PROGRAMME CO-CHAIRPERSONS

Jean H. Soul-Lawton
Global Medical Writing Director, GlaxoSmithKline R&D, UK

Barbara R. Kamm
Senior Medical Writing Projects Manager, Allergan Inc., USA

PROGRAMME COMMITTEE

Helle Mai Gawrylewski
Director, Medical Writing, Johnson & Johnson Pharmaceuticals R&D, USA

Sandra J. Hecker
President, Hecker & Associates LLC, USA

Sharon Obeng
Medical Writing Manager Europe, Allergan Inc., France

Christopher Preston
International Documentation Manager, F. Hoffmann-La Roche Ltd., Switzerland

CONFERENCE OVERVIEW

The format and preparation of clinical trial applications and submissions to the EU and US continues to evolve, and the consequences of this on medical writing, workflow and process will be presented. The impact of the Clinical Trial Directive and specific regional requirements on global organisations will also be discussed. The advantages and challenges of medical writing outsourcing will be reviewed now that countries such as India are offering this service. The skills required in communication of safety data and in the presentation of information to patients will also be included.

Please note, this conference is preceded by a joint one-day workshop (Medical Writing, Data Management and Statistics) on Operational Interfaces from Study Planning to Report. This optional workshop, on Wednesday, October 17, is offered free of charge to all attendees of the Global Trends in Medical Writing and the Evolving Regulatory Environment conference.

WHO SHOULD ATTEND?

Professionals involved in the following areas:

- Clinical Research and Development
- Clinical Safety/Pharmacovigilance
- Document Management
- eClinical
- Medical Communications
- Medical Writing
- Outsourcing
- Regulatory Affairs / Operations
- Statistics

To register online, please visit: www.diahome.org > Educational Offerings > keyword: 07122
Or contact DIA Europe on +41 61 225 51 51, Fax: +41 61 225 51 52, Email: diaeurope@diaeurope.org
THURSDAY, OCTOBER 18, 2007

07:30  REGISTRATION AND WELCOME COFFEE

09:00  SESSION 1

EVOLVING ROLE OF INVESTIGATOR BROCHURES IN GLOBAL SUBMISSIONS
Confirmed Chairperson:
Christopher Preston, International Documentation Manager
F. Hoffmann-La Roche Ltd., Switzerland

Use of the Investigator Brochure in the IMPD – Initial Submissions and Substantial Amendments
Inger Magnusson, Global Documentation and Dossier Management, Bristol-Myers Squibb, USA

How to Organise the IB for Clarity and Purpose
Vicki Antipatis, Senior Clinical Documentation Specialist
F. Hoffmann-La Roche Ltd., Switzerland

IMPD versus IB: What Additional Information is Needed?
Irene Gander-Meisterernst, Senior Director, Regulatory Affairs, MediGene AG, Germany

10:30  COFFEE BREAK

11:00  SESSION 2

ELECTRONIC CTA AND CTD SUBMISSIONS: STATUS AND BEST PRACTICES
Session Chairperson:
Sandy Hecker, President, Hecker & Associates, LLC, USA

Status of MEB eCTD Implementation and eSubs
Rob de Haan, Adjunct Director/Deputy Director, CBG Medicines Evaluation Board, The Netherlands

Electronic Clinical Trial Applications: Lack of Harmonisation and Challenges for the Industry
Michael Braun, Regulatory Affairs Manager, CT Applications Nycomed GmbH, Germany

The eCTD Conformable Document and its Impact on Medical Writing
Olaf Schoepke, Managing Director, Extedo Limited, UK

12:30  LUNCH BREAK

14:00  SESSION 3

OUTSOURCING ON-SHORE AND OFF-SHORE
Session Chairperson:
Jean H. Soul-Lawton, Global Medical Writing Director, GlaxoSmithKline R&D, UK

Working with a Contractor - Getting the Best Out of an Agency
Mark Hughes, Technical Director, Complete Regulatory Writing, UK

Clinical Documents as World Literature: Making the Data Tell the Story
Anne Packer, Medical Writer, Anne Packer Consulting, USA

Outsourcing of Medical Writing to a Business Process Organisation (BPO) in India
Maria Grosse, Medical Writing Manager, GlaxoSmithKline R&D, UK

15:30  COFFEE BREAK

16:00  SESSION 4

MEDICAL WRITING FOR RISK MANAGEMENT AND PHARMACOVIGILANCE

Session Chairperson:
Barbara Kamm, Senior Medical Writing Projects Manager, Allergan Inc., USA

Not Again! Preparing Painless PSURs in a Small Company
Laurie Haynes, Senior Director, Medical Writing, QLT Inc., Canada

Annual Safety Reports - What They Are, and How the Medical Writer Can Create Them
Alison Rapley, Director, Medical Writing Services Europe, PAREXEL International Ltd., UK

Role of Regulatory Documentation as the Foundation for the Risk Management Plan
Susan L DiMaggio, Associate Director, Pfizer Inc., USA

17:30  END OF DAY 1

FRIDAY, OCTOBER 19, 2007

09:00  SESSION 5

WRITING FOR THE CTD

Session Chairperson:
Mary Gardner Stewart, Head of Medical Writing Department, H. Lundbeck, Denmark

CTD Documents as Key Reviewer Tools
Michelle Herrera Foster, Regulatory Affairs Consultant, CTD Quality Consulting, USA

Utilising the FDA Clinical Safety Reviewer’s Guidance Proactively in the Preparation of the Summary of Clinical Safety
Patricia Valencia, Associate Director, Pfizer Inc., USA

Writing and Re-Using CTD Documents
Mary Gardner Stewart, Head of Medical Writing Department, H. Lundbeck, Denmark

10:30  COFFEE BREAK

11:00  SESSION 6

WRITING FOR PATIENTS

Session Chairperson:
Virginia Watson, Director of Clinical Operations and Medical Writing, Catalent Pharma Solutions, UK

Is Patient Information and Informed Consent Fit for Purpose?
Tine Kold Olesen, Director, Global Clinical Research and Development, Urology, Ferring Pharmaceuticals Inc., USA

Clinical Trial Registries
Doreen Beattie, Clinical Trials Posting Editor, Roche Products Ltd., UK

Evidence-Based Tips for Better Leaflets from the Findings of a Systematic Review
Theo Raynor, Professor of Pharmacy Practice, University of Leeds, UK & Executive Chairman, LUTO Research Ltd., UK

12:30  END OF WORKSHOP
GENERAL INFORMATION FOR DELEGATES
The DIA has blocked a number of rooms at special rates and conditions in the hotels mentioned below. Attendees must make their own hotel reservations through our contracted travel agent ECIS.

Contact:
ECIS, Francesc Carbonell, 36 Local, (08036 Barcelona, Spain)
E-mail: reservations@incoming-ecis.com
Fax: +34 93 280 61 30  Tel: +34 93 206 04 04

Demand for hotel accommodation in Madrid during the Conference dates is high. We recommend that delegates reserve accommodation as soon as possible.

Final Deadline: September 5, 2007
Rates are per room and night and include buffet breakfast and taxes. Special Conference rates are not guaranteed outside the Conference housing block.

Special Clinical Forum Hotel Offers:

<table>
<thead>
<tr>
<th>HOTEL</th>
<th>PRICE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Auditorium (4*)</td>
<td>SGL € 145,00</td>
</tr>
<tr>
<td>Vincci Soho (4*)</td>
<td>SGL € 180,00</td>
</tr>
<tr>
<td>Vincci Centrum (4*)</td>
<td>SGL € 180,00</td>
</tr>
<tr>
<td>Petit Palace Londres (3*)</td>
<td>SGL € 150,00</td>
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</tbody>
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Please book directly through ECIS at: www.incoming-ecis.com/clinicalforum2007

AIRPORT TRANSFER
Complimentary Shuttle from the Airport to Hotel Auditorium:
Daily from 5.00am to 2.00am
Terminal 1: Every hour at 5 minutes past the hour
Terminal 2: Every hour at 5 minutes to the hour
Terminal 4: Every hour at 20 minutes to the hour

Complimentary Shuttle from Hotel Auditorium to the Airport:
Every 30 minutes from 5.00am to 2.00am

Taxi:
20 minutes, approx. EUR 20.00
Buses:
221 - 222 - 223 - 224 - 225 - 281
282 - 283 - 284 - 285

THE CITY OF MADRID
Madrid is characterised by intense cultural and artistic activity and a very lively nightlife. It is a cosmopolitan city, a business centre, headquarters for the public administration, government and the Spanish parliament and the home of the Spanish Royal Family. Madrid is also one of the major capitals for the arts.

CLIMATE
The average temperature in October is 15°C - 22°C. However, the temperature can drop between 5 and 10 degrees, particularly at night. Most buildings and public facilities are air conditioned.

PASSPORT AND VISA REQUIREMENTS
Delegates from countries within the European Union will only need a valid passport or ID to travel to Spain. All other delegates should contact the nearest Spanish embassy or consulate for visa requirements.

TRANSPORTATION
Fortunately, most of Old Madrid can be reached on foot, however Madrid's public transportation network and taxis are generally safe and reasonably priced.

CONFERENCE VENUE INFORMATION
The event will take place at the Auditorium Hotel, Av. Aragon, 400 28022 Madrid, Spain.

The Auditorium Madrid Hotel is located in one of Madrid's major business districts, near the Juan Carlos I Exhibition Site and the Airport, in the northern section of the city. Guests can easily access this hotel off the M-40 or the Avenida America. With 894 rooms, this is the largest hotel in Europe. The hotel has two bars, a fine dining restaurant and a buffet.

The Auditorium also offers complimentary hourly shuttle bus service to the city center. Each room comes equipped with a work desk with internet connection. The Auditorium has a business center and 24-hour medical services.

CONFERENCE, WORKSHOP AND TRAINING COURSE CANCELLATION POLICY
On or before October 11, 2007
An administrative fee will be deducted from the registration fee:
Member and Non-Member = EUR 200.00
Government & Academia (Member/Nonmember) = EUR 100.00
Registrants who do not cancel by the date above and do not attend, will be liable to pay the full registration fee. Registrants are responsible for cancelling their own hotel reservations. Cancellations must be in writing. You may transfer your registration to a colleague at any time prior to the meeting. Please notify DIA of any such substitutions as soon as possible. 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.
Cancellations received in writing on or before October 8, 2007 will be charged an administrative fee of EUR 200.00. 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 prior to the meeting. 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.

Four easy ways to register:

ONLINE: www.diahome.org
FAX: +41 61 225 51 52
EMAIL: diaeurope@diaeurope.org

MAIL: DIA European Branch Office
Postfach, 4002 Basel, Switzerland

DIA would like to help you "Build Your Own Conference"!
The DIA Europe Customer Services Team will be pleased to guide you through the registration process to help you get the best value from your experience at the Clinical Forum 2007 in Madrid.

Simply call +41 61 225 51 51 or email diaeurope@diaeurope.org for more information.

The conference fee includes coffee breaks, lunch and relevant conference material. The fee does not include travel or accommodation.

Terms and Conditions
Cancellations received in writing on or before October 8, 2007 will be charged an administrative fee of EUR 200.00. 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 prior to the meeting. 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.

Three easy ways to pay:

- Please charge my credit card
- VISA □ MC □ Amex

Card Number
Exp. Date /
Today’s Date

Name on card
Cardholder’s Signature

Cheques: Mail your cheque together with the registration form to:
DIA, Elisabethenanlage 11, Postfach, 4002 Basel, Switzerland

Bank transfers: An invoice will be sent with bank transfer instructions. Payment should be in EURO and the invoice number as well as the Meeting Code must be included on the transfer document to ensure payment to your account.

Delegale Details - Please enter below or attach business card

Prof. □ Dr. □ Ms. □ Mr.

Last Name
First Name
Company
Job Title
Street Address / P.O. Box

City
Post Code
Country
Telephone
Fax (Required for confirmation)
Email (Required for confirmation)