EUCRAF

5th Annual Biopharmaceuticals Meeting
What currently matters for Biopharmaceuticals

5 – 6 February 2015
Munich, Germany

EUCRAF

Chairs: Johannes Löwer, Gabriele Dallmann

DAY 1, THURSDAY, 5 FEBRUARY 2015

09.00 – 09.45	Registration and welcome coffee
09.45 – 10.00	Welcome to the Annual Meeting
10.00 – 10.30	Regulation and other factors influencing the development of biopharmaceuticals The innovators' perspective Joyce Tait, Innogen Institute, UK
10.30 – 10.45	Discussion
SESSION 1:	ROUNDUP OF THE LAST YEAR ON REGULATORY ACTIVITIES IN EUROPE AND THE US
10.45 – 11.15	News and trends in Europe: Update on the last year Marketing Authorisations and guideline activities Christian Schneider, Danish Health and Medicines Authority, CHMP Member
11.15 – 11.45	An update on the activities of the CAT Sol Ruiz, Spanish Medicines Agency, CAT Member
11.45 – 12.00	Session 1 panel discussion Featuring: Christian Schneider (Danish Health and Medicines Authority, CHMP Member), Sol Ruiz (Spanish Medicines Agency, CAT Member) and Jian Wang (Health Canada)
SESSION 2:	AN UPDATE ON THE PDCO ACTIVITIES
12.00 – 12.30	Where to go in the EU with the Paediatric Investigational Plan (PIP)? An update on the most recent PDCO work Dirk Mentzer, Paul-Ehrlich-Institut, PDCO Chairman
12.30 – 12.45	Discussion
12.45 – 13.45	Lunch break
SESSION 3:	BIOSIMILARS
13.45 – 14.15	News and trends in Europe: An update on the EMA Biosimilar Medicinal Products Working Party (BMWP) Martina Weise, BfArM, Vice-Chair BMWP
14.15 – 15.00	News and trends in the US: Update on biosimilars in the US Steven Kozlowski, FDA
15.00 – 15.30	Case study: Approval of biosimilar infliximab in Canada Jian Wang, Health Canada
15.30 – 16.00	Session 3 panel discussion Featuring: Martina Weise (BfArM), Christian Schneider (Danish Health and Medicines Authority), Steven Kozlowski (FDA), Jian Wang (Health Canada)
16.00 – 16.20	Coffee break
SESSION 4:	HTA
16.20 – 16.50	How is the approved SmPC understood by the HTA Bodies and why does it matter Beate Schäfer, BMS and Jan Müller-Berghaus, Paul-Ehrlich-Institut, CHMP Member
16.50 – 17.00	Discussion
SESSION 5:	APPROVAL OF DRUG-DEVICE COMBINATIONS
17.00 – 17.30	The trend in Marketing Authorisation Applications for biologicals covering drug-device combinations – how do we deal with them? Ilona Reischl, Austrian Medicines and Medical Devices Agency, CAT member
17.30 – 17.45	Discussion
17.45	Close of day one
18.30	Bus departure to the social event
19.00	Social event

DAY 2: FRIDAY, 6 FEBRUARY 2015

08.00 – 08.30	Welcome coffee with snacks
SESSION 6:	UPDATE ON THE CLINICAL TRIAL REGULATION
08.30 – 09.00	Preparedness for the Clinical Trial Regulation in the EU – A company perspective Surendra Gokhale, Roche
09.00 – 09.15	Discussion
SESSION 7:	UPDATE ON THE PRAC ACTIVITIES
09.15 – 09.45	Pharmacovigilance in the EU with emphasis on biopharmaceuticals – PRAC activities update Post-approval efficacy studies Doris Irene Stenver, Danish Health and Medicines Authority, PRAC Member
09.45 – 10.00	Discussion
SESSION 8:	SCIENCE AND STRATEGY OF DEVELOPMENT
10.00 – 10.30	Summary of the NC3R workshop held in June 2014: a future vision for non-clinical protein-based biotherapeutic development Jennifer Sims, Integrated Biologix GmbH
10.30 – 10.45	Discussion
10.45 – 11.10	Coffee break
11.10 – 11.45	New treatments for Ebola or other emerging diseases outbreaks – how does the expedited pathway work to make them available to patients? Michael Pfleiderer, Paul-Ehrlich-Institut, BWP Chairman
11.45 – 12.00	Discussion
SESSION 9:	LOOKING AT OTHER REGIONS: CANADA
12.00 – 12.45	Authorising biopharmaceuticals in Canada – pathways for biotech products, biologicals, vaccines, biosimilars and ATMPs Jian Wang, Health Canada
12.45 – 13.00	Discussion
13.00 – 13.30	Coffee breaks and snacks
SESSION 10:	NEWS IN CMC OF BIOPHARMACEUTICALS
13.30 – 14.15	Current topics discussed related to CMC of biopharmaceuticals - QbD – is this reality for Biopharma? - Critical findings in variations - Requirements for CMC changes of biosimilars Steffen Gross, Paul-Ehrlich-Institut
14.15 – 14.30	Discussion
SESSION 11:	NEWER DEVELOPMENTS EXPECTED DUE TO CURRENTLY PENDING COURT CASES
14.30 – 15.15	Protection of Biological Medicinal Products – Latest Developments - Data exclusivity: The concept of global MA under dispute? - CHMP opinions regarding "new active substance" status - Market exclusivity decisions - Paediatric exclusivity decisions - Supplementary protection certificates (SPCs): Biological substances as a challenge for national patent offices and courts Geneviève Michaux, Hunton & Williams
15.15 – 15.30	Discussion
15.30	Wrap-up and concluding remarks Chairs of the meeting
15.45	Close of the Annual Meeting

LIST OF SPEAKERS:

Joyce Tait, Innogen Institute, UK
Surendra Gokhale, Roche
Steffen Gross, Paul-Ehrlich-Institut
Steven Kozlowski, FDA
Dirk Mentzer, Paul-Ehrlich-Institut, PDCO Chairman
Geneviève Michaux, Hunton & Williams
Jan Müller-Berghaus, Paul-Ehrlich-Institut, CHMP Member
Michael Pfleiderer, Paul-Ehrlich-Institut BWP Chairman
Ilona Reischl, Austrian Medicines and Medical Devices Agency, CAT member
Sol Ruiz, Spanish Medicines Agency, CAT Member
Beate Schäfer, BMS
Christian Schneider, Danish Health and Medicines Authority, CHMP Member
Jennifer Sims, Integrated Biologix GmbH
Doris Irene Stenver, Danish Health and Medicines Authority, PRAC Member
Jian Wang, Health Canada
Martina Weise, BfArM, Vice-Chair BMWP

VENUE:

Holiday Inn Munich – City Centre
Hochstrasse 3
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Phone: +49-89-4803 - 0
Web: http://www.munich-meeting-centre.de/index.php/en/

EUCRAF

5TH ANNUAL BIOPHARMACEUTICALS MEETING

Please send your registration form to:
European Centre for Regulatory Affairs
EUCRAF Ltd.
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79100 Freiburg
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or via e-mail to: booking@eucraf.eu
or fax to fax number: +49 (0)761 13 73 444

Download the Registration Form:
http://eucraf.eu/annual-meeting-2015-registration
5 – 6 February 2015 - MUNICH, Germany

For any questions, please contact us
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http://www.eucraf.eu/annual-meeting-2015/

Please check appropriate Fee

	After 15 November
Industry	1250 € + 19% VAT ☐
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Academics/Health Authorities	500 € + 19% VAT ☐
EUCRAF Course Students	400 € + 19% VAT ☐

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Special dietary requirements

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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 31 January 2015 at the latest.

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) 13 73 444. If your written request is received on or before 18 January 2015, you will receive a full refund minus a 100 € processing fee. After that time, no refunds will be accepted.

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Signature

Date