

EU Health Authorities Scientific and Regulatory Advice

24 April 2017

NH Berlin Alexanderplatz, Berlin, Germany



OVERVIEW

Meetings with Health Authorities (HA) constitute milestones during both the initial drug development process as well as during lifecycle management. This course will equip you and your team with the skills required to adequately decide on, prepare for and execute a successful meeting. The course is built up as a dialogue between the industry and regulator perspective with Do's and Don'ts and will teach you what authorities pay attention to, what kind of inquiries they make and what they expect to hear from sponsors.

The course is built around participant interaction and advanced level teaching for experienced professionals as well as those attending their first meetings. The focus is on authority meetings in the EU but will also touch upon FDA meeting specificities.

LEARNING OBJECTIVES

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

- Work with their project teams to make the right decisions regarding HA meetings
- Present their case, make their point and use their time managing HA meetings efficiently
- Understand how HAs think and act – by putting themselves in the shoes of the authority
- Know how to listen to regulators, anticipate their questions
- Implement the advice received

WHO WILL ATTEND

Professionals in regulatory affairs, project management and product development. The course will serve as a good preparation for an upcoming authority meeting.

FACULTY

Birka Lehmann

Senior Expert Drug Regulatory Affairs
Bundesinstitut für Arzneimittel und
Medizinprodukte (BfArM), Germany

Trine B Moulvad

Vice President, Regulatory &
Pharmacovigilance
Zealand Pharma, Denmark

08:00 REGISTRATION

08:30 SESSION 1

STRATEGY FOR SCIENTIFIC/REGULATORY ADVICE

Finding the right strategy for scientific advice is the most important task of the whole process. There are multiple bodies offering advice, timing of advice vary and there are various intended outcomes, which depends on the stage of development.

In this session, the participants will discuss the following:

- Whether to seek scientific advice or not
- When is the right time to seek Scientific/Regulatory Advice
- Types of Scientific/Regulatory Advice EU and US
- Which agencies? Focus on EU and US
- How to select the EU route for scientific advice: EU CHMP or National

10:00 COFFEE BREAK

10:30 GROUP EXERCISE TO REFLECT ON THE TOPICS COVERED IN SESSION 1

11:00 SESSION 2

PLANNING, PREPARING AND MANAGING THE MEETING – EMA & FDA

This session will help you to plan and prepare properly for the meeting after a decision to seek advice is made. The session will discuss in-depth understanding and equip you with the right skill set for a successfully conducted meeting.

The session will include a “Preparing the right questions” group exercise.

- Initial planning and preparations from an industry perspective
- What kind of questions should be asked incl. group exercise
- Meeting requests and meeting packages EU and FDA

12:30 LUNCH BREAK

13:30 SESSION 2 CONTINUED

PLANNING, PREPARING AND MANAGING THE MEETING – EMA & FDA

- Storyline and key messages
- Rehearsals and Challenges
- How does the Agency prepare?
- Do's and don'ts – how to conduct the meeting

15:00 COFFEE BREAK

15:30 SESSION 3

WHAT HAPPENS AFTER THE AGENCY MEETING/FEEDBACK

- Debrief
- Meeting minutes
- What does the advice received mean and how it should be used? How to apply the learnings from the meeting and follow up where necessary
- Transparency

16:30 END OF THE TRAINING COURSE

Training Course Venue

Venue

NH Berlin Alexanderplatz

Landsberger Allee 26-32

10249 Berlin, Germany

Tel: +49 30 422 61 30

Email: nhberlinalexanderplatz@nh-hotels.com

www.nh-hotels.com/hotel/nh-berlin-alexanderplatz

DIA has booked a limited number of hotel rooms at the rate of EUR 96.90 per standard single room per night including breakfast, service charges and VAT.

If you would like to make a booking, please contact the hotel directly and quote the reference “DIA”:

Tel: +49 30 2238 02 33 or +800 0115 0116

Email: reservierungen@nh-hotels.com

The room rate is available until 26 March 2017 or until the room block is sold-out, whichever comes first.

HOW TO GET THERE

From Airport Berlin Tegel:

Travel by bus TXL until S+U Alexanderplatz Station.

Transfer to the M5 tram towards Zingster Strasse or the M6 tram towards Riesaer Strasse and exit at Klinikum im Friedrichshain Station.

The hotel is located across the street from the tram station.

Alternatively, travel by taxi for a 15-20 minute trip.

From Airport Berlin-Schönefeld:

Travel on the S9 train towards Westkreuz and exit at Alexanderplatz.

Transfer to either the M5 tram towards Zingster Strasse or the M6 tram towards Riesaer Strasse and exit at Klinikum im Friedrichshain Station.

The hotel is located across the street from the tram station.

Alternatively, travel by taxi for a 30-35 minute trip.

www.bvg.de/en

Continuing Education

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 4.5 credits.



Group Discounts

Register 3 individuals from the same company and receive a 50% discount for a 4th! All 4 individuals must register and prepay at the same time without exception. DIA will apply the value of the lowest applicable fee to this discounted registration; it does NOT include fees for optional events or DIA membership. You may substitute group participants of the same membership status at any time; however, administrative fees may be incurred.

Group registration is not available online and only available for the industry rate.

To take advantage of this offer, please print the registration form for each of the four registrants from your company. Include the names of all four group registrants on each of the forms and return them together to DIA.

For groups of 5 or more individuals, please contact Vishal.Bharadwaj@DIAGlobal.org for a custom group rate.

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About DIA

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The dedicated efforts of DIA staff, members and speakers enable DIA to provide a comprehensive catalogue of conferences, workshops, training courses, scientific publications and educational materials. DIA is a global community representing thousands of stakeholders working together to bring safe and effective products to patients.

DIA is an independent, non-profit organisation has its Global Center in Washington, DC, USA with the European office in Basel, Switzerland, and additional regional offices in Horsham, Pennsylvania, USA; Tokyo, Japan; Mumbai, India; and Beijing, China

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REGISTRATION FORM

EU Competent Authorities Scientific and Regulatory Advice #17544
24 April 2017, Berlin, Germany



REGISTRATION FEES

Registration fee includes refreshment breaks and lunches and electronic access to training course material. Please check:

FEES	MEMBER	NON-MEMBER
INDUSTRY	€ 800.00 q	€ 955.00 q
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	€ 400.00 q	€ 555.00 q

All registration fees are subject to applicable German VAT

Please enter your company's German VAT number: _____

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee.

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

DIA MEMBERSHIP

All non-members fees include a one year membership option. If you registered at one of the non-member rates noted above, you will automatically become a DIA member. Join DIA now to qualify to save on future events and to receive all the benefits of membership. Visit www.diaglobal.org and click on Membership for more details.

If you do not want a membership, please indicate your preference below:

I do not want complimentary membership

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: EMEA@DIAglobal.org **Mail:** DIA Europe, Middle East & Africa, Küchengasse 16, 4051 Basel, Switzerland

Web: www.DIAglobal.org

CANCELLATION POLICY

All cancellations must be made in writing and be received at the DIA Europe, Middle East and 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

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ATTENDEE DETAILS

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

Prof Dr Ms Mr

Last Name

First Name

Job Title

Company

Address

Postal Code

City

Country

Telephone Number

Fax Number

Attendee email required for course material access

PAYMENT METHODS

Credit cards: Payments by VISA, Mastercard or AMEX can be made by completing the details below. Please note that other types of credit card cannot be accepted.

Please charge my VISA MC AMEX

Card N°

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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 # 17544 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 and Africa.**

By signing below, I confirm that I agree with DIA's Terms and Conditions of booking. These are available from the office or on <http://www.diaglobal.org/EUTerms>

Date

Signature