



PORTABLE INHALERS

20 & 21 November 2012 - N11-8312

BIOEQUIVALENCE FOR INHALED PRODUCTS

19 November 2012 - N11-8212

Application to Register

20 & 21 November 2012, Conf. No. N11-8312
19 November 2012, Conf No. N11-8212

Registration Information

Please PRINT your details:

Title First Name.....
(Dr, Mr, Mrs, etc)
Family name
Position
Department.....
Company
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Country.....
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Secretary's Name
Signature

Substitutions may be made at any time at no extra charge

Payment by either: VISA MASTERCARD AMEX

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AMEX:

Cheque enclosed payable to Management Forum Limited

Bank transfer on receipt of invoice

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Management Forum Ltd, 98-100
Maybury Road, Woking, Surrey GU21 5JL, UK
www.management-forum.co.uk
E-mail: registrations@management-forum.co.uk

To Register

If you have NOT received confirmation seven days after registering, please contact Registration Department.

If you do not want to receive future mailings from Management Forum please contact nick@management-forum.co.uk
If you do not wish to receive selected third party mailings please contact nick@management-forum.co.uk

Exhibition spaces and promotional opportunities will be available at this meeting.
For further information please contact Vicki Elliot
(email: vicki@management-forum.co.uk)

MANAGEMENT FORUM LTD, 98-100 Maybury Road, Woking, Surrey GU21 5JL, UK
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PORTABLE INHALERS 2012

Dates 20 & 21 November 2012:
Times 20 November 2012: Start 09.30 – Finish 17.45
Conference Dinner Start 19.30
21 November 2012: Start 09.00 – Finish 15.45

BIOEQUIVALENCE FOR INHALED PRODUCTS Registration & Coffee

Conference: 19 November 2012: Start 09.30 – Finish 16.30

Venue and Accommodation

The Rembrandt Hotel, 11 Thurloe Place,
London SW7 2RS
Hotel Tel: +44(0)20 7589 8100.
Hotel Fax: +44(0)20 7225 3476.
Email: reservations_rembrandt@sarova.co.uk

Subject to availability, a limited number of bedrooms have been reserved at the hotel at a special rate.

All bookings should be made directly with the hotel or online at www.sarova.com/rembrandt, quoting promo code 'manforum'.

Directions

Opposite V&A Museum. Nearest Underground station: South Kensington. Map available on Website under Hotels and Venues.

Conference Fees:

Please tick

Portable Inhalers – N11-8312 = £1,399 + VAT if applicable (including drinks & dinner)

Bioequivalence for Inhaled Products – N11-8212 = £599 + VAT if applicable

Both Events N11-8312 & N11-8212 = £1,699 + VAT if applicable

Discounted Rates

Available on application for personnel from non-profit making organisations and registered charities.
Group discount available on request

Cancellation Policy:

Over 14 days prior to the Seminar: Cancellation fee of £75. 7/14 days prior to the Seminar: 50% of the fee. Fewer than 7 days or if no notification received: Registrant liable to pay FULL seminar fee.

NB: Cancellations must be received in writing by registrations@management-forum.co.uk

In the event of circumstances beyond its control, Management Forum reserves the right to cancel/alter the programme, the speakers, the date or the venue.

International Conference

PORTABLE INHALERS

Hear the latest therapeutic advances and device developments in the respiratory world

EXHIBITORS TO INCLUDE



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Benefits in Attending:

- Don't miss the shared experience from key industry experts
- Gain an overview of recent developments in the Portable Inhaler Market
- Hear the results of a pioneering clinical trial in asthma
- Discover where industry should be focusing on research in drugs and dosage forms
- Consider whether MDIs can be formulated to meet cotemporary bioequivalence guidelines
- Explore how to breath design into the medical device sector
- Hear case studies on new technology
- Review inhalers in emerging markets
- Understand the relevance of clinical outcomes with lung modelling and deposition
- Consider the clinical need for breath actuated inhalers
- Discover the benefit of the Asthma Triple A Test
- Understand the CMC guidelines for gaining regulatory approval in for inhaled generic products

Key panel of speakers to include:

- Professor Ratko Djukanovic, Director – Southampton NIHR Respiratory Biomedical Research Unit, UK
- Dr Salman Siddiqui, Senior Lecturer/ Honorary Respiratory Consultant, University of Leicester, Department of Infection, Immunity and Inflammation, Glenfield Hospital, UK
- Dr Ben Forbes, Head of the Drug Delivery Research Group of the Pharmaceutical Section, Kings College, London
- Gerallt Williams, Director Scientific Affairs, Aptar pharma, France
- Dr Herbert Watchel, Respiratory Drug Delivery, Boehringer Ingelheim, Germany
- David Turner, Creative Director, Scruffy Dog Design, UK
- Dr Ray Bacon, Director, Trig1 Ltd, UK
- Beverley Bostock-Cox, Clinical Lead for Asthma, Education for Health, UK
- Dr Steve Turner, Senior Clinical Lecturer in Child Health and Honorary Consultant Paediatrician, University of Aberdeen
- Melanie Conteh, Pharmaceutical Assessor, MHRA, UK

Co-Chairmen:

Dr Steve Nichols, OINDP Specialist Consultant, UK

Dr Ian Smith, Director H12 Consulting, UK

Gain in-depth knowledge by attending the pre-conference seminar:
BIOEQUIVALENCE FOR INHALED PRODUCTS - 19 NOVEMBER 2012
The Rembrandt Hotel, London

20 & 21 November 2012
The Rembrandt Hotel, London



PROGRAMME

Day One - 20 November 2012

- 09.30 ▶ **Chairman's Welcome and Introduction**
Dr Steve Nichols, OINDP Specialist Consultant, UK
- 09.40 ▶ **Overview of Recent Developments in the Portable Inhaler Market**
- New devices & technologies
 - Disease & new drugs
 - Patient matters
 - Market forecasts and statistics
- Dr Steve Nichols, OINDP Specialist Consultant, UK*
- 10.20 ▶ **Advances in Asthma/COPD: Where Should Industry be Focusing its Research in Drugs and Dosage Forms**
Speaker Invited
- 11.00 ▶ **Discussion**
- 11.10 ▶ **Coffee**
- FORMULATION SESSION**
- 11.30 ▶ **Determining Bioequivalence for Solution Pressurised Metered Dose Inhalers (pMDIs)**
Dr Ben Forbes, Head of the Pharmaceutics Teaching Section and the Drug Delivery Research Group of the Pharmaceutical Science Division, Kings College London, UK
- 12.10 ▶ **Advances in Formulation and Novel Approaches**
Speaker Invited
- 12.50 ▶ **Discussion**
- 13.00 ▶ **Lunch**
- DELIVERY SYSTEMS SESSION**
- 14.10 ▶ **Breathing Design Into the Medical Sector- A Truce Between Form and Function**
- Modernising common medical devices
 - Form or function
 - Sustainability
 - Enhancing design properties
 - Designing for a new generation
 - The concept, design, development and the future
- David Turner, Creative Director, Scruffy Dog Design, UK*
- 14.50 ▶ **Breath Actuated Inhalers (BAIs)**
- The pros and cons of BAIs
 - Clinical studies supporting BAIs
 - Why pMDIs are not converted to BAIs
 - Application in Children
- Dr Steve Turner, Senior Clinical Lecturer in Child Health and Honorary Consultant Paediatrician, University of Aberdeen*
- 15.30 ▶ **Discussion**
- 15.40 ▶ **Tea**
- 16.10 ▶ **Running on Empty - Affordable Dose Content Indicator for pMDI's**
- What patients want from a dose indicator (DCI)
 - What is really important to the patient
 - What does it feel like not knowing if you are about to run out of medication
 - Regulatory requirements and the real world problems for DCIs
 - Trig 1's approach to the problems
 - Current solution as an affordable DCI
- Dr Ray Bacon, Trig1 Ltd, UK*
- 16.50 ▶ **Review of Devices/Inhalers for Emerging Markets**
- Review of markets including China, India & Latin America
 - Current device preferences and future opportunities
- Gerallt Williams, Director Scientific Affairs, Aptar pharma, France*
- 17.30 ▶ **Discussion**
- 17.45 ▶ **End of Day One**
- 19.30 ▶ **Drinks Reception Followed by Dinner in the Hotel**

Programme

Day Two - 21 November 2012

- 09.15 ▶ **Review of Day One**
Dr Ian Smith, Director H12 Consulting, UK
- PATIENT BENEFITS SESSION**
- 09.30 ▶ **Investigating the Potential for SNG001 to Protect Asthmatics from Respiratory Virus Infections**
- Promising breakthrough for the future treatment of Asthma
 - Phase II clinical trial – positive data
 - Evidence of an anti-viral drug that can boost the asthmatic patient's immune system to fight viruses
- Professor Rako Djukanovic, Director- Southampton NIHR Respiratory Biomedical Research Unit, UK*
- 10.10 ▶ **Studying Compliance – Call on Electronic Monitoring of Respimat in Children**
- Benefits of inhaler proficiency and adherence
 - Electronic measurement principles
 - Possible technical realizations
 - Electronics tell how children inhale
- Dr Herbert Watchel, Respiratory Drug Delivery, Boehringer Ingelheim, Germany*
- 10.50 ▶ **Discussion**
- 11.00 ▶ **Coffee**
- 11.30 ▶ **Lung Modelling and Deposition**
- Relevance to clinical outcomes
 - Patient benefits
 - Examples
- Dr Salman Siddiqui, Senior Lecturer / Honorary Respiratory Consultant, University of Leicester, Department of Infection, Immunity and Inflammation, Glenfield Hospital, UK*
- 12.10 ▶ **'Straight As' for Asthma – Optimising Care in the Clinic**
- An explanation of the background to the triple A test
 - Examples of how the test can be used in practice
 - Examination of the use of the triple A test to identify poor control
 - Discussion on the advantages and disadvantages of the test
- Beverley Bostock-Cox, Clinical Lead for Asthma, Cardio-Respiratory Assessment and Diagnosis, CVD Risk and Smoking Cessation, Education for Health, UK*
- 12.50 ▶ **Discussion**
- 13.00 ▶ **Lunch**
- REGULATORY SESSION**
- 14.10 ▶ **FDA Contemporary Challenges and Issues for Inhaled Products**
- Comparative effectiveness
 - Combination products
 - Latest guidance
- Speaker Invited*
- 14.50 ▶ **CMC Guidelines for Gaining Regulatory Approval for Inhaled Generic Products via the In-Vitro Equivalence Route.**
Melanie Conteh, Pharmaceutical Assessor MHRA, UK
- 15.30 ▶ **Discussion**
- 15.40 ▶ **Chairman's Concluding Remarks**
- 16.45 ▶ **Close of Conference and Tea**

Programme

PRE-CONFERENCE SEMINAR

BIOEQUIVALENCE FOR INHALED PRODUCTS 19 November 2012

With:
Dr Steve Nichols,
OINPD Specialist Consultant
Dr John Warren,
Consultant, (formerly with the MHRA)
Dr Jag Shur,
Director, Nanopharm Ltd
Martin Oliver,
Director Branded Generics, Vectura

PROGRAMME

- 09.30 ▶ **Chairman's Welcome and Introduction**
- 10.00 ▶ **Bioequivalence – Use of OIP Guidelines**
- Application of the EMEA BE OIP guideline to generic products
- 11.00 ▶ **Discussion**
- 11.10 ▶ **Coffee**
- 11.30 ▶ **Regulatory Review of Generic Approvals**
- Case studies: Review and assessment of the judgement for approval of Advair (Elpen) and Salmeterol pMDI (Cipla)
 - Comparison to guideline requirements and reasons for Agencies comments in the judgements
- 12.30 ▶ **Discussion**
- 12.45 ▶ **Lunch**
- 13.45 ▶ **Device Characteristics**
- Effect of in-vitro device characteristics
 - Recent device in-vitro resistance measurements and appraisal of device characteristics that could cause in vitro in-equivalence
- 14.45 ▶ **Discussion**
- 15.00 ▶ **Tea**
- 15.20 ▶ **Developing Inhaled Generic Products for the US Market:**
- Description and contrast the 505(b)(2) and ANDA routes for generics
 - The development and commercial considerations
 - Case study: pMDI
- 16.20 ▶ **Panel Discussion**
- 16.30 ▶ **Concluding Remarks and Close**