

16th DGRA Annual Congress

8 and 9 May, 2014 in Bonn

Scientific Advice, Pharmakovigilanz

- Scientific Advice EMA, NCA-HTA: Joint or Parallel?
- Pharmacovigilance – Status of Implementation of the new Rules

with

Prof. Dr. Karl Broich

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

Dr. Ulrich Granzer

Granzer Consulting, München

Dr. Anja Langeneckert

Roche Pharma Deutschland, Grenzach

Thomas Müller

Federal Joint Committee (G-BA), Berlin

Dr. Norbert Paeschke

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

Britta Paschen

Merck KG aA, Darmstadt

Dr. Dirk Mentzer

Paul-Ehrlich Institute (PEI), Langen

Dr. Tomas Salmonson

European Medicine Agency (EMA), London

Moderation: Prof. Burkhard Sträter

Rechtsanwalt, Bonn

The Program on May 8, 2014

Moderator: Prof. Burkhard Sträter, Attorney

9.30 am Opening of the Annual Congress and introduction to sessions, Dr. Ulrich Granzer

09.45 Uhr I. Joint Scientific Advice (JSA) - BfArM G-BA

- End points, Biomarkers, Surrogat Endpoints, Comparative Therapy
- Procedures of BfArM - Routine or Exception?

Prof. Dr. Karl Broich, Vice President BfArM

II. JSA in Germany with BfArM/PEI and G-BA

- Joined Scientific Advice by G-BA with BfArM and PEI
- Right Time in Product Development
- Level of Commitment of the Early Benefit Assessment
- Participation of the G-BA in Scientific Advice Pilots at European Level

*Thomas Müller, Head of Pharmaceuticals Department
Federal Joint Committee G-BA*

11.00 am Coffee break

11.30 am III. National Review from the Perspective of the Pharmaceutical Industry

- Experiences with early G-BA advice and involvement of BfArM/PEI
- Procedure of National Scientific Advice with GBA

Dr. Anja Langeneckert, Head of Regulatory Affairs, Roche Pharma

IV. Parallel Scientific Advice by EMA with MAHs and HTAs

- EMA procedures – Experiences and Outlook
- Participation of HTA Bodies
- Assessment of HTA aspects in EPAR

Dr. Tomas Salmonson, CHMP Chair EMA

12.15 pm Panel Diskussion

12.45 pm Lunch break

14.15 pm V. European Review from the Perspective of the Pharmaceutical Industry

- Experiences with EMA/HTA Bodies and EUnet/HTA
- What are the Industrial Expectations?
- What is realistic? What is desirable?

Britta Paschen, Vice President Health Services Research, Merck KG aA

14.45 pm Panel Discussion with all Speakers

15.00 pm “Walter-Cyran-Medaille” award

15.30 am Coffee break

16.00 pm DGRA Members’ Meeting
(ends at around 6.00 pm)

19.00 Uhr Pre-dinner Speech
Reception and buffet

Shuttle from Wasserwerk to the restaurant Godesburg

The Program on May 09, 2014

9.30 am “DGRA-Förderpreis“ award

10.00 am VI. Pharmacovigilance Update Europe

- EU Risk Management Plan (RMP)/Risk Minimisation Measures
- PASS (Post Authorisation Safety Studies)
- Medication Errors / Off Label Use
- Paediatric Pharmacovigilance

*Dr. Dirk Mentzer, PEI Head of Pharmacovigilance Unit I,
PDCO Chair*

11.00 am Coffee break

11.30 am VII. National Pharmacovigilance update

- Adverse Drug Reactions (ADRs) reporting (new EMA Business rules in accordance with E2B (R3))
- PSURs, PSUR repository
- Implementation of PRAC Decisions during the signal procedure
- AWB: Announcement and database
- News in the Development of MedDRA:
Results of Blue Ribbon Panel of MSSO

Dr. Norbert Paeschke, Head of Pharmacovigilance BfArM

12.15 pm VIII. Review from the perspective of the pharmaceutical industry

Dr. Ulrich Granzer, Munich

13.00 pm Panel Discussion with all speakers

13.15 pm Lunch / Snack

(Program subject to change without prior notice)

Dates:

May 8, 2014 Wasserwerk 9.30 am
Followed by 4.00 pm
Restaurant Godesburg 7.00 pm

Presentations and Discussions
DGRA Members' Meeting
Pre-Dinner Speech, Reception

May 9, 2014 Wasserwerk 9.30 am

Presentations and Discussions

Presentations and discussions

Venue:

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

Restaurant Godesburg
Auf dem Godesberg
D-53177 Bonn - Bad Godesberg

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(24-April-2014): € 50; up to one week
before the first day of the conference (01-May-2014): 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

Some photographic material will be
published.

Note:

Photographers will accompany the
workshop.

Workshop documents will include a list of
participants.

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. 2a
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
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