



WHAT CURRENTLY MATTERS FOR BIOPHARMACEUTICALS IN EUROPE

2nd Annual EUCRAF Workshop

2 – 3 February 2012
Freiburg i. Br., Germany

- **CHANGING REGULATORY ENVIRONMENT**

- Agencies' news and typical practical issues of the last year
- The new Pharmacovigilance legislation
- Biosimilar monoclonal antibodies
- Agency experience with Type II variations in manufacture
- EU and U.S. practice for new formulations and dosage forms
- Virus safety
- Clinical trials in the EU
- Academic research undergoing ATMP regulation
- Biopharmaceuticals in other regions
 - Japan
 - China

- **SCIENCE AND STRATEGY OF DEVELOPMENT**

- Personalised medicine
- Update on the ICH S6 guideline revision process
- Regulatory pathways and HTA



Limited number of places only – register early!

DEAR COLLEAGUES,

Following the particularly well received first workshop in 2011 concentrating on the product class of monoclonal antibodies it is a great pleasure to announce the programme of the second annual EUCRAF workshop. We would like to invite you to Freiburg again to meet colleagues to exchange ideas, share experiences and listen to talks covering topics of highest current interest and importance. This will be the second annual EUCRAF workshop and due to the overwhelmingly positive feedback we got after the first in 2011, we thought we stay with Freiburg as the location. Sounds as an invitation to the Freiburg biopharma summit to be scheduled regularly into your coming years' agenda!

Session 1 of the 2012 Workshop is dedicated to the changing regulatory environment. We cover the last years' news relevant for the European environment; the upcoming European Pharmacovigilance legislation; the status of biosimilars; the increase in manufacturing changes; formulation and changes of dosage forms in the EU and U.S.; the current status of adventitious virus risk assessment; the current and future considerations on the clinical trial authorization; clinical trials with ATMPs in the EU and requirements for authorization of biopharmaceuticals in Japan and China.

Session 2 is dedicated to the science and strategy of development of innovative biopharmaceuticals. Here we present current experience with personalised medicine developments; potential regulatory pathways taking into account the European HTA requirements and news from the ICH S6 guideline revision process.

With this mixture of regulatory and scientific themes we not only want to reach specialists from agencies and industry involved in the approval of new biopharmaceuticals but also those who define the relevant strategy and development programme.

Looking forward to welcoming you again in Freiburg!

Yours sincerely,
Gabriele Schäffner-Dallmann

On behalf of the Workshop Programme Committee

Jan Müller-Berghaus (Paul-Ehrlich-Institut) | Gabriele Dallmann (EUCRAF, Dallmann Life Science) |
Paul Chamberlain (NDA Advisory Board) | Anja Langeneckert (Roche) |
Johannes Löwer (Former President PEI & BfArM, President IABS) | Silvia Pfaff (Novartis) |
Monika Pietrek (Pietrek Associates) | Gertrud Thormann (HTS Consulting)

Thursday, 2.02.2012 9.00 am to 6.00 pm
Friday, 3.02.2012 8.15 am to 4.45 pm

Chair: Prof. Dr. Johannes Löwer

CHANGING REGULATORY ENVIRONMENT

Clinical trials for biopharmaceuticals in the EU – experience with the VHP, numbers, challenges and changes and overview on the review of the legislation

Ilona Reischl, AGES

The ONE Study as an example for daily practice in ATMP research – clinical research on a new somatic cell concept in renal organ transplantation

Edward Geissler, University Hospital Regensburg

Follow up on activities related to the guideline on biosimilar monoclonal antibodies

Christian Schneider, Paul-Ehrlich-Institut

Impact of the new Pharmacovigilance legislation on biopharmaceuticals – procedures, processes, impact

Monika Pietrek, Pietrek Associates

Don't forget them! Risks associated with virus contaminations

Johannes Löwer, President IABS

Introducing changes in the manufacture – nowadays common but also easy?

The current practice for an assessor

Steffen Gross, Paul-Ehrlich-Institut

Experience with the regulatory landscape in the EU and U.S. for the introduction of new formulations and new dosage forms

Lois Hinman, Novartis

A regular day-to-day schedule in the life of a European regulator – news, typical practical issues and concerns to deal with and wish list to industry

Gopalan Narayanan, MHRA

Recent trends in the regulatory practice of authorizing biopharmaceuticals in Japan

Tetsuya Tanimoto, PMDA

Requirements of authorization of biopharmaceuticals in China

Martina Schwinger, Novartis

Q & A Session for each topic!

SCIENCE AND STRATEGY OF DEVELOPMENT

Current scientific considerations in the preclinical development of biopharmaceuticals in 2012 following the news from the ICH S6 guideline revision process

Jennifer Sims, Novartis

Personalised medicine to deliver innovations of the future – what is the focus in development and what are the scientific and regulatory challenges?

Anja Langeneckert, F. Hoffmann-La Roche

Potential future regulatory pathways taking into account the European HTA requirements

Jan Müller-Berghaus, Paul-Ehrlich-Institut

EVENING RECEPTION on 2 February 2011, 7.00 pm
Network and exchange with other experts!



YOUR CONTACT PERSON



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VENUE

Novotel
Modern 4-star hotel in the heart of Freiburg within walking distance from the train station.
Konrad-Adenauer-Platz 2
79098 Freiburg im Breisgau

HOTELS

Hotel contingents available in

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www.hotel-victoria.de

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 (www.db.com).

By car:
By car you reach Freiburg via highway A5.

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Please send your registration form to:
European Centre for Regulatory Affairs, Freiburg
EUCRAF Ltd.
Wippertstr. 2
79100 Freiburg
GERMANY

or via email to: booking@eucraf.eu
or fax to fax number: +49 (0)761 13 73 444

Download the Registration Form: www.eucraf.eu
2 – 3 February 2012 – Freiburg i. Br., Germany

For any questions, please contact us
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www.eucraf.eu

Please check appropriate Fee

Before December 15th 2011

After December 15th 2011

Industry

Fee
1150 € + 19% VAT

Fee
1350 € + 19% VAT

SME

625 € + 19% VAT

725€ + 19% VAT

Academics/Health Authorities

250 € + 19% VAT

300 € + 19% VAT

EUCRAF Course Students

250 € + 19% VAT

300 € + 19% VAT

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if different

Name, First Name

Email

Job Title

Phone

Address

Company

Fax

City

Address

Special dietary requirements

Postal Code

City

Country

Postal Code

On receipt of your registration form we will confirm in writing your provisional place and provide you with the details of the payment method. An invoice will be sent separately. Payment must be received by January 19, 2012 at the latest. Final confirmation will be sent to you once payment is received.

SUBSTITUTIONS: If you are unable to attend, substitutions can be made at any time. In this case, please send the name and contact details of the substitute attendee to EUCRAF via email booking@eucraf.eu. **REFUNDS:** Refund requests must be in writing and faxed to +49 (761) 1373444. If your written request is received on or before January 10, 2012, you will receive a full refund minus a 100 € processing fee. After that time, no refunds will be accepted.

EVENT CANCELLATION: EUCRAF reserves the right to modify the material without notice or to cancel this event. If the event must be cancelled, registrants will be notified by EUCRAF in writing as soon as possible and will receive a full refund. EUCRAF will not be responsible for any costs incurred due to cancellation such as airfare penalties or others.

PHOTOS: EUCRAF reserves the right to take pictures of the workshop and to use them for marketing purposes such as flyer, brochure, etc.

Signature

Date

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