



SCIENTIFIC ADVICE, REGULATORY STRATEGY AND HEALTH TECHNOLOGY ASSESSMENT



5 – 7 SEPTEMBER 2012

Freiburg i. Br., Germany

- Regulatory strategy and global positioning of newly developed and existing products
- Pre-marketing interactions with regulatory agencies: scientific advice and pre-IND
- Concepts and tools to support regulatory processes
- Regulatory strategy for the introduction of changes in the manufacturing process
- Intellectual Property Rights
- Health Technology Assessment

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

According to the records of the EMA, constantly 25% of newly developed medicinal products submitted to the centralised authorisation procedure in Europe fail. This high failure rate is remarkable taking into account all the efforts installed in Europe within the 15 years from the time the EMA had been inaugurated. Numerous incentives are in place to stimulate regular pre-submission interactions with agencies to discuss the compliance of development programs with regulatory principles. Regulatory guidelines for all areas of drug development are available describing the regulatory standards. In order to translate these efforts into higher success rates of marketing authorisations an essential component of the overall regulatory strategy is the establishment of regular cross-functional interactions between teams of drug discovery and development, pharmaceutical development, marketing. Regulatory affairs should play an important role in this process. Health technology assessment is another increasingly important aspect of drug development, which requires earlier consideration in development concepts in the future. The seminar addresses concepts and tools by which strategic bridging is established and conducted efficiently in practice throughout the life cycle of the medicinal product.

WHO WILL ATTEND:

Regulatory affairs professionals and Health Policy Managers.

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

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

SPEAKERS



Stephane Andre
F. Hoffmann-La Roche Ltd.



Gabriele Dallmann
Study Director EUCRAF,
Biopharmaceuticals Expert, Former PEI



Thomas Ecker
EPC HealthCare GmbH



Susanne Heiland-Kunath
Senior Director, Head of IRA Konstanz,
International Regulatory Affairs, Takeda



Michelle Jessen
Senior Director of Regulatory Affairs, Micromet US



Boris Kreye
Bird & Bird



Jacques Mascaro
Elan



Jan Müller-Berghaus
Paul-Ehrlich-Institut



Michael Soldan
Senior Vice President Medical/Regulatory Affairs,
Biotest AG



Heike Wachenhausen
Lützeler Klümper Wachenhausen Rechtsanwälte,
formerly Novartis



5 SEPTEMBER 2012, 10.30 – 17.00

STEPHANE ANDRE

- Welcome and Introduction

JACQUES MASCARO

- Regulatory strategy
 - What is a regulatory strategy and when is it needed?
 - Which implication has a global development for a company and for the agencies involved?
 - Stakeholder and liaison functions
 - Active participation in development of new requirements
 - Choice of submission type and procedure
 - Management of product life cycle
 - Regulatory risk evaluation

THOMAS ECKER

- HTA as a new element of the regulatory strategy – national requirements and European initiatives
- Reimbursement in Europe
- Considerations on how to design clinical development programmes to be used for approval and HTA

6 SEPTEMBER 2012, 09.00 – 18.00

GABRIELE DALLMANN

- Strategic considerations on interactions with regulatory agencies
 - Introduction
 - Examples of how to plan national and EMA scientific advice activities

JAN MÜLLER-BERGHAUS

- Interactions with regulatory agencies in the EU to receive scientific advice
 - The procedure of the European scientific advice at the EMA
 - Process and experience
 - Documentation, discussion meeting
 - Follow-up and clarification
 - EU/US parallel scientific advice
 - The EMA's Innovation Task Force
- Scientific advice from the national competent authorities
 - Experience and process followed at the German competent authority, Paul-Ehrlich-Institut

STEPHANE ANDRE & JAN MÜLLER-BERGHAUS

- Interactive tandem session: Interactions of companies and agencies in the development of biopharmaceuticals

MICHELLE JESSEN

- Interactions with FDA in the pre-IND process
 - Pre-phase I and post-phase II meetings
 - Preparation, documentation, meeting, telephone conference, written procedure

7 SEPTEMBER 2012, 09.00 – 18.00

BORIS KREYE

- Pharmaceutical Intellectual Property (IP) strategy and practical considerations related to application and enforcement of patents in the EU

HEIKE WACHENHAUSEN

- Regulatory protection of medicinal products
 - Regulatory data exclusivity and lifecycle management
 - PIP compliance and SPC extension
 - Market exclusivity for orphan drugs

SUSANNE HEILAND-KUNATH

- A cross-functional strategic forum to support decision-making for regulatory processes
 - Life cycle of development projects
 - Regular interactions of regulatory affairs, clinical development, marketing, pharmaceutical development, pharmacovigilance
 - Tools, teams and deliverables
 - Preparation, briefing book, questions, discussion, minutes, internal communication
 - Gap analysis of data packages available for regulatory submissions
 - Involvement of external experts

MICHAEL SOLDAN

- Regulatory strategy for the introduction of changes in the manufacturing process
 - What is important in the manufacturing process
 - Planning changes of manufacture and comparability projects
 - When to demonstrate consistency
 - When to introduce a pre-clinical and clinical bridging study
 - Change control processes in practice

REGULATORY AFFAIRS FOR BIOPHARMACEUTICALS

SEMINAR 8: SCIENTIFIC ADVICE, REGULATORY STRATEGY AND HEALTH TECHNOLOGY ASSESSMENT

Please send your registration form to: **BOOKING FORM FOR SEMINAR 8**

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E-mail: info@eucraf.eu

or via homepage: www.eucraf.eu

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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

Freiburg:

Freiburg i. Breisgau is located in the South West of Germany, in the tri-national region of France-Germany-Switzerland.

By plane:

Freiburg is served by EuroAirport Basel-Mulhouse-Freiburg (<http://www.euroairport.com>). There is an airport shuttle bus to Freiburg.

Zürich, Stuttgart, Strasbourg or Frankfurt airports are other options.

By train:

Freiburg has an excellent connection via ICE express trains (<http://www.deutschebahn.com>).

By car:

By car you reach Freiburg via highway A5.



YOUR CONTACT PERSON



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THE VENUE

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