Conference Chairman
Prof. Stuart Walker, UK

Programme Committee
Sheherazad Aftabroushad, Eli Lilly Export S.A., Switzerland
Kerstin Ahrendt-Sölter, Novartis Vaccines, Italy
Marie-Claire Beurier, F. Hoffmann-La Roche Ltd., Switzerland
Afschin Khodaverdi-Afaghi, Schering AG, Germany (Co-Chairperson)
Estelle P. Michael, GlaxoSmithKline R&D, UK
Nadine Otin, sanofi-aventis, France
Fraser Stodart, Pfizer Ltd., UK
Elaine Whiting, AstraZeneca UK Ltd., UK (Chairperson)

Programme Advisors
Dr. Mohammed Al Haidary, Executive Board of the Health Ministers Council for G.C.C. States
Dr. Lama Al-Hmoud, Jordan
Dr. Easa Ahmed Jakka Al Mansoori, Ministry of Health, United Arab Emirates
Dr. Hajed Hashan, SFDA, Saudi Arabia
Dr. Sawsan Ahmed Jaffar, Ministry of Health, Oman
Dr. Layla A. Rahman, Bahrain
Dr. Samia Salah, Ministry of Health & Population, Egypt

Background
Since its inception nearly 10 years ago, the Middle East Regulatory Conference has grown to become an important forum for discussion of matters related to the provision of healthcare in the region, with a specific focus on issues around the evaluation and supervision of medicines for human use. The conference offers the opportunity for key stakeholders active in the region, including representatives from ministries of health, local and multinational pharmaceutical companies, to meet to exchange views, discuss topics of interest and identify actions to increase patient access to new and improved medicines and therapies.

Themes and Objectives
Following on from successful discussions held during MERC 6 in September 2004, MERC 7 will look to build on progress made and to identify further opportunities for stakeholders to work together on the enhancement of healthcare in the region. The format of the conference, which will include workshop-style discussions, will offer the chance for all participants to make real contributions to the choice of subject matter for debate and through active discussion, to be involved in determining overall outcomes of the conference.

Key Issues
• Updates on global regulatory developments
  - EU New Medicines Legislation and how it will impact regulatory requirements
  - Clinical trial data availability
• Middle East Regional Regulatory Developments (including GCC-DR update)
• Importance of product lifecycle management
• Elements of quality review in the Middle East

Including update on Middle East Regulatory Workshop, Dubai - May 2006
Monday, November 13, 2006
18:00 - 19:30  Pre-registration

Tuesday, November 14, 2006
08:00  Registration and Welcome Coffee

08:45  DIA OPENING
Brigitte Franke-Bray, Director DIA Europe, Switzerland

09:00  INTRODUCTORY REMARKS AND WELCOME
Prof. Stuart Walker, CMR International Institute for Regulatory Science, UK
Representative from Ministry of Health, UAE

09:45- Coffee Break

10:15  Keynote Address
LIFECYCLE MANAGEMENT (INCLUDING PHARMACOECONOMICS)
Trevor Jones, UK

11:00  SESSION 1
THE CHANGING REGULATORY ENVIRONMENT
CMR Speaker

11:30  CPP DEVELOPMENTS AND IMPLICATIONS OF RECENT EU LEGISLATION CHANGES FOR MIDDLE EAST MARKETS
WHO and Industry Speaker

Panel Discussion

12:00- 13:30  Lunch Break

13:30  SESSION 2
THE PHARMACEUTICAL INSPECTION COOPERATION SCHEME (PIC/S) - OPPORTUNITIES FOR THE MIDDLE EAST
PIC/S Representative invited

14:30  CHANGES SINCE MERC 2004 (including update on Middle East Regulatory Workshop held in Dubai, May 2006)
Speaker to be invited

15:00  Coffee Break

15:30  SESSION 2 (continued)

REGULATORS WORKSHOP
This session offers delegates from Regulatory Authorities the opportunity to meet in a closed session, together with colleagues from other Regulatory Authorities in a facilitated discussion on specific themes or topics.

INDUSTRY DELEGATES WORKSHOP
During the Regulators closed session, industry delegates will have the chance to participate in a workshop aimed at surfacing regulatory issues important in the region and making suggestions or proposals for working towards solutions. This will be a unique opportunity to gather contributions from the whole spectrum of Industry, including multinational research based companies, regional companies, local agents and distributors.

17:30  End of Day 1
19:00  Networking Dinner

Wednesday, November 15, 2006
08:30  FEEDBACK FROM WORKSHOPS
Regulators and Industry
Panel Discussion

09:30  SESSION 3
MARKET UPDATES

GCC-DR UPDATE
Dr. Mohammed Al Haidary, GCC-DR Central Registration Department, Saudi Arabia

10:00  INDUSTRY PERSPECTIVE OF GCC-DR
Local Gulf Regulatory Affairs Working Group (RAWG) Representative

Panel Discussion

10:30- Coffee Break

11:00  SAUDI FDA UPDATE
SFDA Representative

11:45  EGYPT - NEW REGULATIONS
Egypt MoH Representative

12:30- 14:00  Lunch Break

14:00  SUBMISSIONS MANAGEMENT IN SINGAPORE - A MODEL FOR SMALLER AGENCIES (BUILDING ON EXCELLENCE)
John Lim, Health Sciences Authority, Singapore

15:00  SESSION 4
FUTURE TRENDS

CLINICAL DATA DISCLOSURE
Dr. Yves Juillet, LEEM, France

15:30- Coffee Break

16:00  DEVELOPMENT AND ASSESSMENT OF BIOTECH PRODUCTS
Trevor Jones, UK

16:45  CONFERENCE REVIEW AND NEXT STEPS
Prof. Stuart Walker, CMR International Institute for Regulatory Science, UK

17:00  Conference Close
7th Middle East Regulatory Conference  
MERC 2006

INVITATION TO ATTEND THE  
CONFERENCE REVIEW MEETING

taking place at the:

JW Marriott Hotel, Dubai  
on Thursday, November 16, 2006  
from 09:30 - 11:30

Hosted by the MERC 2006  
Programme Committee:

Sheherazad Aftabroushad, Eli Lilly Export S.A., Switzerland  
Kerstin Ahrendt-Sölter, Novartis Vaccines, Italy  
Marie-Claire Beurier, F. Hoffmann-La Roche Ltd., Switzerland  
Afschin Khodaverdi-Afagh, Schering AG, Germany  
Estelle P. Michael, GlaxoSmithKline R&D, UK  
Nadine Otin, sanofi-aventis, France  
Fraser Stodart, Pfizer Ltd., UK  
Elaine Whiting, AstraZeneca UK Ltd., UK (Chairperson)

The Meeting will provide a forum for Industry representatives to discuss the 7th Middle East Regulatory Conference. The Discussion will be lead by the Programme Committee and members of local industry groups.

Note:  
Only Registered Participants of the Middle East Regulatory Conference are entitled to attend the Conference Review Meeting.

Hotel Information

The DIA has blocked a number of rooms at the:  
JW Marriott Hotel  
Abu Baker Al Siddique Road, Adjacent to the Hamarain Shopping Center  
Dubai, PO Box 16590, United Arab Emirates

Tel: +971 4-607 7191  
Fax: +971 4-607 7774  
Email: mhrs.dxbae.group.sales.coordinator@marriotthotels.com

at the special rate of:

Deluxe Room  
Single Occupancy  Dhs 950.00  
Double Occupancy  Dhs 1050.00

The rate is per room and night, excluding 10% municipality tax and 10% service charge. Breakfast is available at Dhs 92.00 net per person and night.

IMPORTANT:  
To be assured of accommodation at the JW Marriott Hotel, registrants are recommended to complete their reservation, by October 23, 2006.

Accommodation Booking Form

1 FORM PER RESERVATION

Guest  
Prof.  Dr.  Ms.  Mr.

Last Name  
First Name & Middle Initial  
Company  
Job Title  
Street Address / P.O. Box  
Postal Code  
City  
Country  
Telephone  
Telefax  
E-Mail  

Room  
Deluxe  Dhs 950.00  
Double  Dhs 1050.00

The rate is per room and night, excluding 10% municipality tax and 10% service charge. Breakfast is available at Dhs 92.00 net per person and night.

Arrival date:  Expected Time of Arrival:  
Departure Date:  Number of Nights:  

In case of cancellation: Cancellation must be in writing. One night deposit will be kept as cancellation fee. All no shows will be billed for the entire stay.

Payment  

I hereby authorize the JW Marriott Hotel to charge my credit card according to the conditions mentioned above.  

Visa  MC  AMEX  Diners  Other: ____________

Card Number  
Exp.date  
Cardholder's Name  
Date  
Cardholder's signature
**REGISTRATION FORM - I.D. CODE # 06104**

**MIDDLE EAST REGULATORY CONFERENCE, MERC 2006**

**NOVEMBER 14 - 16, 2006 - JW MARRIOTT HOTEL, DUBAI, UNITED ARAB EMIRATES**

**MEMBERSHIP**

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 below. Does not apply to government or academia/nonprofit members.

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**TOTAL AMOUNT DUE:** €

**Group Discount Available! Send 3, the 4th is FREE**

Register 3 individuals from the same company and receive complimentary registration for a 4th! **All 4 individuals must be registered and pay at the same time.**

DIA will apply the value of the lowest applicable fee to this complimentary registration. It does NOT include fees for optional events or DIA membership. Substitutions of enrolled delegates of similar membership may be made at any time. Group registration is not available online. To take advantage of this offer, please make a copy of this registration form for EACH of the four registrants from your company and return them together to DIA.

- Please indicate that this form is part of a group registration by ticking this box. **Please indicate the full names of the other three registrants from your company.**

**PAYMENT METHODS**

- 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.

  - **VISA**
  - **MC**
  - **AMEX**

- Card Number
- Exp. Date
- Cardholder’s Name

- Cheques should be made payable to: Drug Information Association. Mail your cheque together with the registration form to facilitate identification of attendee to: DIA, Elisabethenallee 11, 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. Payment should be in EURO and your name and company, as well as the Meeting I.D. # must be included on the transfer document to ensure payment to your DIA account.

Persons under 18 are not allowed to attend DIA meetings.

**WORKSHOP CANCELLATION POLICY**

All cancellations must be in writing and be received at the DIA office by 17:00 on November 7, 2006.

Cancellations received in writing on or before November 7, 2006 – Administrative fee that will be deducted from fee paid: Full Meeting Cancellation: Member/Nonmember = EUR 200.00 Government/Academia/Nonprofit (Member/Nonmember) = EUR 100.00

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 airline and hotel reservations. You may transfer your registration to a colleague at any time. Please notify DIA of any such substitutions as soon as possible. Substitute registrants will be responsible for nonmember fee, if applicable. DIA reserves the right to alter the venue, if necessary. If an event is cancelled, DIA is not responsible for airfare, hotel or other costs incurred by registrants.

Hotel and travel reservations should be made ONLY after receipt of written registration confirmation from DIA.

If you have not received your confirmation letter via fax within five working days, please contact the DIA Basel Office.

**EUROPEAN BRANCH OFFICE:** Elisabethenallee 11, Postfach 4002 Basel, Switzerland / Phone: +41 61 225 51 51 / Fax: +41 61 225 51 52 / Email: diaeurope@diaeurope.org

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**DIA INFORMATION ASSOCIATION LLC (JAPAN):** Level 2, Toranomon 10モニ BUILDING, 1-18-1, Toranomon, Minato-ku, Tokyo 105-0001, Japan / Phone: +81 3 5511 1131 / Fax: +81 3 5511 0100 / Email: diajapan@diajapan.org