

10th DGRA Annual Congress

on 17 and 18 June 2008 in Bonn

“Heading for a New Decade”

- **Pharmaceuticals in the EU: Heading for the Future
"Have your Say" Initiative**
- **Transatlantic Simplification of Administrative Procedures
in the Area of Pharmaceuticals**
- **Heading for New Approaches –
Future of the BfArM in the EU MA System**
- **Advanced Therapies: Implementing New Regulations**
- **One Year Pediatric Committee – PDCO**
- **EU Variations Regulations**

With

Prof. Dr. Daniel Brasseur
EMA, London

Prof. Dr. Claus Cichutek
PEI, Langen

Dr. Rüdiger Faust
Grünenthal GmbH, Aachen

Dr. Ulrich Granzer
Granzer Regulatory Consulting, Munich

Dr. Truus Janse-de Hoog
MEB, The Hague

Christine-Lise Joulou
EFPIA, Brussels

Dr. Aginus Kalis
MEB, The Hague

Dr. Susanne Keitel
EDQM / DEQM, Strasbourg

Prof. Dr. Johannes Löwer
BfArM, Bonn

Arielle North
EMA, London

Dr. Gabriele Schäffner
NDA, Freiburg

Martin Terberger
EU Commission, Brussels

Susanne Winterscheid
BfArM, Bonn

Chair: Prof. Burkhard Sträter
Attorney, Bonn

The Programme on 17 June 2008

Moderation: Prof. Burkhard Sträter

9.30 am Welcoming Speech by Dr. Ulrich Granzer

9.45 am Pharmaceuticals in the EU: Heading for the Future – "Have your Say" Initiative

➤ **Initiative of the EU Commission: Public consultation on the future of pharmaceuticals for human use in the EU**

▪ Background and present state of play

Martin Terberger, EU Commission, Brussels

➤ **Revising the pharmaceutical landscape in the EU – The industry's perspective**

Christine-Lise Joulou, EFPIA, Brussels

10.45 am Coffee break

11.15 pm ➤ An Eu-Member State position

Dr. Aginus Kalis, MEB, The Hague

Transatlantic Simplification of Administrative Procedures in the Area of Pharmaceuticals

Arielle North, EMEA, London

12.15 pm Panel Discussion

12.45 pm Lunch break

2.15 pm Heading for New Approaches – Future of the BfArM in the EU MA System

Prof. Dr. Johannes Löwer, BfArM, Bonn

Advanced Therapies: Implementing New Regulations

➤ **Products concerned**

➤ **Authorisation procedures**

Prof. Dr. Claus Cichutek, PEI, Langen

3.15 pm Coffee break

3.45 pm ➤ Consequences for research-based industry

Dr. Gabriele Schäffner, NDA, Freiburg

- 4.15 pm Panel Discussion with all Speakers**
- 4.40 pm One Year Pediatric Committee – PDCO**
- **Main tasks**
 - **Problems of ongoing PIP's**
 - **Experience and outcome**
- Prof. Daniel Brasseur, EMEA, London*
- 5.00 pm Award of the Walter Cyran Medal**
(ends at around 5.30)
- 7.00 pm Pre-Dinner Speech: 10 Years DGRA – What Next?**
Dr. Ulrich Granzer, Chair of the DGRA
- Reception and buffet

The Programme on 18 June 2008

- 9.30 am EU Variations Regulations**
- **Revision of the EU Variations Regulations – outcome of the consultation process and further steps**
Dr. Susanne Keitel, EDQM/DEQM, Strasbourg
 - **Consequences for the pharmaceutical industry – Will the changes make the EU a more competitive market place?**
Dr. Rüdiger Faust, Grünenthal GmbH, Aachen
- 11.00 am Coffee break**
- 11.30 am**
- **Consequences for competent authorities - Will the change simplify administrative hurdles?**
Dr. Truus Janse-de Hoog, MEB, The Hague
 - **EU Variation System binding for national MA? – Consequences for authorities**
Susanne Winterscheid, BfArM, Bonn
- 12.30 pm Panel Discussion with all Speakers**
- 1.00 pm End**
- 2.00 pm DGRA Members' Meeting**
- (Programme subject to change without prior notice.)

Dates:

17 June 2008 Wasserwerk 9.30 am
Hotel Königshof 7.00 pm

Presentations and discussions
Pre-Dinner Speech, reception

18 June 2008 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: € 450
For non-members: € 590

Students special: Students of the DRA
courses (MDRA I to IX) and delegates of
bodies who are members of the DGRA:
€ 240

Cancellation terms:

Up to two weeks before the first day of the conference: € 50; up to one week before the
first day of the conference: 50% of fee; later 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

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
D-53111 Bonn
Tel.: +49 (0) 228/7269-0
Fax: +49 (0) 228/7269-700

Hotel (Günnewig) Residence
Kaiserplatz 11
D-53113 Bonn
Tel.: +49 (0) 228/2697-0
Fax: +49 (0) 228/2697-777

Hotel Königshof
Adenauerallee 9
D-53111 Bonn
Tel.: +49 (0) 228/26 01-0
Fax: +49 (0) 228/26 01-529

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

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