DIA Training Course on

The Development of Biopharmaceuticals

24-26 October 2016
Mercure Paris La défense Grande Arche, Paris, France

OVERVIEW

The scientific basis and data requirements for dossiers at different stages of development will be communicated for the quality, preclinical and clinical parts of regulatory submissions. Case-studies will be inserted for the practical application of knowledge gained. The training will be delivered as presentations on individual topics, interspersed by case studies and conclude with an outlook on further developments in this fast moving field.

This 3-day training course focuses on drug development of biopharmaceuticals which have become a pivotal point of pharmaceutical innovation and currently represent 30% to 50% of newly authorised medicinal products.

Participants will learn about the legislative and regulatory framework for biopharmaceuticals in Europe and the roles of the European Medicines Agency and National Competent Authorities in market access. This covers the clinical trial stage, licensing and the life-cycle of these products. Specific development paths will be delineated, such as those for biosimilars and Advanced Therapy Medicinal Products (ATMPs), the latter comprising somatic cell therapies, gene therapies and tissue engineered products.

LEARNING OBJECTIVES

- Identify the relevant stakeholders and pathways of the EU regulatory framework
- Understand the necessary steps and unique requirements in biopharmaceutical development
- Identify the key quality issues specific to biopharmaceuticals, including implications of changes in the manufacturing process
- Identify the required documentation for the non-clinical part of dossiers
- Know the clinical dossier aspects and considerations
- Understand the concept and peculiarities of the biosimilar path in the EU and beyond
- Classify ATMPs and understand the specific provisions and requirement for this class of products
- Have an awareness of common flaws in regulatory submissions and be able to apply best practices for regulatory submissions
- Have an outlook on future regulatory developments in Europe

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

- Regulatory pathways for clinical trials, scientific advice, early access and marketing authorisations of biopharmaceuticals
- Definition and characteristics of biopharmaceuticals
- Dossier requirements for clinical trials and modules 3, 4 and 5 of the EU Common Technical Document (CTD) of biopharmaceuticals
- Biosimilar medicinal products
- ATMPs
- Topics of particular relevance to biopharmaceuticals such as comparability, immunogenicity, bioassays, adventitious agents, quality by design, combination products

WHO WILL ATTEND

Regulatory affairs and clinical research professionals who wish to learn about biopharmaceuticals or update their knowledge

Early stage drug developers who need to chart their path for development

Practising physicians and pharmacists wanting to understand how these innovative products reach the market

DIA DEVELOP INNOVATE ADVANCE

PharmaTrain MASTERING MEDICINES DEVELOPMENT

FACULTY

Ilona Reischl
Senior Assessor
Austrian Medicines and Medical Devices Agency (AGES/BASG)
Austria

Domenico Criscuolo
Chief Executive Officer
Genovax
Italy

Tina Jovanovic Zinck
Regulatory Project Manager
Novo Nordisk A/S
Denmark

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 WELCOME AND INTRODUCTION

08:45 SESSION 1

REGULATORY PATHWAYS FOR CLINICAL TRIALS, LEGAL ASPECTS, SCIENTIFIC ADVICE AND MARKETING AUTHORISATION OF BIOPHARMACEUTICALS IN THE EU

Domenico Criscuolo, Tina Jovanovic Zinck, Ilona Reischl

- Regulatory procedures:
  - Clinical Studies:
  - Current procedure and Voluntary Harmonization Procedure (VHP)
- Non-interventional studies
- Clinical trials
  - Compassionate use/Named patient use
  - Marketing Authorisations
- Legal aspects
- Scientific advice procedure

10:30 COFFEE BREAK

11:00 SESSION 2

DEFINITION AND CHARACTERISTICS OF BIOPHARMACEUTICALS

Ilona Reischl

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

12:30 LUNCH

13:30 SESSION 3

THE QUALITY REQUIREMENTS FOR BIOPHARMACEUTICALS

Ilona Reischl

- 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
- Special considerations for Antibody Drug-conjugates and (Medical Device-) Combination products
- During clinical trials – Investigational Medicinal Product Dossier (IMPD)
- For Marketing Authorisation Module 3

15:30 COFFEE BREAK

16:00 SESSION 4

GROUP DISCUSSION ON TYPICAL CMC ISSUES

Domenico Criscuolo, Ilona Reischl

17:00 SESSION 5

ADVENTITIOUS AGENTS' SAFETY EVALUATION AND EDQM TSE-RELATED CERTIFICATION

Ilona Reischl

17:30 QUESTIONS AND ANSWERS

18:00 DRINKS RECEPTION

19:00 END OF DAY ONE

DAY 2

08:30 SESSION 6

THE NON-CLINICAL DEVELOPMENT PROGRAMME FOR RECOMBINANT PROTEINS

Tina Jovanovic Zinck

- What is special about recombinant proteins?
- Non-clinical data requirements for early phase clinical trials
- ICH S6, MABEL, NOAEL
- Module 4 of the CTD

10:30 COFFEE BREAK

11:00 SESSION 7

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

Domenico Criscuolo, Tina Jovanovic Zinck, Ilona Reischl

12:30 LUNCH

13:30 SESSION 8

THE CLINICAL DEVELOPMENT OF BIOPHARMACEUTICALS

Domenico Criscuolo

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

15:30 COFFEE BREAK

16:00 SESSION 9

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

Domenico Criscuolo

16:30 SESSION 10

THE COMPARABILITY EXERCISE FOR MANUFACTURING PROCESS CHANGES

Tina Jovanovic Zinck, Ilona Reischl

- 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

17:00 QUESTIONS AND ANSWERS

17:15 END OF DAY TWO

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.

Follow **@DrugInfoAssn**

Continuing Education

The Faculty of Pharmaceutical Medicine of the Royal Colleges of Physicians of the United Kingdom has accredited this training course with 21 CPD credits. The Swiss Association of Pharmaceutical Professionals (SwAPP) and the Swiss Society for Pharmaceutical Medicine (SGPM) have accredited this training course with 21 credits.

SwAPP Swiss Association of Pharmaceutical Professionals

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

DAY 3

08:30 SESSION 11

IREGULATORY PRINCIPLES OF DEVELOPMENT OF BIOSIMILAR MEDICINAL PRODUCTS

Domenico Criscuolo, Ilona Reischl

- EU legal basis and current guidelines
- EU product experience of authorised biosimilars
- Global development perspective

10:30 COFFEE BREAK

11:00 SESSION 12

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

Ilona Reischl

- Experience with recent ATMP submissions
- Certification
- Guidelines
- Principle data requirements as compared to recombinant proteins
- Data requirements for later phases of clinical development and for marketing authorisation applications

13:00 LUNCH

14:00 SESSION 13

OUTLOOK

Domenico Criscuolo, Ilona Reischl

- Transparency
- Accelerating market access – Adaptive pathways
- Involvement of Health Technology Assessment in regulatory procedures

16:30 END OF TRAINING COURSE

Training Course Venue

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
Website

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 19 August 2016 or until the room block is sold-out, whichever comes first.

REGISTRATION FORM

The Development of Biopharmaceuticals # 16545
24-26 October 2016 | Mercure Paris La défense Grande Arche | Paris, France

DIA DEVELOP INNOVATE ADVANCE

REGISTRATION FEES

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

FEES	MEMBER	NON-MEMBER
INDUSTRY	€ 1'870.00 ❑	€ 2'025.00 ❑
ACADEMIA/CHARITABLE/GOVERNMENT/NON-PROFIT (FULL-TIME)	€ 935.00 ❑	€ 1,090.00 ❑

All fees will be subject to the 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 # 16545 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