

Risk Management

DGRA-Memberworkshop

07. November 2007

Wissenschaftszentrum Bonn

Chair: RA Burkhard Sträter

09.30 Needs and expectations on Risk Management Plans from a regulatory perspective

Prof. Ingemar Persson, MPA, Uppsala

10.00 How can Agencies and Industry ensure that one EU RMP is acceptable in all Member States and within a global context?

Afssaps experience and internal organisation

Dr. Anne Castot, Afssaps, Saint-Denis

Risk Management during product development and life cycle

Dr. Barry Arnold, AstraZeneca, Cheshire

11.00 coffee break

BfArM experiences in assessment of RMP

Dr. Ulrich Hagemann, BfArM, Bonn

12.00 Special paediatric perspectives in assessment of RMP

Dr. Dirk Mentzer, PEI, Langen

12.30 lunch

13.30 Further defining post authorisation safety studies: their role in the EU RMP

Company perspective

Dr. Janet Hormbrey, MSD Inc., Brussels

Agency perspective

Prof. Ingemar Persson, MPA, Uppsala

14.30 The value of pharmacoepidemiology studies

Cohort follow-up and case-control studies

Prof. Edeltraut Garbe, BIPS, Bremen

Spontaneous reporting – randomized studies – drug application research

Prof. Joerg Hasford, University of Munich

15.30 coffee break

16.00 National Risk Minimisation Plans – what are typical measures?

Assessment of educational material

Dr. Ulrich Hagemann, BfArM, Bonn

Possible answers to risk management questions

Prof. Barbara Sickmüller, BPI, Berlin

17.00 Panel discussion with Speakers

ca. 17.30 end

(Programme subject to change without prior notice.)

Date:

07. November 2007

Wissenschaftszentrum Bonn

Start: 9.30

End: ca. 17.30

Venue:

Wissenschaftszentrum Bonn, Ahrstraße 45,
D-53175 Bonn, Tel.: 0228/302-0

Cost contribution::

For DGRA-members: € 230,-

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

Room reservation:

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

Special condition in the Hotel Königshof,

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

(Buchungscode: DGRA_HK)

Registration:

DGRA-Geschäftsstelle, Schedestraße 9,

D-53113 Bonn,

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E-mail: info@dgra.de

Cancellation terms:

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