DIA Learning

Essentials and Overview of the Regulatory Framework in Europe

3-4 June 2019
DIA, Europe, Middle East, and Africa office, Basel, Switzerland

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 an online knowledge check at the end of the course to ensure learning objectives are attained.

KEY TOPICS

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

WHO WILL ATTEND

Professionals with 1-2 years' experience in regulatory affairs, project management and product development.

FACULTY

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

Birka Lehmann
Senior Expert Drug Regulatory Affairs
Germany

PharmaTrain
MASTERING MEDICINES DEVELOPMENT

DAY 1

08:00 REGISTRATION

08:30 INTRODUCTION

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 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

HANDS-ON WORKSHOP AND PRACTICAL EXAMPLES

Birka Lehmann and Katarina Jelic Maiboe

12:00 SESSION 7

HARMONISATION AND 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

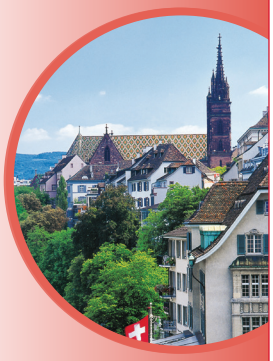
Birka Lehmann

- 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



DIA, EUROPE, MIDDLE EAST, AND AFRICA OFFICE
Küchengasse 16
4051 Basel, Switzerland
Tel: +41 61 225 51 51
Email: basel@diaglobal.org

The office is located within 1 min walking distance from the Basel SBB train station.

HOW TO GET THERE
Route from the EuroAirport Basel Mulhouse Freiburg
Please exit the Airport through the Exit to Switzerland.
Take Bus Nr 50 towards Basel SBB.

Arrival by Train
From Germany: exit at station Badischer Bahnhof and take Bus Nr 30 towards Basel SBB.
From Switzerland: exit at station Basel SBB.

Arrival from Zurich Airport
There is a direct train service every hour from Zurich Airport to Basel SBB (travel time approx 1 h 30 min).

Hotel Accommodation

Participants are kindly requested to make their own hotel bookings at any of the nearby hotels.
www.basel.com

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.

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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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.

REGISTRATION FORM

Essentials and Overview of the Regulatory Framework in Europe # 19541

3-4 June 2019 | DIA, Europe, Middle East, and Africa office | Basel, Switzerland

DIA Learning

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	€ 1'450.00 ❑	€ 1'605.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	€ 725.00 ❑	€ 880.00 ❑
A special discount for SMEs on the standard fee is available for a limited number of places. To prove your status as an SME, a confirmation of the European Medicines Agency is necessary. Please contact DIA for more information.		

All registration fees are subject to applicable Swiss VAT

Please enter your company's Swiss 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 nonmember fees include a one year DIA membership, at no additional cost. Explore membership benefits at **DIAglobal.org/Membership**.

DIA membership will renew automatically at the end of the complimentary membership term, at the then current membership rates. You may cancel automatic membership renewal at any time by accessing your account online at **DIAglobal.org**. If you would like to decline complimentary membership, please indicate your preference below.

❑ **I would like to decline a one year complimentary DIA membership.**

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

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

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 #19541 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