Date:
March 21, 2012 9:00 a.m. - 5:30 p.m.
March 22, 2012 9.00 a.m. - 4:30 p.m.

Venue
Günnewig Hotel Residence
Kaiserplatz 11
53113 Bonn

phone : +49 - 228/2 69 70
Fax: +49 - 228/26 97-777

Conference language:
English

Participation fee
€ 750 for DGRA Members and M.D.R.A. students course 13.
Number of participants is limited.

Cancellation terms:
Up to two weeks before the first day of the school (7-Mar 12): € 50; up to one week before the first day of the school (14-Mar 12): 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 February) please refer to DGRA.
Günnewig Hotel Residence Bonn
Phone: +49 - 228/26970

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

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

DGRA
DEUTSCHE GESELLSCHAFT FÜR REGULATORY AFFAIRS

1. DGRA-School

March 21/22, 2012 in Bonn

Regulatory Procedures in the USA

Moderation: Dr. Ekkehard Baader

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

Speakers:

Dr. Ulrich Granzer,
Granzer Regulatory Consulting & Services, Munich

Dr. Isabelle Stöckert,
Head GRA Europe/Canada, Bayer Pharma AG, Wuppertal

Dr. Max Wegner,
Vice President, Head GRA General Medicine, Bayer Pharma AG, Wuppertal

Programme(subject to alterations)

Programme March 21, 2012:

9.00 – 09:30 a.m.
I. Introduction: US Pharma Market
- Defintion, characterization
  Dr. Max Wegner

09.30 – 10:30 a.m:
II. History of Key Regulations
- Organisation of HHS
- Structure of FDA
- FDA Activities
  Dr. Ulrich Granzer

10:30 – 11:00 a.m. Coffee break

11:00 – 12:30 a.m.
III. IND Process
- Principles, process, IND Regulations
- Responsibilities of Sponsors and Investigators
  Dr. Isabelle Stöckert

12:30 – 01:30 p.m. Lunch break

01:30 – 03:00 p.m.
IV. NDA Process
- US Code of Federal Regulations (CFR)
- PDUFA
- Good Review Management Principles and Practices
- Successful NDA submission
  Dr. Max Wegner

03:00 – 03:30 p.m. Coffee break

03:30 – 04:30 p.m.
V. VIII. Biologicals
- Defintion, characterization
- Principles, process, US Regulations
  Dr. Ulrich Granzer

04:30 – 05:30 p.m.
VI. Medical Devices
- Defintion, characterization
- Principles, process, US Regulations
  Dr. Ulrich Granzer

Programme March 22, 2012:

09:00 – 09.45 a.m.:
VII Marketing Exclusivity/ANDA
- Patent extensions
- Data exclusivity
- ANDA Process
  Dr. Ulrich Granzer

09.45 – 10.15 a.m. Coffee break

10.15 – 12.15 a.m.:
VIII. How to co-operate with FDA
- Regulatory Strategy
- Meetings with FDA
  Dr. Isabelle Stöckert, Dr. Max Wegner

12:15 – 01:15 p.m. Lunch break

01.15 – 02:15 p.m.:
IX. Pediatrics
- Pedriatric Initiatives, Clinical Studies
- Legislation: PREA, BDCA, PeRC
  Dr. Max Wegner

02:15 - 03.00 p.m.:
VI. Post-Approval Activities
- Reporting requirements to FDA
- Changes to an approved product
  Dr. Isabelle Stöckert

03:00– 3:30 p.m. Coffee break

03.30– 04:30 p.m.
XI. Comparison US vs. EU
- Legislation, Legal Bodies, Timelines
- Regulatory Enviroment, Scientific Advice, Procedures
  Dr. Isabelle Stöckert