

New Strategies for the development of New Molecular Entities

DGRA-Memberworkshop
27.02.08
Wissenschaftszentrum Bonn

Chair: Dr. U. Granzner

09.30 Introduction: New Strategies for the development of New Molecular Entities

- **Why are they necessary?**
- **Which trends and new ideas are being introduced?**

Dr. U. Granzner, Granzner Regulatory Consulting and Services, Munich

10.00 The role of biomarkers and surrogate parameters in the development of new drugs

Dr. Steffen Bassus, PEI, Langen

Prof. Dr. Wolfgang Meyer-Sabellek, AstraZeneca, Bruxelles

10.45 coffee break

11.15 Phases in clinical trials, are they outdated?

- **Pre-Phase I developments: Earlier into man?**

Dr. Ian Hudson, MHRA, London

PD Dr. Michael Kirchengast, Pharmaceutical Research Associates GmbH, Mannheim

- **Adaptive designs to combine clinical development phases**

Dr. Peter Volkers, PEI, Langen

Dr. Martin Krauss, FGK, Munich

12.30 discussion

13.00 lunch

14.00 Interaction between Industry and Regulatory Authorities, new ways for drug approvals

➤ **Translational medicine and critical path initiative of FDA**
Dr. U. Granzer, Granzer Regulatory Consulting and Services, Munich

New ways to obtain an early approval: Conditional approval: Approval under exceptional circumstances; compassionate use programmes

Dr. Birka Lehmann, BfArM, Bonn
Dr. ChristineMayer-Nicolai, Merck Serono, Darmstadt

15.30 discussion

ca. 16.00 end

(programme subject to change without prior notice)

Date:

27. February 2008

Wissenschaftszentrum Bonn

Start: 9.30 Uhr

End: ca. 16.00 Uhr

Room reservation:

www.carisma-engine.de, www.hrs.de

Special Conditions at the Hotel Königshof,

Adenauerallee 9, 53111 Bonn, Tel.: 0228/2601-0

(Buchungscode: DGRA_HK)

Venue:

Wissenschaftszentrum Bonn, Ahrstraße 45,

D-53175 Bonn, Tel.: 0228/302-0

Registration:

DGRA-Geschäftsstelle, Schedestraße 9,

D-53113 Bonn,

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E-mail: info@dgra.de

Cost contribution:

For DGRA-members: € 230,-

(Lunch can be taken on one's own account in the Casino.)

Cancellation terms:

<http://www.dgra.de/fortbildung>