DIA Training Course on

Essentials and Overview of the Regulatory Framework in Europe

19-20 April 2016
Mercure Paris La Défense Grande Arche, Paris, France

OVERVIEW

The course will give an overview of the European regulatory system for human medicines, including the legislative processes and European networks, the different routes for obtaining a licence for the European market, the centralised, the decentralised and the mutual recognition procedures, and the national procedures. Different steps and timelines for the various procedures will be covered. An introduction to pharmacovigilance, variations and renewals will be given in the context of the lifecycle. In addition, the specific European procedures for orphan drugs, paediatrics, advanced therapies and combination products will be discussed.

The course will cover the current registration systems available for approval of human medicinal products:

- Regulation EC726/2004 on the centralised procedure, including specific marketing authorisations and the European Medicines Agency
- Directive 2001/83/EC 'the Community Code' on the Mutual Recognition Procedures

A case study will enable participants to apply the freshly gained knowledge into their daily practice.

This is a hands-on course. It is necessary that you bring your laptop/electronic device with you.

KEY TOPICS

- The European Regulatory Framework
- Marketing Authorisation for Medicinal products in the EU
- Lifecycle Management

WHO WILL ATTEND

Professionals in regulatory affairs, project management and product development.

LEARNING OBJECTIVES

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

- Explain the European Regulatory Framework and registration procedures
- Describe the concepts of marketing authorisation and regulatory data protection
- Discuss the key issues that impact the choice of the registration procedure
- Describe the lifecycle management

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

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PharmaTrain MASTERING MEDICINES DEVELOPMENT

FACULTY

Katarina Jelic Maiboe
Director, Regulatory Department
Novo Nordisk A/S, Denmark

Birka Lehmann
Director, Head of EU & International Affairs
Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM), Germany

CONTINUING EDUCATION

The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 13 credits.

DIA is an authorised training organisation accredited under the number 11 99 53383 75 to the Préfet of Ile-de-France.

DEVELOP. INNOVATE. ADVANCE.

DIA volunteers, members and staff provide a comprehensive catalogue of conferences, workshops, training courses, scientific publications and educational materials, throughout the year, all around the world.

DIAglobal.org

DAY 1

08:00 REGISTRATION

08:30 SESSION 1

EUROPEAN UNION – ROLE AND RESPONSIBILITIES OF EUROPEAN INSTITUTIONS. A COMPREHENSIVE OVERVIEW

Birka Lehmann

- Key organisations in the Marketing Authorisation Process
  - o European Commission
  - o European Medicines Agency (EMA)
    - Scientific Committees
  - o National Competent Authorities (NCAs)
    - Heads of Medicine Agencies (HMA)
- European Directorate for the Quality of Medicines (EDQM) and the European Pharmacopeia
  - o Cooperation between the organisations
- European Economic Area
  - o Importance of single market

10:00 COFFEE BREAK

10:30 SESSION 2

LIFECYCLE OF A MEDICINAL PRODUCT

Katarina Jelic Maiboe

- Short overview of the lifecycle of a medicinal product and the relevant procedures: From development to post-marketing – an overall reference
- Scientific Advice – Clinical Trials – Market Authorisation – Pharmacovigilance – Variations – Renewal

12:30 LUNCH BREAK

13:30 SESSION 3

EU LICENSING PROCEDURES – PART I

Birka Lehmann

- Basics for market authorisation
- National procedure
- Mutual recognition procedure
- Decentralised procedure

15:30 COFFEE BREAK

16:00 SESSION 4

EU LICENSING PROCEDURES – PART II

Katarina Jelic Maiboe

- Centralised procedure, incl. specific procedures like conditional approval

17:30 DRINKS RECEPTION

18:30 END OF DAY ONE

DAY 2

08:30 SESSION 5

VARIATIONS / POST APPROVAL CHANGES

Katarina Jelic Maiboe

- Definition of variations
- Classification of a variation
- Procedural guidance
- Renewals

09:30 SESSION 6

HANDS-ON WORKSHOP AND PRACTICAL EXAMPLES

Birka Lehmann and Katarina Jelic Maiboe

10:30 COFFEE BREAK

11:00 SESSION 6 CONTINUED

12:00 SESSION 7

HARMONISATION & DEFINED MEDICINAL PRODUCTS

Birka Lehmann

- Referrals
- Paediatric regulation
- Orphan medicinal products
- Herbals, homeopathics, advanced therapies
- Specific possibilities for Small & Medium size Enterprises (SME's)

12:30 LUNCH BREAK

13:30 SESSION 8

PHARMACOVIGILANCE

Katarina Jelic Maiboe

- Pharmacovigilance legislation
- Post-authorisation Safety Study (PASS) & Post-Authorisation Efficacy Study (PAES)
- Dossier requirements: Risk Management Plan (RMP), Periodic Safety Update Report (PSUR)
- Safety procedures / referrals
- Pharmacovigilance Risk Assessment Committee (PRAC)

15:00 COFFEE BREAK

15:30 SESSION 9

COMBINATION PRODUCTS

Birka Lehmann

- Combination of medicinal products and medical devices
- Which legislations are relevant?

16:00 KEY MESSAGES AND WHAT'S IN PIPELINE

16:30 END OF THE 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.

Training Course Venue

Mercure Paris La Défense Grande Arche
17/20 Esplanade Ch. de Gaulle - Rue des Trois Fontanot
92000 Nanterre/Paris, 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 180.00 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 the DIA website and send it per email to H1982@accor.com with a reference "DIA". The room rate is available until 18 March 2016 or until the room block is sold-out, whichever comes first.

About DIA

DIA is a neutral, non-profit organisation founded in 1964 with its global center located in Washington, DC, US and with regional offices covering North and South America (Horsham, Pennsylvania, US); China (Beijing); Europe, Middle East & Africa (Basel, Switzerland); India (Mumbai); and Japan (Tokyo).

Over the past 50 years, DIA grew to a global organisation with members from more than 80 countries. During this time, as the options to treat disease evolved, DIA's scope has expanded to keep pace with these innovations and smooth that rugged research path in a variety of ways.

DIA is the only organisation that enables everyone involved in health product development to share information on a global scale, in a neutral setting. Our goal is simple: To improve health and well-being by transferring knowledge from those who have it to those who need it.

DIA members—regulators, researchers, industry professionals, advocates and patients— join for a variety of reasons but share the common goal of improving human health and well-being worldwide.

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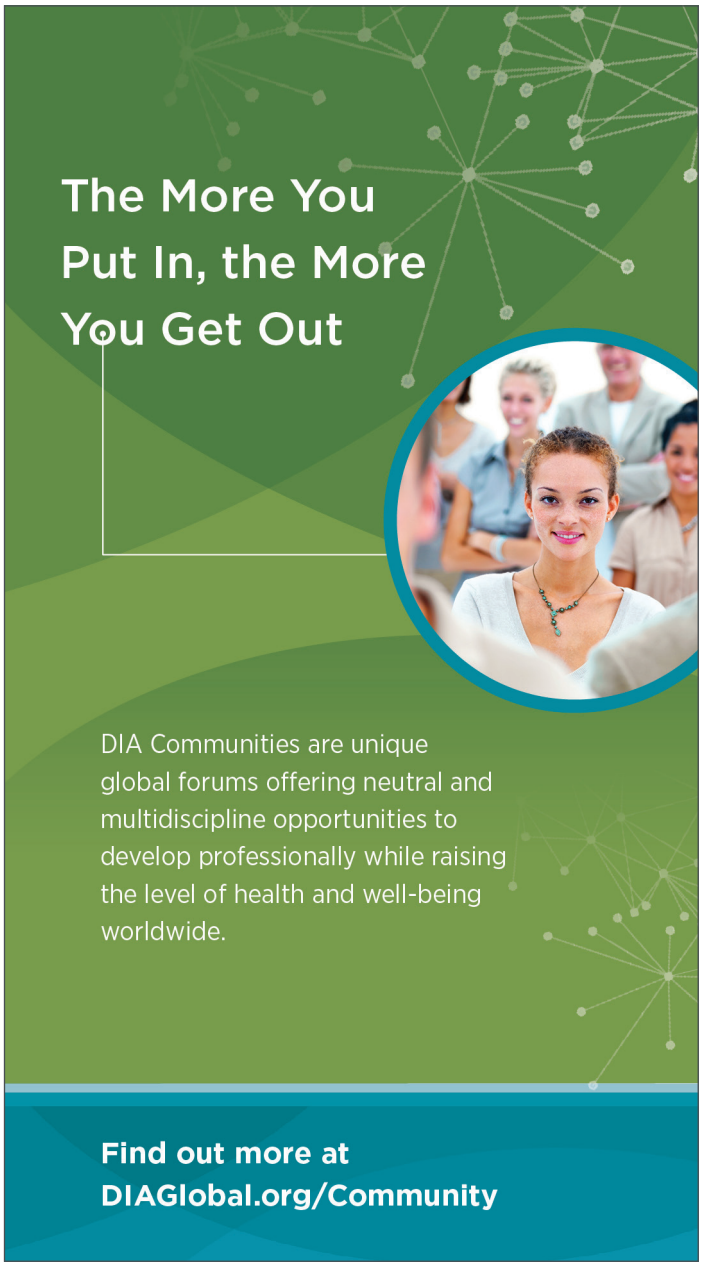

REGISTRATION FORM

Essentials and Overview of the Regulatory Framework in Europe # 16541
19-20 April 2016 | Mercure Paris La Défense Grande Arche | Paris, France

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REGISTRATION FEES

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

FEES	MEMBER	NON-MEMBER
INDUSTRY	€ 1'450.00 ❑	€ 1'605.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	€ 725.00 ❑	€ 880.00 ❑

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-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

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.

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

email (Required for confirmation) 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 # 16541 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

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