DIA/EUCRAF Training Course on

Authorisation of Biopharmaceuticals, Biosimilars, and Advanced Therapies in Europe

Course #13546
18-20 September 2013
Dorint Hotel an der Messe, Basel, Switzerland

Faculty

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Learning Objectives

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

- Identify the relevant stakeholders and pathways for regulatory submissions in the EU
- Describe the unique approach required to develop and to authorise complex biopharmaceuticals, compared to conventional pharmaceutical products
- Describe the key quality issues specific to biopharmaceuticals and apply them to the regulatory process
- Identify the implications of changes in the manufacturing process on the quality of the product
- Identify the relevant documentation for the non-clinical and clinical parts of submissions of biopharmaceuticals
- Explain the particulars of, and the data requirements specific to, the main product classes of biopharmaceuticals, ATMPs and biosimilars
- Understand common flaws in regulatory submissions and best practices relevant for European submissions

This course has limited capacity. Register early.

This 3-day training course focuses on the highly important contribution of biopharmaceuticals to new drug development. As the functions of biopharmaceuticals are fully explored and utilised, they will become increasingly relevant to the drug development community.

Serious estimates suggest that 30% to 50% of newly authorised medicinal products are biopharmaceutical in nature. Biopharmaceuticals stem from a biological source with their protein structure transcribed from genetic information and expressed by a living cell. They are usually large and complex and their quality is determined by the manufacturing process where consistency and stability are extremely important. Biopharmaceuticals are pleiotropic and immunogenic and their non-clinical pharmacodynamic and safety characterisation is often hampered by lack of relevant animal models. Advanced Therapy Medicinal Products (ATMPs) are examples of innovative technologies used to develop and manufacture biopharmaceuticals. All these factors have implications for the way biopharmaceuticals are developed and regulated. European pharmaceutical legislation contains regulations specific to biopharmaceuticals and these will be covered in this course.

Overview

The course introduction provides an overview of both classical and biotechnology derived medicinal products and of the pathways used for scientific advice, clinical trials and marketing authorisations in Europe. The course will also cover in detail the particular requirements for the Chemistry, Manufacturing and Controls (CMC) section, comparability packages, and the important safety procedures required for infectious agents.

The particular aspects of non-clinical and clinical development of biopharmaceuticals will be presented. A case study discussing how to develop a protein, without the relevant animal model, will also be examined. Case studies on mono-clonal antibodies will illustrate the approach taken to identify benefit/risk ratio. An overview will be given on the most essential issues relating to ATMPs. A detailed presentation of the specific considerations for the development of biosimilar medicinal products, part of the EU provisions related to biopharmaceuticals, will be given during the course.

Key Topics

- Definition and characteristics of biopharmaceuticals
- Topics of particular relevance to biopharmaceuticals such as comparability, immunogenicity, adventitious safety, bioassays
- ATMPs
- Biosimilar medicinal products
- Modules 3, 4 and 5 of the EU Common Technical Document (CTD) of biopharmaceuticals
- Regulatory pathways for scientific advice, clinical trials and marketing authorisations of biopharmaceuticals

Who Will Attend

Regulatory affairs and clinical research professionals who wish to focus their career on biopharmaceuticals or who wish to update their existing knowledge.
This course is particularly relevant to junior and intermediate level regulatory affairs professionals.

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.

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DAY ONE

08:00 REGISTRATION

08:30 WELCOME AND INTRODUCTION

08:45 Session 1

DEFINITION AND CHARACTERISTICS OF BIOPHARMACEUTICALS

- Definition of biopharmaceuticals
- What is special about biopharmaceuticals compared to conventional medicinal products?
- Product classes and therapeutic areas
  - o Recombinant products
  - o Classical biological products
  - o ATMPs
  - o Biosimilars

10:00 COFFEE BREAK

10:30 Session 2

ESSENTIALS OF THE EUROPEAN REGULATORY PROCEDURES FOR SCIENTIFIC ADVICE AND SUBMISSIONS OF CLINICAL TRIAL AND MARKETING AUTHORISATIONS

- Regulatory procedures applicable to clinical trials and marketing authorisations
- Agencies involved
- Scientific advice
- Best practices for regulatory submissions in the EU

12:30 LUNCH

13:45 Session 3

THE QUALITY MODULE 3 OF THE CTD FOR BIOPHARMACEUTICALS

- Overview of Module 3 requirements for biopharmaceuticals
- Pharmaceutical development
- Manufacture of drug substance and drug product
- Consistency, validation, batch analysis
- Impurities - sources, detection methods and removal
- Characterisation, analytical testing and bioassay particulars
- Drug product delivery systems and stability

15:45 COFFEE BREAK

16:15 Session 4

THE COMPARABILITY EXERCISE FOR MANUFACTURING PROCESS CHANGES

- Concept, relevant guidelines, experience
- Practical cases to illustrate how to establish the comparability package
- Relevance of analytical data and the need for non-clinical or clinical data
- Regulatory strategy for preparing submissions of comparability packages for regulatory approval

18:15 DRINKS RECEPTION

19:00 END OF DAY ONE

DAY TWO

08:30 Session 5

ADVENTITIOUS AGENTS' SAFETY EVALUATION AND EDQM TSE-RELATED CERTIFICATION

10:30 COFFEE BREAK

11:00 Session 6

GROUP DISCUSSION ON TYPICAL CMC ISSUES

12:00 LUNCH

13:15 Session 7

REGULATORY PRINCIPLES RELEVANT FOR ATMPs AND CURRENT EXPERIENCE WITH MARKETING AUTHORISATION APPLICATIONS AND CLINICAL TRIAL APPLICATIONS

- Experience with recent ATMP submissions
- Certification
- Guidelines
- Principle data requirements as compared to recombinant proteins

14:30 COFFEE BREAK

15:00 Session 8

THE NON-CLINICAL DEVELOPMENT PROGRAMME FOR RECOMBINANT PROTEINS

- What is special about recombinant proteins?
- Module 4 of the CTD
- Non-clinical data requirements for early phase clinical trials
- Data requirements for later phases of clinical development and for marketing authorisation applications
- Guidelines on first-in-man (FIM) clinical trials

17:00 Session 9

GROUP WORK: A CASE STUDY ON A NON-CLINICAL PROGRAMME OF A CHALLENGING MOLECULE

18:15 END OF DAY TWO

DAY THREE

08:30 Session 10

THE CLINICAL DEVELOPMENT OF BIOPHARMACEUTICALS

- Success factors for marketing authorisation applications
- What is special in early phase development?
- Target indication determines the pivotal trial design
- Efficacy and safety data requirements
- Benefit/risk assessment

10:00 COFFEE BREAK

10:30 Session 11

GROUP WORK: CASE STUDY OF MONOCLONAL ANTIBODIES ILLUSTRATING HOW THE BENEFIT-RISK RATIO IS DETERMINED

11:30 Session 12

REGULATORY PRINCIPLES OF DEVELOPMENT OF BIOSIMILAR MEDICINAL PRODUCTS

- EU legal basis and guidelines
- EU product experience of authorised biosimilars
- The guideline on biosimilar mono-clonal antibodies

12:30 LUNCH

13:30 Session 12 (continued)

REGULATORY PRINCIPLES OF DEVELOPMENT OF BIOSIMILAR MEDICINAL PRODUCTS

15:30 Session 13

DISCUSSION AND WRAP-UP

16:00 END OF TRAINING COURSE

HOTEL INFORMATION

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

Dorint Hotel an der Messe
Schoenaustrasse 10
4058 Basel
Switzerland

Tel.: +41 61 695 7000
Fax: +41 61 695 7100
Email: info.basel@dorint.com
Website: www.dorint.com

at the rate of:
CHF 230.00 per room inclusive of breakfast, service charge and VAT, exclusive of city tax of CHF 3.50 per day.

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

Cancellations of reservations are possible until +31 days prior to arrival.

IMPORTANT: Please complete your reservation by 19 August 2013. Reservations received after this date will be subject to hotel availability and room rate may vary.

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.

REGISTRATION FORM

DIA/EUCRAF Training Course on Authorisation of Biopharmaceuticals, Biosimilars, and Advanced Therapies in Europe | 18-20 September 2013 | Dorint Hotel an der Messe, Basel, Switzerland

www.diahome.org

ID #13546

FEES

		Member*	Non-Member*
Industry	€	1'785.00 ❑	€ 1'900.00 ❑
Academia/Charitable/Government/Non-profit (Full-Time)	€	893.00 ❑	€ 1'008.00 ❑
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, Course ID #13546 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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