IMMUNOGENICITY: Understanding The Regulatory Philosophy
13 – 14 October 2014, Munich, Germany
Following its inaugural introduction in 2012, EUCRAF is proud to announce its 2nd workshop on Immunogenicity taking place in Munich, Germany on October 13 - 14, 2014. The central theme of this workshop is understanding the regulatory philosophy that will specifically examine topics on how to comply and fulfill regulatory expectations for presentation of information required to mitigate immunogenicity-related risks of biotherapeutics.

Objective
The aim of this 1.5-day interactive workshop is to discuss and clarify suitable approaches for satisfying regulatory expectations for presentation of the information required to enable a balanced assessment of risks of undesirable immunogenicity.

Synopsis
The available regulatory guidelines explain the factors to be considered in planning and presenting studies on immunogenicity. However, the format of the regulatory dossier – both for clinical trial applications and marketing authorisation applications – does not provide an obvious opportunity to present a balanced and integrated assessment of the multitude of factors that could potentially interact to induce undesirable immunogenicity as well as the tailored measures to detect and mitigate the risks in order to contribute to a positive benefit/risk of the product.

In this workshop, EUCRAF brings together two experienced practitioners, Pekka Kurki from the Finnish Medicines Agency, a leading regulatory expert who has been closely involved in defining the EU regulatory approach, and Paul Chamberlain, an industry representative who has prepared immunogenicity data sections of regulatory dossiers for diverse product types, to debate options for an optimal strategy.

The programme incorporates presentations and interactive discussions that will explain the regulator’s perspective, allied to case examples to illustrate the nature of the information that should be included in regulatory submissions. Particular emphasis will be placed on explaining how the different elements of the risk identification process – intrinsic immunogenicity, systems biology, product quality attributes and conditions of use – may be integrated with the results of the non-clinical and clinical immunogenicity risk evaluation, and then linked to the Risk Management Plan.

Distinguishing features of this workshop
• Applied approach based on substantial experience of regulatory procedures
• Multi-disciplinary perspective
• Linkage of data presentation to a structured risk assessment

MODERATOR

Gabriele Schäffner-Dallmann
Study Director EUCRAF/ Biopharmaceuticals Expert
Dr. Gabriele Schäffner-Dallmann is an internationally renowned biopharmaceutical expert with more than 25 years of experience in drug development and regulatory affairs of biopharmaceuticals. At the Paul-Ehrlich-Institut where she was Head of the Section „Momo- and polyclonal antibodies“ she has been involved in the European process of authorisation of biopharmaceuticals and represented the PEI in committees and working parties of the EMA in London. Stimulated by discussions on the lack of an adequate training platform providing young professionals with the distinctive knowledge on biopharmaceutical-related regulatory affairs she initiated in 2006 an intensive dialogue with distinguished experts from authorities, universities and companies to develop EUCRAF. Dr. Dallmann works as a biopharmaceutical consultant and is involved in development, strategic and market access projects, regulatory submissions, scientific advice and due diligence procedures.

She is biologist with a PhD in immunology from Berlin University and visiting lecturer on biopharmaceuticals at Freiburg University.

SPEAKERS

Pekka Kurki
Finnish Medicines Agency
Dr. Pekka Kurki, M.D, Ph.D, acts as a research professor at the Finnish Medicines Agency (Fimea).
Before joining the Finnish regulatory agency in 1997, he worked in the pharmaceutical industry (clinical research), both in Europe and in the U.S.A. Dr. Kurki’s clinical specialty is internal medicine with sub-speciality in rheumatology. He has a teaching affiliation to the University of Helsinki (clinical immunology). His scientific interest also includes cell biology, immunology, rheumatology and regulatory science.

He has had several scientific positions at the European Medicines Agency (EMA), including the membership the Committee of Human Medicinal Products (CHMP, 2000-7), chairmanships of the working parties for comparability (2002-3), biosimilars (BMWP, 2004-7), cell therapy (2002-4), and cell-based medicinal products (CPWP 2005-7). In addition, he acted as the chair of the ad hoc group for xenogeneic cell therapy (2001-3), a member of the biologicals working party (BWP, 1998-9) and a member of the ad hoc innovation Think Tank group of EMA (2005-7).
Currently, he is an alternate member of the EMA management board and an expert in the BWP.

Paul Chamberlain
NDA Advisory Board / bioLOGICA Consulting
He has accumulated substantial industrial experience in the development of biopharmaceutical products. This experience includes a broad scientific background, incorporating the application of analytical and bioanalytical technologies to the quality control of therapeutic proteins. At MDS Pharma Services Paul was responsible for providing expert consulting on strategies for biopharmaceutical development programs as well as leading development teams responsible for the execution of contracted analytical, bioanalytical, non-clinical, clinical and regulatory services. In this role Paul prepared briefing packages to support Pre-IND and other regulatory agency discussions and defined activities associated with pertinent stagegates in the product development cycle – including lead candidate selection, manufacturability assessment and IND-enabling studies. He also served as a member of the Scientific and Regulatory Advisory Boards of different companies and was involved in due diligence assessments of various in/out-licensing opportunities. In order to focus on strategic planning and the preparation of responses to regulatory agency questions Paul formed his own consulting practice, bioLOGICA Consulting, in July 2007. In addition, in October 2007, Paul was appointed to the Advisory Board of NDA Regulatory Science (www.ndareg.com), where he collaborates with former senior European regulators. FDA-facing experience includes involvement in the preparation of IND’s and BLA’s for recombinant proteins, as well as direct interactions up to the level of FDA Advisory Committee meetings to support product registration decisions.
DAY 1 (MONDAY, 13 OCTOBER 2014)

11.30 – 13.00 Registration and welcome snacks and refreshments
14.30 Coffee break
17.30 End of the day
18.30 Social event

SESSION 1: OVERVIEW OF REGULATORY PHILOSOPHY

- Evolution of the regulatory approach related to the immunogenicity requirements (Pekka Kurki)
- What is meant by a "risk-based approach" to immunogenicity assessment from the regulator’s perspective? (Pekka Kurki)
- How is immunogenicity assessed for different product types, from biosimilars to enzyme/factor replacement therapies? (Paul Chamberlain)
- What are the implications of this philosophy for data presentation? (Pekka Kurki and Paul Chamberlain)
- Q & A / Discussion (All)

SESSION 2: WHAT ARE THE PERTINENT RISK FACTORS?

- Intrinsic immunogenicity & systems biology (Paul Chamberlain)
- Conditions of use & patient-related factors (Pekka Kurki)
- Product quality (Paul Chamberlain)
- Q & A / Discussion (All)

DAY 2 (TUESDAY, 14 OCTOBER 2014)

09.00 Start with session 3
10.30 Coffee break
13.00 – 14.00 Lunch break
16.30 End of the workshop

SESSION 3: EVALUATION OF RISKS AND CONTRIBUTION OF IMMUNOGENICITY ASSESSMENT TO THE OVERALL BENEFIT-RISK ASSESSMENT

- Case examples illustrating impact of product type on nature of bioanalytical data package (Paul Chamberlain)
  - Recombinant analogue of endogenous protein / peptide
  - Yeast-derived therapeutic protein
  - Biosimilar anti-TNF mAb
- Clinical evaluation of immunogenicity and how does it contribute to the benefit-risk assessment (Pekka Kurki)
- Dealing with "Tricky cases": 2 examples (Paul Chamberlain)
- Q & A / Discussion (All)

SESSION 4: MANAGING UNCERTAINTY IN THE POST-AUTHORISATION SETTING

- Role of the Risk Management Plan (Pekka Kurki)
- Q & A / Discussion (All)

SESSION 5: EFFECTIVE PRESENTATION OF DATA IN THE CTD FORMAT

- The "Integrated Summary of Immunogenicity" model (Paul Chamberlain)
- How to tell a good story (Pekka Kurki)
- Q & A / Discussion (All)

For more information go to www.eucraf.eu
Please send your registration form to:
EUCRAF Ltd.
Wippertstr. 2
79100 Freiburg
GERMANY

For any questions please contact us by phone: +49 (0)761 13 73 44 24
or via homepage: www.eucraf.eu

BOOKING FORM for Immunogenicity Workshop

<table>
<thead>
<tr>
<th>Title</th>
<th>E-mail</th>
<th>Address</th>
<th>City</th>
<th>Postal Code</th>
<th>Country</th>
</tr>
</thead>
<tbody>
<tr>
<td>SurName. First Name</td>
<td>Phone</td>
<td>Address</td>
<td>City</td>
<td>Postal Code</td>
<td>Country</td>
</tr>
<tr>
<td>Job Title</td>
<td>Fax</td>
<td>Special dietary requirements</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Company</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

INVOICE ADDRESS if different

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 6 October 2014 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 e-mail booking@eucraf.eu.

REFUNDS: Refund requests must be in writing and faxed to +49 (0)761 13 73 444. Refund requests are accepted until 15 September, till when 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/VIDEOS: EUCRAF reserves the right to take pictures of the workshop and record it and to use them for marketing purposes such as flyer, brochure, website etc.

Signature Date

Please check appropriate fee
- Industry
- SME
- Academics/ Health Authorities
- EUCRAF Students

<table>
<thead>
<tr>
<th>Fee Until 31 August 2014</th>
<th>Fee From 1 September 2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>820 € + 19% VAT (975,80 €)</td>
<td>910 € + 19% VAT (1082,90 €)</td>
</tr>
<tr>
<td>670 € + 19% VAT (797,30 €)</td>
<td>780 € + 19% VAT (928,20 €)</td>
</tr>
<tr>
<td>450 € + 19% VAT (535,50 €)</td>
<td>520 € + 19% VAT (618,80 €)</td>
</tr>
<tr>
<td>175 € + 19% VAT (208,25 €)</td>
<td>250 € + 19% VAT (297,5 €)</td>
</tr>
</tbody>
</table>

EUCRAF
Wippertstr. 2
79100 Freiburg
Phone: +49 (0)761 13734424
Fax: +49 (0)761 1373444
E-mail: anita.dioszegi@eucraf.eu
www.eucraf.eu

Gabriele Schäffner-Dallmann
Study Director

Anita Dioszegi
Programme Manager

VENUE AND HOTEL

Munich is the capital city of Bavaria (German Federal State) in Germany, located in south east Germany on the River Isar north of the Bavarian Alps.

Sheraton München Arabellapark Hotel
Arabellastrasse 5
81925 München, Germany
Phone: +49 89 9232 0
Web: http://www.sheratonarabella-park.com/en