# EU Accession - Preparing for Day 1

Organised by the DIA Advisory Council of Europe

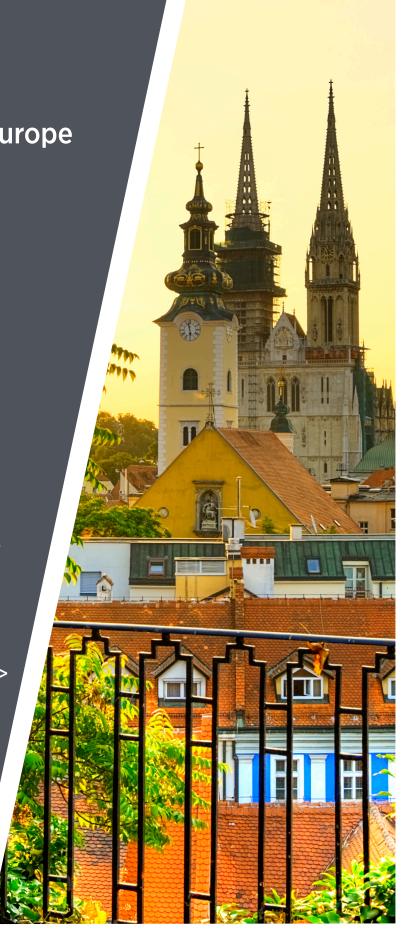
Zagreb, Croatia 30 November 2010

# Free Workshop!

This workshop has limited capacity - Please register early.

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#### TUESDAY | 30 NOVEMBER 2010

#### 13:30 Welcome Address DIA

Dr. Brigitte Franke-Bray FFPM, Specialist in Pharmaceutical Medicine FMH, Director DIA Europe, Switzerland

#### Welcome Address Croatian Agency

Working within the EU regulator's Network - Future Vision

Prof. Siniša Tomić, Head of Agency, Agency for Medicinal Products and Medical Devices, Croatia

#### 13:50 Session 1

## **Preparing for European Marketing Authorisation**Session Chairperson:

**Prof. Siniša Tomić**, Head of Agency, Agency for Medicinal Products and Medical Devices, Croatia

# Accession Tools & EU Requirements for CP Products What Does the EMA Expect from New Member States?

Anthony Humphreys, Head of Regulatory, Procedural and Committee Support, European Medicines Agency, European Union

## Regulators Assisting Regulators through Close Collaboration and Twinning Projects

Dr. Peter Bachmann, European Drug and International Affairs, BfArM, Germany, (CMD(h) Member)

#### What Did We Learn from Previous Accessions?

Anu Tummavuori-Liemann, Associate Director European Regulatory Liaison, Celgene, Switzerland

#### 15:00 Coffee Break

#### 15:30 Session 2

## Facilitating Smooth Transition into the New Era Session Chairperson:

Ivana Ferber, Regulatory Lead Croatia / Bosnia and Herzegovina, Merck Sharp and Dohme d.o.o., CARPC Member, Croatia

# How Did Candidate Agencies Smoothly Transition into the EU Regulators Network?- Practical Experiences from EU Accession

Dr. Dagmar Stara, Teacher at Faculty of Pharmacy, Comenius University, Bratislava, former Head of the EU Affairs Coordination Unit at State Institute for Drug Control, Bratislava, Slovak Republic

# What Are the Current Challenges and Expectations Industry Is Facing?

Ivana Ferber, Regulatory Lead Croatia / Bosnia and Herzegovina, Merck Sharp and Dohme d.o.o., CARPC Member, Croatia

Local Generic Industry association representative invited

#### Co-ordination of MR and DC Procedures

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

#### 17:00 End of Workshop

For more information on this workshop or the registration, please contact us by email: Sarah.Schuppener@diaeurope.org or call: +41 61 225 51 51

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