

Influence of the EU Legislation on the Bulgarian Drug Industry

Organised by the DIA Advisory Council of Europe

Hotel Hilton | Sofia, Bulgaria

26 May 2011 | 13:30-16:30



FINAL PROGRAMME

THURSDAY | 26 MAY 2011

13:30 Welcome Addresses DIA

Brigitte Franke-Bray, Director DIA Europe
Yves Juillet, DIA President-elect

Welcome Address Ministry of Health, Bulgaria

Gergana Pavlova, Deputy Minister of Health

13:50 Session 1

CLINICAL TRIALS AND PHARMACOVIGILANCE - NEW CHALLENGES

Session Chairperson:

Beat Widler, ACE Chair and DIA Board Member

Clinical Trials – Report of the European Commission and new Guidelines on Adverse Event Reporting and Publication in EUDRACT

Birka Lehmann, Head of Licensing Division 3, BfArM, Germany

New Pharmacovigilance Regulation

Yavor V. Pomakov, Clinical Manager, PPD Bulgaria

Discussion

14:30 Session 2

PHARMA PACKAGE - NEW REQUIREMENTS IN PHARMACOVIGILANCE

Session Chairperson:

Gesine Bejeuhr, Senior Manager Regulatory Affairs/Quality, vfa Research-based Pharmaceutical Companies, Germany

Key Changes in Pharmacovigilance Legislation

Christer Backman, EU Coordinator & Senior Expert, Medical Products Agency, MPA, Sweden

The New Pharmacovigilance Legislation in the EU – Challenges and expectations

Maria Popova, Head of Medicines Use Control Department, Bulgarian Drug Agency

Discussion

15:10 COFFEE BREAK

15:40 Session 3

HEALTH TECHNOLOGY IN THE EU AND IN BULGARIA

Session Chairperson:

Tatyana Benicheva, Assoc. Prof. in Drug Regulatory Affairs, Medical University, Sofia, Bulgaria

Benefit/Risk Assessment and Reimbursement in EU – The Italian experience

Luca De Nigro, PM Drugs Monitoring Registers, Research & Clinical Trials Unit, AIFA – Italian Medicines Agency, Italy

Benefit/Risk Assessment and Reimbursement in Bulgaria

Deyan Denev, Executive Director of ARPharM, Bulgaria

Discussion

16:30 END OF WORKSHOP

Unless otherwise disclosed, DIA Europe acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organisation they represent, or that of DIA Europe.

Speakers and agenda are subject to change without notice. Recording of any DIA Europe tutorial/workshop information in any type of media is prohibited without prior written consent from DIA Europe.

Register for upcoming DIA conferences in Europe



European Regulatory Affairs Forum

6-7 June 2011 | London, UK | ID 11108



Product Information Forum

8 June 2011 | London, UK | ID 11110



Joint DIA/EFGCP/EMA Paediatric Forum

26-27 September 2011 | London, UK | ID 11115



5th Annual Clinical Forum

10-12 October 2011 | Basel, Switzerland | ID 11103



Quality Risk Management in Clinical Drug Development Conference

27-28 October 2011 | Berlin, Germany | ID 11113



2nd Joint DIA/EMA Statistics Workshop

26-28 October 2011 | London, UK | ID 11107



5th European Cardiovascular Safety Conference

3-4 November 2011 | Barcelona, Spain | ID 11112



2nd Joint DIA/EMA ENCePP Information Day

7 November 2011 | London, UK | ID 11118



Joint DIA/EMA/FDA Orphan Drug Designation Workshop

10-11 November 2011 | London, UK | ID 11120



Joint DIA/MHRA Advanced Therapy Medicinal Products Workshop

18 November 2011 | London, UK | ID 11111



12th Conference on European Electronic Document Management (eDM)

30 November - 2 December 2011 | Zurich, Switzerland | ID 11104



24th Annual EuroMeeting

26-28 March 2012 | Copenhagen, Denmark | ID 12101

Register for upcoming DIA Training Courses in Europe



Clinical Research

Advanced GCP Study Monitoring

19 September 2011 | Paris, France | ID 11531

Clinical Project Management – Part I

5-7 October 2011 | Vienna, Austria | ID 11528

Clinical Statistics for Non-Statisticians

6-7 October 2011 | Vienna, Austria | ID 11566

Essentials of Clinical Study Management

2-4 November 2011 | Paris, France | ID 11536

Practical GCP Compliance Auditing of Trials & Systems

26-28 October 2011 | London, United Kingdom | ID 11538

Regulatory Affairs

Building the eCTD - Practical Solutions to Compile Electronic Submissions

October 2011 | Location to be confirmed | ID 11529

CTD Dossier Requirements: Focus on EU Module 1 and Quality Module 3

27-29 November 2011 | Abu Dhabi, United Arab Emirates | ID 11533

eCTD Submissions in Switzerland

16 June 2011 | Bern, Switzerland | ID 11545

8 December 2011 | Zurich, Switzerland | ID 11590

European Regulatory Affairs: In-depth Review of Current Registration Procedures in the European Union

30-31 May 2011 | Basel, Switzerland | ID 11535

3-4 November 2011 | Paris, France | ID 11546

Good Management of Medical Devices including In Vitro Diagnostics and Companion Diagnostics: Legal and Practical Aspects as used in Personalised Medicine

6-9 June 2011 | Basel, Switzerland | ID 11539

November 2011 | Location to be confirmed | ID 11568

Quality by Design: New Concepts for Development & Manufacturing - A Hands-on Course for Pharma

3-4 November 2011 | Vienna, Austria | ID 11572

US Regulatory Affairs: A Comprehensive Review of Regulatory Procedures for INDs and NDAs in the US

14-16 November 2011 | Paris, France | ID 11582

Safety and Pharmacovigilance

Excellence in Pharmacovigilance: Clinical Trials and Post-Marketing

3-7 October 2011 | Zagreb, Croatia | ID 11548

How to Prepare for Pharmacovigilance Audits and Inspections

November 2011 | Location to be confirmed | ID 11570

Introduction to Signal Detection and Data Mining in Pharmacovigilance

November 2011 | Location to be confirmed | ID 11569

Medical Approach in Diagnosis and Management of ADRs

19-20 September 2011 | Paris, France | ID 11530

EudraVigilance Information Day at the European Medicines Agency

15 November 2011 | London, United Kingdom | ID 11522

Information Day on the Development Safety Update Report (DSUR) Guidelines ICH E2F

04 July 2011 | London, United Kingdom | ID 11591

IDMP Information Day at the European Medicines Agency

23 September 2011 | London, United Kingdom | ID 11524

ICSR Information Day at the European Medicines Agency

16 November 2011 | London, United Kingdom | ID 11525

ICSR Technical Implementation Training at the European Medicines Agency

17 November 2011 | London, United Kingdom | ID 11526

Introduction to Pharmacovigilance and Electronic Transmission of Individual Case Safety Reports (ICSR) for the Use of EudraVigilance at the European Medicines Agency

7 June 2011 | London, United Kingdom | ID 11551

13 September 2011 | London, United Kingdom | ID 11552

6 December 2011 | London, United Kingdom | ID 11553

EudraVigilance (EV) and EudraVigilance Medicinal Product Dictionary (EVMPD)

Courses throughout the year | European Medicines Agency, London, United Kingdom and selected European cities.

For course details on EV, please visit www.diahome.org > Training > EudraVigilance > Click on > Related Courses

Non-Clinical Sciences

Non-Clinical Safety Sciences and Their Regulatory Aspects

21-25 November 2011 | Lisbon, Portugal | ID 11567

For more information and a complete listing of all training courses, please visit www.diahome.org and click on Training.