Date:
- October 14, 2014 9:00 a.m. - 5:30 p.m.
–October 15, 2014 9.00 a.m. - 4:30 p.m.

Venue
Günnewig Hotel Bristol phone : +49 - 228/ 26 98-0
Prinz-Albert-Str. 2 fax: +49 - 228/ 26 98-222
53113 Bonn

Conference language:
English

Participation fee
€ 750 for DGRA Members and M.D.R.A. students course 15.
Number of participants is limited.

Cancellation terms:
Up to two weeks before the first day of the school (September 30th 2014): € 50; up to one week before the first day of the school (October 7th 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.

Room reservation
A limited number of rooms are available for participants at special rates in the hotel below When making reservations (up to end of August) please refer to DGRA. Günnewig Hotel Bristol Bonn

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

Note:
Photographers will accompany the workshop.
Some photographic material will be published.
Workshop documents will include a list of participants.

DGRA-office, Adenauerallee 15, D- 53111 Bonn,
phone: +49 228 3682646 , info@dgra.de

DB BAHN

Mit der Deutschen Bahn ab 99,- € zu jeder DGRA-Veranstaltung hin und zurück, informieren Sie sich hier: http://dgra.de/deutsch/dgra/aktuelles/2014/Reisen-Sie-bequem-zu-Ihrer-DGRA-Veranstaltung

DGRA
DEUTSCHE GESELLSCHAFT FÜR REGULATORY AFFAIRS

1. DGRA-School

October 14/15, 2014 in Bonn

Regulatory Procedures in Asia

Moderation: Dr. Ekkehard Baader
Head of European Regulatory Affairs Branded Products,
Teva Pharma GmbH;
M.D.R.A.-Modulleiter “Internationale Zulassung“

Speakers:

Dr. Michael Gebauer
Bayer Pharma AG, Wuppertal

Dr. Santiago Figueroa Pérez
Bayer Pharma AG, Wuppertal

Hsueh-Yung (Mary) Tai
TFDA, Taiwan Food and Drug Administration

Xenia Freifrau von Maltzan
Xendo Deutschland GmbH

Dr. Manuel Zahn
3R Pharma Consulting GmbH

Programme (subject to alterations)

Programme October 14, 2014:

9.00 – 09:30 a.m.

I. Introduction: Asian Market

- Defintion, characterization
  Dr. Michael Gebauer

09.30 – 10:30 a.m:

II. Requirements of Clincial Trials //Scientific advice

- Where and why to conduct clinical studies in Asia
- Ethnical Sensitivity (ICH E5 in non ICH countries)
- Regulatory hurdles (CTA/IND; processes)
- Scientific Advice in Asia
- *Dr. Michael Gebauer*

10:30 – 11:00 a.m. Coffee break

11:00 – 12:30 a.m.

III. Quality/ Stability Requirements

- CMC documentation (is ICH QOS + M3 sufficient?)
- Special Attention for stability data
- [SMF/PMF]
- PIC´s [asian members), Inspections
- Samples and analytical tests
  Dr. Manuel Zahn

12:30 – 01:30 p.m. Lunch break

01:30 – 03:00 p.m.

IV. Certificates

- CPP´s (Certificate of Pharmaceutical Product)
- Other Autorisations [PoA´s], Translations
- Successful submission
- *Dr. Michael Gebauer*

03:00 – 03:30 p.m. Coffee break

03:30 – 05:30 p.m.

V. Generic Marketing Authorization in Taiwan

- Regulatory Enviroment, Scientific Advice, Procedures
  Dr. Hsueh-Yung (Mary) Tai, TFDA

Programme October 15, 2014:

09:00 – 09.45 a.m.:

VII Marketing Authorization in China

- CFDA, CDE
- Drug classification (category I-IV) RA processes, timelines
- IDL vs local manufacture
  Dr. Santiago Figueroa Pérez

09.45 – 10.00 a.m. break

VII Marketing Authorization in China (continued)

11.00 – 12:00 p.m

VIII. Marketing Authorization in India

- CDSCO, DCG(I)
- General registration processes, timelines
- Impact of recent developments on regulatory processes (Clinical Trials, Patents)
  Xenia Freifrau von Maltzan

12:15 – 01:15 p.m. Lunch break

01.15 – 02:30 p.m.:

IX. Marketing Authorization in Taiwan

- T-FDA, CDE
- Bridging Evaluation
- PMF / Manufacturer inspections
  Dr. Hsueh-Yung (Mary) Tai, TFDA

02:30– 2:45 p.m. break

02:45 - 03.45 p.m.:

X. Marketing Authorization in South Korea

- MFDS (Ministry of Food and Drug Safety),
- Korean Bridging guideline,
- IND and NDA, Re-examination
  Dr. Michael Gebauer

03:45– 4:00 p.m. Coffee break

04.00– 04:30 p.m.

XI. ASEAN

- ASEAN harmonization approach
- ASEAN guidelines, ACTD
  Xenia Freifrau von Maltzan