



NON-CLINICAL AND CLINICAL DEVELOPMENT OF BIOPHARMACEUTICALS INCLUDING BIOSIMILARS AND THE MODULE 4 AND 5 REQUIREMENTS



06 – 09 MARCH 2012

University of Strasbourg, France

- Principles of non-clinical development
- Principles of clinical development
- Immunogenicity
- Case studies on monoclonal antibodies, erythropoietin and a biosimilar
- Case presentation on the tri-functional monoclonal antibody Catumaxomab
- Development and registration of biosimilars

EUCRAF - the European Centre for Regulatory Affairs Freiburg offers in collaboration with the University of Strasbourg the postgraduate Diploma „Regulatory Affairs for Biopharmaceuticals” developed by distinguished experts from authorities, universities and companies. EUCRAF is also a platform for Regulatory Affairs experts to facilitate the exchange on current matters related to biopharmaceuticals.

LIMITED NUMBER OF PLACES ONLY – REGISTER EARLY!

BIOPHARMACEUTICALS ARE SPECIAL – STAY-UP-TO-DATE!

CONTENT

Biopharmaceuticals play an important role in the pharmaceutical industry since they deliver an increasing number of candidates for new product developments. They are however special and require certain considerations in their pre-clinical and clinical development. They are pleiotrop and immunogenic and their non-clinical pharmacodynamic and safety characterisation is often hampered by insufficiently relevant animal models. Biosimilars are developed following a special regulation and expanded programme as compared to conventional generics. This all has implications on the way biopharmaceuticals are developed and regulated. The particulars of the non-clinical and clinical requirements of biopharmaceuticals are covered and the specific considerations on the development of biosimilar medicinal products are part of this seminar as well. This seminar also delivers tandem talks on successfully authorized products, such as a tri-functional monoclonal antibody and on a biosimilar. The seminar also introduces how to perform a benefit-risk assessment at the authorization stage and how to update it during the life-cycle of the product.

WHO WILL ATTEND:

All those who are working in the regulatory affairs department, in the pharmaceutical, pre-clinical and clinical development of recombinant proteins, monoclonal antibodies, vaccines, ATMPs, blood products, biosimilars. Especially regulatory affairs professionals, CROs involved in development, CEOs and CSOs of start-up SMEs who develop biopharmaceuticals.

FULL PROGRAMME: WWW.EUCRAF.EU

TAKE THIS SEMINAR AS FIRST IN THE SERIES OF NINE TO GET THE POSTGRADUATE DIPLOMA ON REGULATORY AFFAIRS FOR BIOPHARMACEUTICALS

UPCOMING SEMINARS IN 2012

SEMINAR 5 (19 – 20 APRIL 2012, Freiburg i. Br.)

Specific considerations for the development and authorizations of medicinal products for children

SEMINAR 6 (31 MAY – 1 JUNE 2012, Freiburg i. Br.)

Pharmacovigilance – Post-authorisation surveillance standards to meet regulatory requirements for product safety

SEMINAR 7 (11 – 13 JULY 2012, Strasbourg EDQM)

The roles of the supervising authorities and the essential characteristics of quality systems

SEMINAR 8 (5 – 7 SEPTEMBER 2012, Freiburg i. Br.)

Scientific advice, regulatory strategy and health technology assessment

SEMINAR 9, (11 – 12 OCTOBER 2012, Freiburg i. Br.)

Good Regulatory Affairs practice: communication skills, project management and tools for the daily practice

SPEAKERS



Paul Chamberlain
NDA Advisory Board



Gabriele Dallmann
Study Director EUCRAF,
Biopharmaceuticals Expert,
Formerly PEI



Simon Day
Statistical Expert, Roche



Ronald Grobe-Einsler
Consultant, Formerly Bayer



Thomas Kirchlechner
Sandoz Biopharmaceuticals Development



Bernd Müller-Beckmann
Formerly Head of Pharmacology and Toxicology,
Roche Diagnostics GmbH, Penzberg



Diane Seimetz
Executive Vice President and Chief Scientific Officer,
Fresenius Biotech



Jennifer Sims
Head of Biologics Safety & Disposition,
Translational Sciences, Novartis



Course Leaders:
Ronald Grobe-Einsler, formerly Bayer
Simon Day, Roche

06 MARCH 2012, 10.30 – 18.00

ROLAND GROBE-EINSLER

- Welcome and Introduction

BERND MÜLLER-BECKMANN

- Principles of non-clinical development
The non-clinical CTD
What is special in the non-clinical development of biopharmaceuticals
 - Unique characteristics of biotech products to be considered when designing a preclinical programme
 - Pharmacodynamic studies and disease models considerations for pharmacodynamic and toxicokinetic studies
 - Immunogenicity in non-clinical models

JENNIFER SIMS

- The Tegenaro case and its implications for the development of new biopharmaceuticals

07 MARCH 2012, 9.00 – 18.00

PAUL CHAMBERLAIN

- Immunogenicity
 - What is immunogenicity
 - How is immunogenicity caused
 - How is immunogenicity tested
 - Risk based approach

- Erythropoietin

SIMON DAY

- The principle of clinical development of biopharmaceuticals
 - Target rationale definition
 - Dose-finding justification
 - Proof of Concept and confirmatory studies
 - Relevant efficacy and safety studies – pivotal trials
 - Principles of the clinical review and decision on the benefit-risk conclusion
 - Module 2 sections 2.5 and 2.7.
 - Presentation of clinical data in Module 5 of the CTD

08 MARCH 2012, 9.00 – 18.00

RONALD GROBE-EINSLER

- Research to early development: a clinical pharmacology perspective
 - Future clinical Proof-of-concept strategies
 - Validity of biomarkers in drug development
 - Why large trials fail -- although effects (efficiency) have been seen in small studies

SIMON DAY AND GABRIELE DALLMANN

- Group work: Benefit-risk assessment for monoclonal antibodies
 - Herceptin
 - Remicade
 - Tysabri
 - Raptiva

DIANE SEIMETZ

- From scientific advice to successful marketing authorization – experience with the European authorization of the tri-functional monoclonal antibody Removab

09 MARCH 2012, 9.00 – 16.30

THOMAS KIRCHLECHNER

- Regulatory principles of development of biosimilar medicinal products in the various regions
 - EU
 - FDA
 - WHO
- Global development, experience with submissions in different regions
- Experience with Sandoz biosimilars
- Current considerations on regulatory requirements for monoclonal antibodies developed as biosimilars
- Biosimilar Case Study

REGULATORY AFFAIRS FOR BIOPHARMACEUTICALS

SEMINAR 4 PART II: NON-CLINICAL AND CLINICAL DEVELOPMENT OF BIOPHARMACEUTICALS
INCLUDING BIOSIMILARS AND THE MODULE 4 AND 5 REQUIREMENTS

Please send your registration form to: REGISTRATION FORM FOR SEMINAR 4 PART II

EUCRAF Ltd.,
Wippertstr. 2
79100 Freiburg,
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For any questions, please contact us by phone: +49 (0)761 13 73 44 24
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or via homepage: www.eucraf.eu

or via e-mail to:
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On receipt of your Registration Form we will confirm your provisional place and provide you with the details of the payment method via e-mail. An invoice will be sent separately. Payment must be received prior to the seminar.

I herewith confirm that I agree with EUCRAF's Terms and Conditions. For Terms and Conditions, please visit our website at www.eucraf.eu.

Signature

Date

HOW TO REACH

Strasbourg:

By plane:

Strasbourg International Airport (SXB) is located about 18 kms away from the city center and operates both domestic and international flights. A train is running every 15 minutes to and from the central train station (€3.60 including a tram connexion). The travel time is about 9 minutes.

For more information:

www.strasbourg.aeroport.fr/E/index.php

Karlsruhe/Baden-Baden Airport (FKB) is located about 60km away from Strasbourg. The easiest way to get to Strasbourg is to catch a bus from the airport to Baden-Baden Hauptbahnhof (Main Station) and then a train to Strasbourg.

For more information: www.badenairpark.de/sub_airport/index-en.html

By train:

Strasbourg can be perfectly reached by train. You can reach the venue by public transport: by tram (e.g from the train station) direction: ILLKIRCH-LIXENBUHL. Get off at LYCEE COUFFIGNA.

YOUR CONTACT PERSON



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