DIA Training Course on

European Regulatory Affairs

In-depth Review of Current Registration Procedures in the European Union

Course # 13550
6-7 June 2013
Dorint an der Messe Basel Hotel, Basel, Switzerland

Instructor

Brenton E. James
Consultant in Strategic Regulatory Affairs in the European Union, UK

Overview

The course will cover the evolution of the registration systems available for approval of products since January 1995 in the European Union, together with major changes in New Medicines Legislation. Title IV of Regulation EC726/2004 on the European Medicines Agency - Responsibilities and Administrative Structure, came into effect on May 20, 2004. The remainder of the Regulation and all of Directive 2004/27/EC became effective in November 20, 2005.

The very important changes in New Medicine Legislation concerning regulatory procedures, access to Centralised and Mutual Recognition Procedures, reduction in Regulatory Data protection will be described in detail.

Detailed review will be offered on the changed Centralised and Mutual Recognition Procedures and New Decentralised Procedure with discussion of practical examples of product types suitable for each procedure.

Other issues that impact on successful regulatory strategy in Europe, Harmonisation of Summary of Product Characteristics, Article 30 and Article 31 referrals and Supplementary Protection Certificate for Patents will be described.

Also reviewed and discussed is the legal status of medicinal products and the procedure for switching from prescription only sale to OTC sale, legislation controlling medical devices and the Clinical Trial Directive.

This course will provide strategic advice on how to file applications for the marketing authorisations in the European Union for staff involved in regulatory affairs.

Regulatory strategy which impacts on commercial, business and licensing arrangements will be of importance to those responsible for business development.

Key Topics

- European Union
- Centralised Procedure
- Decentralised Procedure
- Mutual Recognition Procedure
- National Procedure
- Key issues to consider for business opportunities
- Regulatory strategy
- Legal status of products and switching from Rx to OTC
- Medical devices legislation
- Clinical Trial Directive

Who Will Attend

Professionals in regulatory affairs, clinical research, project management, toxicology, product development and data management.

Objectives

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

- Explain the registration procedures for filing applications for medicinal products in the European Union and recognise which routes are available for each product type (NCE, biotechnology, OTC and generic)
- Describe the concepts of global marketing authorisation and regulatory data protection
- Discuss the key issues that impact the choice of the registration procedure including trademarks and patents
- Describe the legislation effecting medical devices and procedures for obtaining Clinical Trial and Ethics Committee approval in Europe

Continuing Education

DIA meetings and training courses are generally approved by the Commission for Professional Development (CPD) of the Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society of Pharmaceutical Medicine (SGPM) and will be honoured with credits for pharmaceutical medicine. All participants are eligible for these credits.

This course has limited capacity. Register early.

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MASTERING MEDICINES DEVELOPMENT

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www.diahome.org

THURSDAY | 6 JUNE 2013

12:30 REGISTRATION

13:00 Session 1

EUROPEAN UNION
- Development of European Union
- European Economic Area
- Role and responsibilities of European institutions
- European Monetary Union
- Importance of single market
- Medicines Control in the European Union

14:30 COFFEE BREAK

15:00 Session 2

CENTRALISED PROCEDURE
- Centralised Procedure
- Types of Products: Optional and mandatory scope
- European Medicines Agency and its Work Programme
- Committee for Medicinal Products for Human Use
- New Scientific Committees of the European Medicines Agency (PDCO, CAT)
- Presubmission dialogue and scientific advice
- FDA/European Medicines Agency Parallel Scientific Advice
- Procedure for filing applications
- Rapporteurs Nomination Procedure
- Scientific Advisory Groups
- Importance of translations
- Role of European Commission
- Experience to date

17:00 DRINKS RECEPTION

18:00 END OF DAY ONE

FRIDAY | 7 JUNE 2013

08:30 Session 2 (continued)

CENTRALISED PROCEDURE

09:30 Session 3

DECENTRALISED AND MUTUAL RECOGNITION PROCEDURES
- Procedure for filing applications
  - Types of products
- Selection and role of reference Member State
- Coordinating Group for decentralised and mutual recognition procedure [CDMh]
- Access for line extensions
- Grant of National Authorisations
- Variations
- Inspections/samples
- Generic Medicinal Products
- Experience to date

10:45 COFFEE BREAK

11:00 Session 4

NATIONAL PROCEDURE
- EU Commission Communication (July 1998) - Line extensions

11:15 Session 5

KEY ISSUES TO CONSIDER FOR BUSINESS OPPORTUNITIES
- Arbitration - Use of Article 30, 31
- Supplementary Protection Certificates (= Patent Term Restoration)
- Market exclusivity
- Co-marketing and co-promotion
- Trademarks
- CADREAC
- ORPHAN medicinal products

11:45 Session 6

REGULATORY STRATEGY
- Information sources
- How to be successful with registration Procedures in the European Union

12:00 Session 7

NEW MEDICINES LEGISLATION IMPACT
- Regulation for Advanced Therapy Products
- Support for small and medium sized enterprises
- Regulation for financial penalties
- Paediatric regulation

12:30 LUNCH

13:30 Session 7

LEGAL STATUS OF PRODUCTS AND SWITCHING FROM PRESCRIPTION TO OTC
- EU Commission Guideline
- Criteria for classifying a medicinal product without a medical prescription

14:30 COFFEE BREAK

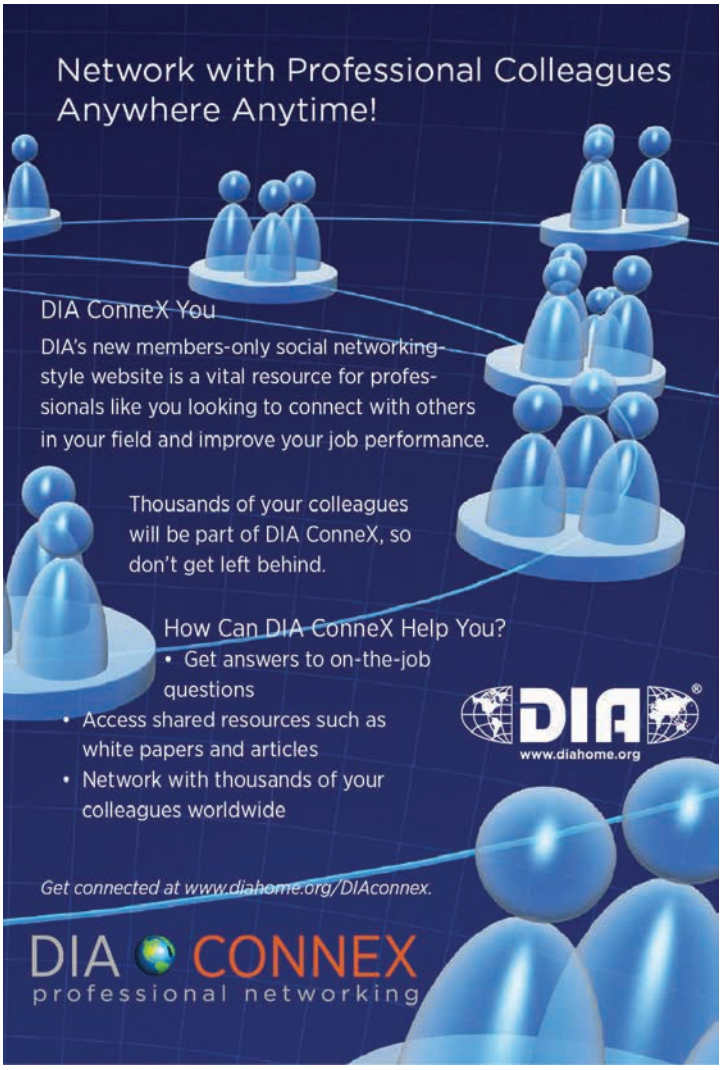
14:45 Session 8

MEDICAL DEVICES
- Three directives on medical devices
- CE marking
- MHRA Guidance on Medical Devices
- Future legislation

15:15 Session 9

CLINICAL TRIAL DIRECTIVE
- Overview of the Directive
- Commission Guidances
- Submission to competent authority

16:00 END OF THE TRAINING COURSE



DIA 2013 Training Courses in Regulatory Affairs

- **Authorisation of Biopharmaceuticals, Biosimilars and Advanced Therapies in Europe**
  18-20 September 2013 | Basel, Switzerland | ID 13546
- **European Regulatory Affairs: In-depth review of current registration procedures in the European Union**
  21-22 February 2013 | Berlin, Germany | ID 13525
  6-7 June 2013 | Basel, Switzerland | ID 13550
  21-22 November 2013 | Paris, France | ID 13553
- **Good Management of Medical Devices including In Vitro Diagnostics and Companion Diagnostics: Legal and practical aspects as used in personalised medicine**
  10-12 June 2013 | Amsterdam, Netherlands | ID 13547
- **Health Authority Interactions – Preparation, consultation and implementation**
  15-16 October 2013 | Location to be confirmed
- **Health Technology Assessment (HTA)**
  26-27 November 2013 | Zurich, Switzerland | ID 13561
- **Paediatric Investigation Plans (PIP)**
  15-16 April 2013 | Amsterdam, Netherlands | ID 13503
- **The Impact of Regulatory Affairs on Chemistry, Manufacturing & Controls (CMC)**
  2-4 October 2013 | Basel, Switzerland | ID 13532
- **US Regulatory Affairs: A comprehensive review of regulatory procedures for INDs and NDAs in the US**
  6-8 November 2013 | Paris, France | ID 13552

ABOUT DIA

The DIA is a global association of approximately 18,000 members who are involved in the discovery, development, regulation, surveillance or marketing of pharmaceuticals or related products. The DIA is committed to the broad dissemination of information on the development of new medicines or generics, biosimilars, medical devices and combination products with continuously improved professional practice as the goal.

The DIA is an independent non-profit organisation. The voluntary efforts of DIA members and speakers allow the DIA to organise conferences, workshops and training courses and provide publications and educational material.

DIA's headquarters are in Horsham, PA, USA, with the European office in Basel, Switzerland, and other regional offices in Tokyo, Japan, Mumbai, India, and Beijing, China.

For more information, visit www.diahome.org or call DIA Europe on +41 61 225 51 51.

HOTEL INFORMATION

The DIA has blocked a limited number of rooms at the following hotel:

Dorint an der Messe Basel Hotel
Schönaustrasse 10
4058 Basel
Switzerland
Email: info.basel@dorint.com
Tel: 0041 61 695 70 00
Fax: 0041 61 695 71 00
Website: www.dorint.com/basel

at the rate of:
CHF 230.00 per standard room, single occupancy inclusive of breakfast buffet, VAT & mobility ticket.

To make your reservation please use this booking form available on the DIA website.

IMPORTANT: Please complete your reservation by 06.05.2013. Reservations received after this date will be subject to hotel availability and room rate may vary.

CANCELLATION: Cancellations of reservations are possible until +31 days prior to arrival. No shows will be billed for the entire stay.

REGISTRATION FORM

DIA Training Course on European Regulatory Affairs
6-7 June 2013 I Dorint an der Messe Basel Hotel, Basel, Switzerland

www.diahome.org
ID # 13550

FEES

		Member*	Non-Member*
Industry	€	1'155.00 ❑	€ 1'270.00 ❑
Academia/Charitable/Government/Non-profit (Full-Time)	€	578.00 ❑	€ 693.00 ❑
Join DIA now to qualify for the member rate	€	115.00 ❑	

*All fees will be subject to the Swiss VAT at 8 %

Group discount/SME rates available. Special rates for students and patient representatives on offer, subject to avaibility – please contact DIA Europe for more information.

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

Registration fee includes: refreshments, lunches and training course material

TOTAL AMOUNT DUE: _____

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

ATTENDEE DETAILS

PLEASE COMPLETE IN BLOCK CAPITAL LETTERS OR ATTACH THE ATTENDEE'S BUSINESS CARD HERE

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name

First Name

Company

Job Title

Address

Postal Code City

Country

Telephone

Fax

Email*

*(Required for confirmation)

DIA reserves the right to include your name and affiliation on the attendee list.

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, Event ID # 13550 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.**

If you require a hardcopy of our terms and conditions, please contact our Customer Service Team.

By signing below, I confirm that I agree with DIA Europe's Terms and Conditions of booking.

Date	Signature

Cancellation Policy

All cancellations must be made in writing and be received at the DIA Europe office five working days prior to the event start date. Cancellations are subject to an administrative fee:

- Full Meeting Cancellation: Industry (Member/Non-member) = € 200.00.
- Academia/Charitable/Government /Non-profit (Full-Time) (Member/Non-member) = € 100.00.
- Tutorial cancellation: € 50.00.

If you do not cancel five working days prior to the event start date and do not attend, you will be responsible for the full registration fee. DIA Europe reserves the right to alter the venue and dates if necessary. If an event is cancelled DIA Europe 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 Europe 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 Europe in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership.

The DIA Europe Customer Services Team will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CET.

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