

EU and US Health Authorities Scientific and Regulatory Advice

15 June 2018

Mercure Paris La Défense Grande Arche Hotel, Nanterre/Paris, France



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 discuss 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
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 questions:

- Whether to seek scientific advice or not
- How to select the route for scientific advice: centralized or national
- What kind of questions should be asked, what can you expect as an answer
- How to assess the right time to seek scientific advice

10:00 COFFEE BREAK

10:15 SESSION 1 CONTINUED

STRATEGY FOR SCIENTIFIC/REGULATORY ADVICE

Group Exercise

11:15 COFFEE BREAK

11:30 SESSION 2

PLANNING, PREPARING AND MANAGING THE MEETING – EMA & FDA

This session will help you to 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 discuss in an interactive manner:

- Preparations from the industry perspective
 - What data is required
 - Who should attend
 - How many should attend
 - Rehearsals – conduct during an agency meeting
- Preparations from the authority perspective

13:30 LUNCH BREAK

14:30 SESSION 2 CONTINUED

PLANNING, PREPARING AND MANAGING THE MEETING – EMA & FDA

Group Exercise – you will practice conducting the meeting with the HA and get feedback from the instructors.

15:30 COFFEE BREAK

15:45 SESSION 3

WHAT HAPPENS AFTER AN AGENCY ADVICE?

What does the advice received mean and how it should be used? At this session, you will learn how to apply the learnings from the meeting and follow up where necessary.

16:30 END OF THE TRAINING COURSE

Training Course Venue

PARIS LA DÉFENSE GRANDE ARCHE

17/20 Esplanade Ch. de Gaulle -
Rue des Trois Fontanot
92000 Nanterre (Paris region), France

Tel: +33 8 2580 5959

Fax: +33 1 4725 4624

Email: H1982@accor.com



DIA has blocked a limited number of hotel rooms at the rate of EUR 210.00 per standard room per night including breakfast and VAT, excl. City-Tax. If you would like to make a booking, please fill in the booking form available on www.DIAGlobal.org/RegAdvice and send it per email to aziza.elkharraze@accor.com with a reference “DIA”. Note: The hotel is located right above the train station, and it is a bit noisy.

The room rate is available until 10 May 2018 or until the room block is sold-out, whichever comes first.

HOW TO GET THERE

From Charles de Gaulle airport take the Blue train line B towards city centre and get off at Chatelet.

Change there to Red train line A towards Cergy/Poissy/St. Germain en-Laye and get off at Nanterre Prefect.

The hotel is located right next to the train station.

[Paris train/metro map](#) (the Nanterre Prefect station/hotel is located just outside this map, left from the square A2)

Plan Your Team's Professional Development

Why not take advantage and train your whole department (or even across different departments!) and benefit from increased:

- Focus
- Flexibility
- Convenience
- Cost Effectiveness

For more information please contact Basel@diaglobal.org.

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.

| 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 Basel@diaglobal.org for a custom group rate.

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| About DIA

DIA is the global connector in the life sciences product development process. Our association of more than 18,000 members builds productive relationships by bringing together regulators, innovators, and influencers to exchange knowledge and collaborate in an impartial setting. DIA's network creates unparalleled opportunities for exchange of knowledge and has the inter-disciplinary experience to prepare for future developments.

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

| Continuing Education

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 6 credits.



REGISTRATION FORM

EU and US Competent Authorities Scientific and Regulatory Advice #18544

15 June 2018 | Mercure Paris La Défense Grande Arche Hotel | Paris, France



REGISTRATION FEES

Registration fee includes refreshment breaks, lunches and electronic access to training course material. Please note that the full amount must be received by DIA by commencement of the course to get the electronic access to the material. Please check:

FEES	MEMBER	NON-MEMBER
INDUSTRY	€ 800.00 <input type="checkbox"/>	€ 955.00 <input type="checkbox"/>
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	€ 400.00 <input type="checkbox"/>	€ 555.00 <input type="checkbox"/>

All registration fees are subject to applicable French VAT

Please enter your company's French 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-member fees include a one year membership option. If you registered at one of the non-member rates, you have the opportunity to **become a DIA member** at no additional cost.

To explore membership benefits, please click [here](#). If you want a membership, please indicate your preference below.

☐ I would like to receive a one year complimentary DIA membership at no additional cost

The DIA 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: Basel@diaglobal.org **Mail:** DIA, Küchengasse 16, 4051 Basel, Switzerland

Web: www.DIAglobal.org

TERMS AND CONDITIONS

Cancellation Policy

All cancellations must be made in writing and be received at the DIA 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.

Event Stream and recording

If you attend a DIA event, we make video and audio recordings of events (both face-to-face and online) that may include your participation in the event, including your image, questions and comments. To view our full photography and video recording policy, click [here](#).

Privacy Policy

DIA respects the privacy of all of its members and customers. To view our privacy policy, click [here](#). You agree that your personal data will be transferred to DIA in the US

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°

Exp. Date /

Cardholder's Name

☐ **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 #18544 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.**

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