK customers and for those EU customers not supplying a registration number for their own country here.

How to Pay (choose one of the following payment options)

Number of delegates:

Industry del(s) Academic del(s) Vendor del(s)

Special Offer: 3 for 2

Offer is only valid on the congress and for those registering at Industry or Academic rates

CREDIT CARD: Visa MasterCard Maestro Amex

Credit Card Number:

Valid from: /

Expiry Date: /

Security code:

Cardholders name: _____

Signature: _____ Date: _____

PLEASE INVOICE ME:

Invoice Address (if different from above) _____

*Please note there is a £50 plus VAT handling charge for payment via invoice
*All card payments will be subject to a 3% bank charge or 4% AMEX charge



If you have any further queries please call the marketing team on +44(0)1865 248455 or email marketing@oxfordglobal.co.uk