DIA Learning

Essentials and Overview of the Regulatory Framework in Europe

25-26 April 2017
NH Berlin Alexanderplatz, Berlin, Germany

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.

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.

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.

ONLINE BEFORE THE COURSE

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

Birka Lehmann

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

FACULTY

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

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

PharmaTrain
MASTERING MEDICINES DEVELOPMENT

DAY 1

08:00 REGISTRATION

08:30 Q&A ON WEBINAR

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

Birka Lehmann

09:00 SESSION 1

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

10:00 COFFEE BREAK

10:30 SESSION 1 CONTINUED

LIFECYCLE OF A MEDICINAL PRODUCT

Katarina Jelic Maiboe

- Scientific Advice – Clinical Trials – Market Authorisation – Pharmacovigilance – Variations – Renewal

11:30 SESSION 2

EU LICENSING PROCEDURES – PART I

Birka Lehmann

- Basics for market authorisation
- National procedure

12:30 LUNCH

13:30 SESSION 2 CONTINUED

EU LICENSING PROCEDURES – PART I

Birka Lehmann

- Mutual recognition procedure
- Decentralised procedure

14:30 SESSION 3

EU LICENSING PROCEDURES – PART II

Katarina Jelic Maiboe

- Centralised procedure, incl. specific procedures like conditional approval

15:30 COFFEE BREAK

16:00 SESSION 3 CONTINUED

EU LICENSING PROCEDURES – PART II

Katarina Jelic Maiboe

- Centralised procedure, incl. specific procedures like conditional approval

16:30 SESSION 4

WHERE TO FIND WHAT / WHAT TO FIND WHERE?

Birka Lehmann

17:00 NETWORKING RECEPTION

18:00 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

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. QUESTIONS AND ANSWERS

16:30 END OF THE TRAINING COURSE

Training Course 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

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 13 credits.

SwAPP Swiss Association of Pharmaceutical Professionals

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REGISTRATION FORM

Essentials and Overview of the Regulatory Framework in Europe # 17541
25-26 April 2017 | NH Berlin Alexanderplatz | Berlin, Germany

DIA Learning

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 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

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

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 # 17541 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