Oncology
DGRA-Memberworkshop September 13, 2011
Wissenschaftszentrum Bonn,
Ahrstraße 45, 53175 Bonn

10.00 a.m. – 4.30 p.m.

Moderation: Dr. Christine Mayer-Nicolai, DGRA Vice Chair
Dr. Ulrich Granzer, DGRA Chair

Speakers: Prof. Dr. Lothar Bergmann, Uni-Klinikum Frankfurt, Oncology Dept.
Dr. Bertil Jonsson, MPA Medical Products Agency
Dr. Jan Müller-Berghaus, PEI Federal Paul-Ehrlich-Institute
Dr. Otmar Pfaff, Merck Serono Head Global Reg. Affairs Oncology Devices
Dr. Christoph Unkrig, BfArM Federal Institute for Drugs and Medical Devices

Programme:

10.00 a.m. I. 15-years EMA experience in Oncology: Guidance – Products – Endpoints
- EMA experience with oncology drugs 1995-2011: trends and shifts. ‘Personalized medicines’ in oncology – myth or reality?
- EMA viewpoint on the use of surrogate endpoints in the cancer setting. Will ‘targeted therapies’ impact on EMA’s viewpoint?

Dr. Bertil Jonsson, MPA

10:45 – 11:15 coffee break
II. Assessment of new applications and type II variations in the cancer setting: The Regulators’ experience

- Beyond the Common Technical Document: Avoiding pitfalls in Art 8.3 and type II variation dossiers for cancer products
- CMC aspects and patterns regarding type I variations for marketed oncology products: do they work like other medicinal products?
- Risk-benefit assessment of oncology products: any particularities in the evaluation of cancer medicines?

Dr. Christoph Unkrig, BfArM

III. Highly innovative medicinal products: how to successfully develop biologicals in oncology

- ‘State-of-the-art’ assessment of immunogenicity for innovative biologicals
- Specific considerations for the early clinical testing – did the 2007 Guideline for ‘first-in-man clinical trials for potential high-risk medicinal products’ deliver?

Dr. Jan Müller-Berghaus, PEI

IV. Global development of new cancer medicines: achievements, hurdles and gaps in the regulatory framework

- Product approval patterns in the EU and US and Japan: similar, but not identical
- Achievements, hurdles and unfilled gaps in the regulatory harmonization of oncology drug product development
- Developing personalized medicines globally: lessons to learn how to integrate emerging regions into the clinical development

Dr. Otmar Pfaff, Merck Serono

V. Pre-and post-approval studies in hematology and oncology: The Investigator’s perspective

Prof. Dr. Lothar Bergmann, University Hospital Frankfurt

VI. Concluding discussion of the panel

all speakers and participants

further information  p.t.o.
**Date:**  
Tuesday, September 13, 2011  
Start: 10.00 a.m.  
End: around 4:30 p.m.

**Venue:**  
Wissenschaftszentrum Bonn, Ahrstraße 45,  
D-53175 Bonn, phone: +49 228/302-0

**Participation fees:**  
For DGRA members and M.D.R.A. students  
course XII: € 250

The Casino is open for lunch (not included)

**Cancellation terms:**  
Up to two weeks before the first day of the  
conference (30-Aug-11): € 50; up to one week  
before the first day of the conference (6-Sep-11):  
50% of fee; late cancellations: full conference  
fee if a substitute participant (DGRA member)  
cannot be put forward.

In the event of cancellation by the organizer, any  
fees already paid will be fully reimbursed.

**Conference language:**  
English

**Room reservation:**  
A limited number of rooms are available for  
participants at special rates in the hotels listed  
below. When making reservations (up to August  
15) please refer to DGRA.

- Hotel Bristol, Bonn-Innenstadt  
  Phone: +49 - 228/269 88 49
- Hotel Stern, Bonn-Innenstadt  
  Phone: +49 - 228 /72 67 0

More available rooms for direct booking  
www.bonnhotels.de (incl. public transport),  
www.hrs.de

**Registration:**  
DGRA members are requested to use the form at  
www.dgra.de or contact us at info@dgra.de

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