EUCRAF

4th Annual Biopharmaceuticals Meeting

What currently matters for Biopharmaceuticals

27-28 FEBRUARY 2014

Munich, Germany

Meeting Co-chairs: Gabriele Dallmann & John Purves

Venue: Gaszählerwerkstatt, Munich, Germany

DAY 1, THURSDAY, 27 FEBRUARY 2014

10.00 – 11.00	**Registration and welcome coffee**
11.00 – 11.15	Welcome to the meeting
SESSION 1:	**ROUNDUP OF THE LAST YEAR ON REGULATORY ACTIVITIES IN EUROPE AND THE US**
11.15 – 12.15	News and trends in Europe: update of EMA activities including the Biosimilar Medicinal Product Working Party (BMWP) and Committee of Advanced Therapies (CAT) activities Christian Schneider (BMWP and CAT Chairman, Danish Health and Medicines Authority), Anne Cook (MHRA)
12.15 – 12.35	Optimising regulatory pathways - Roche examples Andrea Braun-Scherhag (Roche)
12.35 – 13.00	EMA contributions to facilitate innovation: current state of discussion Jan Müller-Berghaus (Paul-Ehrlich-Institut)
13.00 – 14.00	**Lunch**
14.00 – 15.00	News and trends in the US: update of FDA activities including the status of the FDA draft guidance on biosimilar product development Steven Kozlowski (FDA) (per remote video presentation)
15.00 – 15.15	The EMA-FDA biosimilar cluster Christian Schneider (Danish Health and Medicines Authority) and Steven Kozlowski (FDA)
15.15 – 15.45	**Session 1 panel discussion, chaired by workshop co-chairs, featuring:** Christian Schneider (CAT Chairman, Danish Health and Medicines Authority), Jan Müller-Berghaus (Paul-Ehrlich-Institut), Steven Kozlowski (FDA), Ilona Reischl (AGES), Anne Cook (MHRA), Andrea Braun-Scherhag (Roche)
15.45 – 16.15	Coffee break
SESSION 2:	**BIOSIMILAR MONOCLONAL ANTIBODIES: THEIR WAY TO THE MARKET**
16.15 – 17.00	Case study: the approval of the first biosimilar monoclonal antibody Anne Cook (MHRA) and Jan Müller-Berghaus (Paul-Ehrlich-Institut)
17.00 – 17.30	Thoughts on the value of clinical trials to demonstrate similarity: what is their role in the overall similarity package and what do they show us Jan Müller-Berghaus (Paul-Ehrlich-Institut)
17.30 – 18.00	**Session 2 panel discussion, chaired by workshop co-chairs, featuring:** Anne Cook (MHRA), Jan Müller-Berghaus (Paul-Ehrlich-Institut), Christian Schneider (Danish Health and Medicines Authority)
18.00	Close of day one
19.00	Social event

DAY 2: FRIDAY, 28 FEBRUARY 2014

08.00 – 08.30	Welcome coffee with snacks
SESSION 3:	**UPDATE ON THE CLINICAL TRIAL REGULATION AND THE PRAC ACTIVITIES**
08.30 – 09.00	Clinical trials in the EU: where do we stand with the update of the clinical trial regulations Ilona Reischl (AGES)
09.00 – 09.30	Practical implications including transparency initiative. Ilona Reischl (AGES)
09.30 – 10.00	Coffee Break
10.00 – 10.45	Pharmacovigilance in the EU with emphasis on bio pharmaceuticals – PRAC activities update Sabine Straus (CBG-MEB)
10.45 – 11.15	**Session 3 panel discussion, chaired by workshop co-chairs, featuring:** Ilona Reischl (AGES), Sabine Straus (CBG-MEB), Andrea Braun-Scherhag (Roche), Judith Creba (Novartis)
SESSION 4:	**SCIENCE AND STRATEGY OF DEVELOPMENT**
11.15 – 11.45	Experience with the pilot EMA-HTA joint scientific advice Judith Creba (Novartis)
11.45 – 12.15	Break with refreshments and snacks
12.15 – 13.00	Does innovation reach authorities: trends in scientific advice and review procedures: trends towards more Phase II studies, dose finding for biopharmaceuticals - novel Modelling and Simulation Group, devices in ATMP Jens Reinhardt (Paul-Ehrlich-Institut)
13.00 – 13.30	Is the legal pathway ready to regulate drug-diagnostic companion developments? Geneviève Michaux (Hunton & Williams)
13.30 – 14.00	**Session 4 panel discussion, chaired by workshop co-chairs, featuring:** Geneviève Michaux (Hunton & Williams), Jens Reinhardt (Paul-Ehrlich-Institut), Judith Creba (Novartis), Andrea Braun-Scherhag (Roche), Jan Müller-Berghaus (Paul-Ehrlich-Institut)
14.15	Wrap up and concluding remarks Co-chairmen
14.30	Close of meeting