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

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

- 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.

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

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
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
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
17:00 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
18:00 END OF DAY TWO

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.

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DAY 3

08:30  SESSION 11
REGULATORY 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

11:00  SESSION 13
OUTLOOK
Domenico Criscuolo, Ilona Reischl
• Transparency
• Accelerating market access – Adaptive pathways
• Involvement of Health Technology Assessment in regulatory procedures

Questions & Answers, General Discussion

16:00  END OF TRAINING COURSE

VENUE INFORMATION
Fleming’s Hotel Wien-Westbahnhof
Neubauguertel 26-28
1070 Vienna, AT
Tel: +43 1 22 73 70
E-mail: wien@flemings-hotels.com
Website

Limited number of hotel rooms have been booked for DIA course participants at the Fleming’s Hotel Wien-Westbahnhof at rate of EUR 130.00 single room per night including breakfast, service charge, and VAT.

To make a booking please fill in the booking form available on the DIA website and send it to reservation.vie@flemings-hotels.com.

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REGISTRATION FORM
The Development of Biopharmaceuticals
# 15545 | 25-27 November 2015, Vienna, Austria

REGISTRATION FEES
Registration fee includes refreshment breaks and lunches and training course material.

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