DIA European Regulatory Affairs Forum 2010

Event #10106
1-2 June 2010
Hilton London Canary Wharf Hotel, London, UK

Programme Committee

- **Gesine Bejeuhr**
  Regulatory Affairs/Quality, vfa-Researched-Based Pharmaceutical Companies, Germany
- **Anthony Humphreys**
  Head of Regulatory, Procedural and Committee Support, European Medicines Agency, EU
- **Brenton James**
  Strategic Consultant, Strategic Regulatory Affairs in the European Union, UK
- **Henrik Kim Nielsen**
  Corporate Vice President, Novo Nordisk A/S, Denmark

SwAPP and SGPM Credits

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Societyfor Pharmaceutical Medicine (SGPM) have accredited the European Regulatory Affairs Forum with 11 credits.

About the Drug Information Association

DIA serves more than 30,000 biopharmaceutical professionals from industry, academia and regulatory agencies worldwide. Through its domestic and international meetings, training courses, workshops and webinars, DIA provides a neutral global forum for the exchange of information critical to the advancement of the drug discovery and lifecycle management processes.

Headquartered in Horsham, PA, USA, and with offices in Basel, Switzerland, Tokyo, Japan, Mumbai, India, and Beijing, China, the Association is led by its volunteer-based Board of Directors and executive management team.

For more information, visit www.diahome.org or call DIA in Europe +41 61 225 51 51.

Programme Overview

This interactive meeting offers an exceptional opportunity for professionals working in industry, national competent authorities, health ministries, academia, CROs as well as for consultants and interested patient organisation delegates to interact with key speakers from regulatory agencies and industry. The meeting is of particular interest for professionals working in regulatory affairs, clinical research and project management, as well as people involved in labelling, scientific advice and pharmacovigilance. Real-life examples and interesting case studies will be presented, operational topics will be explored and you will hear about:

- New Variation Regulation – Six Months Experience
- SmPC and Labelling
- A New Era in Pharmacovigilance
- Centralised Procedure / CHMP / European Medicines Agency
- Optimal Use of EU Scientific Advice Procedures – Case Stories and Orphan Drug Case Stories
- Clinical Trials Directive - Heads of Medicines Agencies
- Globalisation of Regulatory Affairs, Rules and Authorities

Who Should Attend

- Industry and Health Authority Professionals working in
  - Regulatory Affairs
  - Clinical Research
  - Project Management
- Professionals involved in
  - Labelling
  - Scientific Advice
  - Pharmacovigilance

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TUESDAY | 1 JUNE 2010

09:30 Registration

10:30 Session 1

NEW VARIATIONS REGULATION - SIX MONTHS EXPERIENCE

Session Co-Chairs:
Peter Bachmann
European Drug and International Affairs, BfArM, Germany
Gesine Bejeuhr
Regulatory Affairs/Quality, Vfa-Researched-Based Pharmaceutical Companies, Germany

The New Rules – EMA Experience
Sonia Ribeiro, Scientific Administrator
European Medicines Agency, EU

The New Rules – NCA Experience
Peter Bachmann, European Drug and International Affairs, BfArM, Germany

Practical Implications, Opportunities and Challenges – Industry Experience
Katie Harrison, EU Regulatory Intelligence Manager, Baxter Healthcare Ltd., UK

12:15 Lunch

13:30 Session 2

SmPC AND LABELLING

Session Co-Chairs:
Trine B. Moulvad
Director, RA Marketed Products, Novo Nordisk A/S, Denmark
Alexios M. Skarlatos
Head of Product Information Quality, Medical Information Sector, European Medicines Agency, EU

PIM & QRD
Monica Buch Garcia, Medical Information Sector, European Medicines Agency, EU

Revised SPC Guideline
Patrick Salmon, Senior Medical Officer, Irish Medicines Board, Ireland

User Testing & New QRD Template
Blanca Garcia-Ochoa Martin, Spanish Medicines Agency, AEMPS, Spain

A Vision for a New Concept for the Future SmPC/Info to Health Care Professional and Patient Leaflet
Lisette Vromans, Pharmaceutical Regulations Advisor, Schering-Plough, The Netherlands

15:00 Coffee break

15:30 Session 3

A NEW ERA IN PHARMACOVIGILANCE

Session Co-Chairs:
Angelika Joos
Director, Regulatory Policy, Europe
Merck Sharp & Dohme Inc., Belgium
June Raine
Director, Division of Vigilance Risk Management of Medicines, MHRA and Chair of Pharmacovigilance Working Party, UK

Revision of the Pharmacovigilance Legislation Status of the Political Debate and Views from the Council Working Party
Spanish Medicines Agency speaker invited

Increasing Patient Involvement in Medicines Safety
David Haerry, EATG Representative, European AIDS Treatment Group, Belgium

Building Capacity: Improving Methods
Peter Arlett, Head of Pharmacovigilance and Risk Management, European Medicines Agency, EU

17:00 – 18:00 Drinks Reception

WEDNESDAY | 2 JUNE 2010

08:30 Session 4

CENTRALISED PROCEDURE / CHMP /EMA

Session Co-Chairs:
Anthony Humphreys
Head of Regulatory, Procedural and Committee Support, European Medicines Agency, EU
Brenton James
Strategic Consultant Strategic Regulatory Affairs in the European Union, UK

Overview of CHMP Operations
Anthony Humphreys, Head of Regulatory, Procedural and Committee Support, European Medicines Agency, EU

Centralised Procedure
MHRA speaker invited

Guideline Development
Xavier Luria Oller, Head of Sector Safety and Efficacy of Medicines, European Medicines Agency, EU

10:00 Coffee break

10:30 Session 5

OPTIMAL USE OF EU SCIENTIFIC ADVICE PROCEDURES – CASE STORIES AND ORPHAN DRUG CASE STORIES

Session Co-Chairs:
Anu M. Tummavuori-Liemann
Associate Director European Regulatory Liaison, Celgene International Sarl, Switzerland
Spiros Vamvakas
Head of Scientific Advice, European Medicines Agency, EU

Speakers:

Andrea Laslop, Head of Unit, AGES PharmMed, Austria

Shailesh Dewasthaly, Global Head of Regulatory Affairs, Intercell AG, Austria

MHRA speaker invited

12:00 Lunch

13:30 Session 6

CLINICAL TRIALS DIRECTIVE - HEADS OF MEDICINES AGENCIES

Session Co-Chairs:
Hartmut Krafft
Head, Section Clinical Trials, Paul Ehrlich Institut, Germany
Nick Sykes
Director, Regulatory Policy and Intelligence, Pfizer Ltd., UK

Regulator Perspective
Hartmut Krafft, Head, Section Clinical Trials, Paul Ehrlich Institut, Germany

Industry Perspective
Nick Sykes, Director, Regulatory Policy and Intelligence, Pfizer Ltd., UK

15:00 Coffee break

15:30 Session 7

GLOBALISATION OF REGULATORY AFFAIRS, RULES AND AUTHORITIES

Session Co-Chairs:
Emer Cooke
International Liaison Officer, European Medicines Agency, EU
Henrik Kim Nielsen
Corporate Vice President, Novo Nordisk, Denmark

Transatlantic Collaboration
Janice M Soreth, Deputy Director, Europe Office - Liaison to European Medicines Agency, US Food and Drug Administration, USA

ICH Status and Future Developments - An EMA Perspective
Agency speaker invited

ICH and Global Cooperation - An Industry Perspective
Industry speaker invited

17:00 End of Forum

Hotel Information

The DIA has blocked a number of rooms at the:

Hilton London Canary Wharf Hotel
South Quay Marsh Wall, London E14 9SH, United Kingdom
www.hilton.co.uk/canarywharf
Tel: +44 (20) 3002 2300 - Fax: +44 (20) 3002 2350

at the special rate of:
£148.00 per single standard room inclusive of English Breakfast, excluding VAT

Travel to the Hilton London Canary Wharf hotel, 15 minutes by taxi from London City Airport in the bustling commercial district. The hotel is within easy reach of Greenwich and the West End, on London's river taxi network.
The nearest underground station is Canary Wharf on the Jubilee line or South Quay station on the Docklands Light Railway.

Please make your reservation online at:
http://www.hilton.com/en/hi/groups/personalized/LONCWHI-ADIAB-20100530/index.jhtml?WT.mc_id=POG

Important:
Please complete your reservations by 4 May 2010. A credit card is required to guarantee your reservation.

Cancellation Policy:
Free cancellation can be made up to 16.00 PM (UK time) on the day of arrival. The full accommodation will be charged when cancellations are received after this deadline or in case of no show.

DIA Upcoming Events

Workshop on Statistical Methodology in Clinical R&D
27-29 September 2010 | Vienna, Austria

Joint DIA/EFGCP Pharmacovigilance Audit and Inspection Workshop – Opportunities for Patient Safety
1 October 2010 | London, UK

4th Annual Clinical Forum
Navigating the Future
11-13 October 2010 | Lisbon, Portugal

4th European Cardiac Safety Conference
25-26 October 2010 | Nice, France

Second Health Technology Assessment (HTA) Conference
Building a new System to get Effective Treatment to European Patients
November 2010 | Paris, France

Conference on Combination Products - Finding the Right Regulatory Strategy
November 2010 | Zurich, Switzerland

Future Direction for Orphan Drugs in Europe
November 2010 | Paris, France

2nd Joint DIA / European Medicines Agency Innovation Forum: Is the EU Regulatory Framework Ready?
29-30 November | London, UK

23rd Annual EuroMeeting
28-30 March 2011 | Geneva, Switzerland

REGISTRATION FORM

DIA European Regulatory Affairs Forum

1-2 June, 2010 - Hotel Hilton London Canary Wharf, London, UK

ID# 10106

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee.

Early-Bird rates available for Members: Deadline on or before 20 April 2010

Join DIA now to qualify for the early-bird member fee! To qualify for the early-bird discount, registration form and accompanying payment must be received by the date above. **Does not apply to government/academia/non-profit members**

Early-Bird Fee (on or before 20 April 2010)	FEE
Join DIA now to qualify for the Early-Bird Rate	€ 115.00 ❑
Early-Bird Industry	€ 950.00 ❑

Category	Member Fee (after 20 April 2010) FEE
Industry	€ 1'100.00 ❑
Charitable/Non-profit/Academia (Full-Time)	€ 825.00 ❑
Government (Full-Time)	€ 550.00 ❑

Category	Non-Member Fee FEE
Industry	€ 1'215.00 ❑
Charitable/Non-profit/Academia (Full-Time)	€ 940.00 ❑
Government (Full-Time)	€ 665.00 ❑

A one-year membership to DIA is available to those paying a non-member registration. If paying a non-member fee, please indicate if you do, or do not wish to become a member: YES___ NO___

TOTAL AMOUNT DUE: € _____ **NOTE:** Payment due 30 days after registration and must be paid in full by commencement of the event

GROUP DISCOUNTS AVAILABLE. SPECIAL RATES FOR STUDENTS AND SMEs! PLEASE CONTACT DIA FOR MORE INFORMATION 10106DIAWEB

REGISTRANT

PLEASE COMPLETE IN BLOCK CAPITAL LETTERS OR MAKE REGISTRATION EVEN SIMPLER BY ATTACHING THE REGISTRANT'S BUSINESS CARD HERE

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Last Name

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Please indicate your professional category: ❑ **Academia** ❑ **Government** ❑ **Industry** ❑ **Contract Service Organisation**

PAYMENT METHODS - Credit cards are our preferred payment method.

❑ **Please charge my credit card** - credit card payments by VISA, Mastercard or AMEX can be made by completing the relevant details below. Please note that other types of credit card cannot be accepted.

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❑ **Cheques** should be made payable to: D.I.A. and mailed together with a copy of the registration form to facilitate identification to:

D.I.A., Elisabethenanlage 25, Postfach, 4002 Basel, Switzerland

❑ **Bank transfers:** When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the bank transfer. Payments in EURO should be addressed to "Account Holder: DIA." including your name, company, Meeting ID# 10106 as well as the invoice number to ensure correct allocation of your payment.

Payments must be net of all charges and bank charges must be borne by the payer.

Persons under 18 are not allowed to attend DIA meetings.

CANCELLATION POLICY

All cancellations must be in writing and received at the DIA office by 17:00 CET on 24 May 2010

Cancellations received by the date above are subject to an administrative fee:
Full Meeting Cancellation: Industry (Member/non-member) = € 200.00 Government/Academia/Non-profit (Member/non-member) = € 100.00. Tutorial cancellation: € 50.00. Registrants who do not cancel by the date above and do not attend, will be responsible for the full registration fee. Registrants are responsible for cancelling their own hotel reservations. DIA reserves the right to alter the venue and dates if necessary. If an event is cancelled DIA is not responsible for airfare, hotel or other costs incurred by registrants.

Transfer Policy

You may transfer your registration to a colleague prior to the start of the event but membership is not transferable. Substitute registrants will be responsible for the non-member fee, if applicable. Please notify the DIA office of any such substitutions as soon as possible.

IMPORTANT: Hotel and travel reservations should be made ONLY after receipt of written registration confirmation from DIA. If you have not received your confirmation within five working days, please contact DIA.

HOW TO REGISTER

The DIA Customer Services Team will be pleased to assist you with your registration. Please call us on +41 61 225 51 51 from Monday to Friday between 08:00 and 17:00 CET.

Online	Fax	Email	Mail
www.diahome.org	+41 61 225 51 52	diaeurope@diaeurope.org	DIA European Office Postfach, 4002 Basel, Switzerland