**OVERVIEW**

If you work in pharmaceutical industry, you will sooner or later be faced with health authority meetings, be it during product development, during the application for a marketing authorisation or later in the lifecycle of your drug to discuss pharmacovigilance matters. This important course covers Health Authority (HA) meetings and other interactions in the EU and the US. You will learn by performing role plays, and through many case studies. This course is a hands-on course full of practical work. It is necessary that you bring your laptop with you.

**LEARNING OBJECTIVES**

At the conclusion of this course, participants will be able to:

- Confidently manage HA meetings
- Know when to request a HA meeting
- Be prepared when invited for a meeting
- Be sure which questions to ask, and which not to ask
- Apply the right kind of negotiation skills with HA counterparts
- Understand how to best communicate the outcome of the HA interaction to the management and how to drive implementation

Participants will complete a knowledge check at the end of the course and will be provided with feedback to ensure learning objectives are attained.

**KEY TOPICS**

- Different kinds of HA meetings in the EU and in the US
- How to prepare for HA meetings
- How to compose the best team for a meeting
- How to present your case and get the most out of your meeting
- The questions to ask – and not to ask

Hot Topics will also be covered, e.g. latest updates on FDA and EMA guidances and procedures like

- Draft FDA Guidance on Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products
- Guidance for Industry on Critical Path Innovation Meetings
- EU Adaptive Licensing Pilot Project
- Best Practice guidance for Pilot EMA HTA Parallel Scientific Advice procedures and HTA Network meetings

**FACULTY**

- **Gabriele Disselhoff**
  Managing Director
  Creative Regulatory & Quality Solutions (CRQS), Germany

- **Truus Janse-de Hoog**
  Former Staff Member European cluster Medicines Evaluation Board, the Netherlands

- **Otmar Pfaff**
  Global Regulatory Affairs
  Boehringer Ingelheim Pharma GmbH & Co. KG

**WHO WILL ATTEND**

Professionals likely to be part of a delegation for an HA meeting. Usually, Regulatory Affairs (lead the delegation) and depending on the topics to be discussed, other specialists may be invited, e.g.

- Clinical Research Professionals
- Medical Affairs Professionals
- Statisticians
- Drug Safety / Pharmacovigilance Professionals
- Non-clinical disciplines
- Chemical-pharmaceutical disciplines
- Project Managers

**CONTINUING EDUCATION**

DIA meetings and training courses are generally approved by the Commission for Professional Development (CPD) of the Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society of Pharmaceutical Medicine (SGPM) and will be honoured with 12 credits for pharmaceutical medicine. All participants are eligible for these credits.
DAY 1

08:00  REGISTRATION

08:30  SESSION 1
MEETINGS WITH HEALTH AUTHORITIES DURING PRODUCT DEVELOPMENT, MARKETING APPLICATION AND PRODUCT LIFECYCLE

The different opportunities for Health Authority Interactions in the EU and the US during drug development are discussed.

Group work

10:00  COFFEE BREAK

10:30  SESSION 2
HEALTH AUTHORITIES’ ORGANISATIONAL STRUCTURE AND THEIR MAIN COMMITTEES

EU Regulatory network and system, Committees and Working Parties and their interactions are explained as well as the organisation of FDA and US Advisory Committees.

Group work

12:00  LUNCH

13:00  SESSION 3
TYPES OF INTERACTIONS/MEETINGS IN THE EU: SCIENTIFIC ADVICE – HEARINGS - EXAMPLES

Emphasis of this session is scientific advice in Europe. This includes questions like whether to go for advice and where to go, i.e. making the decision between CHMP or national advice, or which Member State to choose.

Group work

14:30  COFFEE BREAK

15:00  SESSION 4
TYPES OF INTERACTIONS/MEETINGS IN THE US

Different types of meetings with the FDA are dealt with, as well as parallel advice between CHMP and the FDA, a comparison of pre-submission meetings, an update on PDUFA.

Group work

Participants will receive the material for the Role Play on Day 2 at the end of Session 4 and are asked to prepare for it in the evening.

16:30  DRINKS RECEPTION

17:30  END OF DAY ONE

DAY 2

08:30  SESSION 5
APPLYING FOR ADVICE AND PREPARATION FOR THE MEETING

Considerations for meeting requests, application forms, and submission of meeting requests form part of this session, in addition the Briefing Book itself with key considerations, which questions to ask and differences between EU and US.

Group work

10:00  COFFEE BREAK

10:30  SESSION 6
TYPES OF INTERACTIONS/MEETINGS IN EUROPE: EXAMPLES

Examples presented in this session are joint EMA – HTA advice, advice for orphan drug applications, qualification of novel methodologies, Innovation Task Force, protocol assistance.

Group work

12:00  LUNCH

13:00  SESSION 7
HEALTH AUTHORITY MEETING - ROLE PLAY AND DISCUSSION

Central part of this session are the role plays in which participants get the opportunity to prove their negotiation skills either as a health authority side or industry representative. After the role plays, dos and don’ts of meetings will be discussed and information on other types of interaction given.

Group work

14:30  COFFEE BREAK

15:00  SESSION 8
FOLLOW-UP ACTIONS OF MEETINGS DISCUSSION AND WRAP-UP

Participants will learn what needs to be done after a meeting, both internally and for the health authority.

16:30  END OF THE COURSE ASSESSMENT

16:45  END OF TRAINING COURSE

Unless otherwise disclosed, DIA acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organisation they represent, or that of the DIA. Speakers and agenda are subject to change without notice. Recording during DIA sessions is strictly prohibited without prior written consent from DIA.
**HOTEL INFORMATION**

Course venue:
Holiday Inn London Kensington Forum
97 Cromwell Road
London, SW7 4DN
Tel: +44 871 942 9094
www.hikensingtonforumhotel.co.uk

DIA has blocked a limited number of hotel rooms for the course participants from 13 to 15 October 2015 at the rate of GBP 168.00 per single room per night including Full English Breakfast, taxes and service fee. In order to book a hotel room, please call the hotel directly and quote the booking reference “P9K”. The room rate is available until 1 September 2015 or until the room block is sold-out, whichever comes first. Cancellations received after 1 September 2015 will be subject to cancellation fee of 100% of the booking value.

**What participants from previous course say:**

“The role play was particular useful”

“Very good interactions between the instructors and with the students”

“Presentation content was very good, detailed and interactive. Case studies were very helpful”

“Phrasing of questions for SA and selection of the best SA procedure (EMA vs. national) was quite useful for me”

“I thought the syllabus was good and the handouts were very important”

“I appreciated the sharing of experience and concrete examples from the instructors and engagement for the audience to share their own experience”

“I thought the instructors were all very knowledgeable and approachable. Shared important information”

“Varied backgrounds and great breadth of experience”

“A very enjoyable learning experience. I have gained more in-depth knowledge which I can take back and share with my team. All abstracts were excellent”

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**Gabriele Disselhoff, PhD**
Managing Director, Creative Regulatory & Quality Solutions (CRQS), Germany

Gabriele Disselhoff is currently Managing Director of CRQS (Creative Regulatory & Quality Solutions) and has 34 years wide range experience in pharmaceutical development, thereof 28 years in pharmaceutical industry (Merck KGaA, Abbott) and 6 years Consulting. She has extensive industry experience in Regulatory Affairs, Clinical Research and Clinical Quality Assurance, and thorough knowledge of document management and electronic submissions. She has a successful record of global drug registrations, global organisational development and change management and implemented major organisational change across EU, Japan and US. She was industry lead on many Industry/Health Authority projects, e.g. ICH, EFPIA, especially on ICH M2.

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**Truus Janse-de Hoog, PharmD, MSc**
Former Staff Member (now retired), Medicines Evaluation Board, The Netherlands

Truus Janse-de Hoog, Pharm D, retired recently after having served the Dutch Medicines Evaluation Board (MEB) for nearly 25 years. Truus has extensive international experience serving two terms as Chair of Coordination Group for Human Medicines (CMDh) (2005-2008; 2008-2011). In her last position at the MEB she was a staff member and her main area of interest were transparency, information support, and contacts with health professionals and patient organisations. From 2006 to 2013 she served as Co-Chair of the joint HMA/EMA Taskforce on Transparency.

Truus studied Chemistry and Pharmacy and specialised in hospital pharmacy. Prior to her work for the MEB she worked for 10 year as hospital pharmacist and as Head of the Pharmacy in a 300-bed hospital in Rotterdam, The Netherlands.

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**Otmar Pfaff, PharmD**
Global Regulatory Affairs, Boehringer Ingelheim Pharma GmbH und Co. KG, Germany

Otmar Pfaff is currently regulatory therapeutic area leader for the immunology portfolio and chairing the EU clinical trial regulation implementation team both at Boehringer Ingelheim. Previously he was head of global regulatory oncology at Merck KGaA. He has a total of more than 20 years experience in global regulatory affairs comprising of worldwide pharmaceutical drug development, health authority interactions (e.g. with EU EMA, US FDA, South Africa, Taiwan, South Korea, Japanese PMDA, Chinese SFDA) and clinical trial applications.
REGISTRATION FORM
How to manage a successful health authority interaction? # 15546
14-15 October 2015, London, United Kingdom

REGISTRATION FEES
Registration fee includes refreshment breaks and lunches and training course material.

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Join DIA now to qualify to save on future events and to receive all the benefits of membership. Visit www.DIAHome.org and click on Membership for more details.

Payment is due 30 days after registration and must be paid in full by commencement of the course.

The DIA Europe, Middle East & Africa Contact Centre Team will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CET. Tel. +41 61 225 51 51 Fax: +41 61 225 51 52 Email: diaeurope@diaeurope.org Mail: DIA Europe, Middle East & Africa, Küchengasse 16, 4051 Basel, Switzerland Web: www.diahome.org

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All cancellations must be made in writing and be received at the DIA Europe, Middle East & Africa office four weeks prior to the event start date. Cancellations are subject to an administrative fee:

• Industry (Member/Non-member) € 200.00
• Academia/Charitable/Government/Non-profit (Full-time) (Member/Non-member) € 100.00

If you do not cancel four weeks prior to the event start date and do not attend, you will be responsible for the full registration fee.

DIA reserves the right to alter the venue and dates if necessary. If an event is cancelled or postponed, DIA is not responsible for airfare, hotel or other costs incurred by registered attendees. Registered attendees are responsible for cancelling their own hotel and travel reservations.

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

Photography Policy
By attending the event, you give permission for images of you, captured during the conference through video, photo, and/or digital camera, to be used by DIA in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership.

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Please complete in block capital letters or attach the attendee's business card here.

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PAYMENT METHODS

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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.” Please include your name, company, Course ID # 15546 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. If you have not received your confirmation within five working days, please contact DIA Europe, Middle East & Africa.

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Date
Signature

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