

12th DGRA Annual Congress

June 15 and 16, 2010 in Bonn

New Challenges for EMA and National Competent Authorities

- Scientific Committees of EMA - how to optimize co-operation?
- Optimizing Project Management at the EMA
- Pharmacovigilance – legislation quo vadis?
- Variation System in force - first experiences

with

Dr. Karl Broich

German Federal Institute for Drugs and
Medical Devices (BfArM), Bonn

Prof. Klaus Cichutek

Paul Ehrlich Institute (PEI), Langen

Dr. Barbara Gansewendt

Bayer Vital, Leverkusen

Dr. Ulrich Granzer

Granzer Consulting, München

Dr. Ulrich Hagemann

German Federal Institute for Drugs and
Medical Devices (BfArM), Bonn

Dr. Elmar Kroth

BAH, Bonn

Noël Wathion

European Medicines Agency (EMA), London

Dr. Jan Müller-Berghaus

Paul Ehrlich Institute (PEI), Langen

Prof. Philippe Lechat

AFSSAPS, Saint Denis

Prof. Barbara Sickmüller

German Pharmaceutical Industry Association
(BPI), Berlin

Dr. Martin Terberger

EU Commission, Brussels

PD Dr. Walter Schwerdtfeger

- enquired, Königswinter

Chair: Prof. Burkhard Sträter

Attorney, Bonn

The Program on June 15, 2010

Moderator: Prof. Burkhard Sträter, Attorney

9.30 am Opening of the Annual Congress and Introduction to morning session, Dr. Ulrich Granzer

10.00 am I. German Competent Authorities as Part of the Network of European Drug Regulators

- legal tasks
- primary areas of responsibility
- fulfilment of tasks within the network
- possible developments

PD Dr. Walter Schwerdtfeger

A. New challenges for the EMA – Road Map 2015?

Dr. Martin Terberger, EU Commission

11.00 am Coffee break

11.30 am B. News from PEI
Prof. Dr. Klaus Cichutek, PEI

C. News from BfArM
Dr. Karl Broich, BfArM

12.30 pm Panel discussion

01.00 pm Lunch break

2.30 pm II. AFSSAPS - Inclusion of external experts into the review process

Prof. Philippe Lechat, AFSSAPS France

3.15 pm Coffee break

3.45 pm III. Update from the EMA

- Outcome of the public consultation on the Road Map to 2015
- Optimizing project management and scientific assessment

Noël Wathion, EMA

4.30 pm IV. Panel discussion with all speakers

5.15 pm **Award of “DGRA Förderpreis 2009”**
(ends at around 5.30 pm)

7.00 pm **Pre-dinner speech**
Reception and buffet at Hotel Königshof

The Program on June 16, 2010

9.30 am **9th Award of the Walter Cyran Medal**

10.00 am **V. Pharmacovigilance**

Presentation of the new content and Discussion with the panel and participants

- Introduction and general overview
Prof. Dr. Barbara Sickmüller, BPI
- Challenges of BfArM
Dr. Ulrich Hagemann, BfArM
- Industrial view
Dr. Elmar Kroth, BAH

11.00 am **Coffee break**

11.30 am **VI. Variation update**

- Variations of biological products
Dr. Jan Müller-Berghaus, PEI
- Industrial perspective - first experiences
Dr. Barbara Gansewendt, Bayer Vital

12.30 pm **Panel discussion with all speakers**

1.00 pm **Lunch/Snack**

2.00 pm **DGRA Members’ Meeting: including**

- Election of DGRA board
- Amendment of the statutes

(ends at around 3.30 pm)

(Program subject to change without prior notice)

Dates:

June 15, 2010 Wasserwerk 9.30 am
Hotel Königshof 7.00 pm

Presentations and discussions
Pre-dinner speech, reception

June 16, 2010 Wasserwerk 9.30 am
Followed by 2.00 pm

Presentations and discussions
DGRA members' meeting

Venue:

Wasserwerk Bonn
Hermann-Ehlers-Straße
Entrance V
D-53113 Bonn

Hotel Königshof
Adenauerallee 9
D-53113 Bonn

Cost contribution:

For DGRA members: € 460
For non-members: € 590

Student price: Students of DRA course (MDRA XI) and delegates of bodies (Behörden) who are members of the DGRA: € 260

Cancellation terms:

Up to two weeks before the first day of the conference(1-June-2010): € 50; up to one week before the first day of the conference (08-June-2010): 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 languages:

English and German

Room reservation:

A limited number of rooms are available for participants at special rates in the hotels listed below. When making reservations please refer to this event.

Hotel (Günnewig) Bristol
Prinz-Albert-Strasse 2
D-53113 Bonn
Tel.: +49 (0) 228 / 26 98-0
Fax: +49 (0) 228 / 26 98-2 22

Hotel Hilton
Berliner Freiheit 2
53111 Bonn
Tel.: +49 (0) 228 / 72 69-0
Fax: -49 (0) 228 / 72 69-700

Sternhotel
Markt 8
D-53111 Bonn
Tel.: +49 (0) 228 / 72 67-0
Fax: +49 (0) 228 / 72 67-125

Hotel Maritim
Godesberger Allee
D-53175 Bonn
Tel.: +49 (0) 228 / 81 08-0
Fax: +49 (0) 228 / 81 08-811

Hotel (Günnewig) Residence
Kaiserplatz 11
D-53113 Bonn
Tel: +49 (0) 228 / 26 97-0
Fax: +49 (0) 228 / 26 97-777

Villa Godesberg
Mirbacherstr. 2
53173 Bonn - Bad Godesberg
Tel.: +49 (0) 228 / 83 006-0
Fax: +49 (0) 228 / 83 006-90

Registration:

**As a DGRA member please use the form at www.dgra.de or contact us at info@dgra.de
DGRA-Geschäftsstelle, Schedestrasse 9, D-53113 Bonn, Fax: +49 (0) 228/368 26 47**