

## **2nd School**

# **Clinical Documentation**

Intensive introductory seminar following the module 10 of the Master of Drug  
Regulatory Affairs Course

**Oktober 25 and 26, 2011**

**Hotel Bristol, Bonn**

### **Speakers:**

Dr. Cornelia Arras-Reiter, Paul-Ehrlich Institute, Langen

Dr. Ingrid Klingmann, Pharmaplex, Brussels

Dr. Thomas Sudhop, Federal Institute for Drugs and Medical Devices, Bonn,

Dr. Bob Wilffert, Zorggroep Noorderbreedte, Leeuwarden

### **Programme Oktober 25th, 2011**

- 9.00 a.m.**     **Introduction to Clinical Drug Development Process and Basics of  
Clinical Trials Phase I to IV**  
*Dr. I. Klingmann*
- 10.30 a.m.     coffee break
- 11.00 a.m.**     **Ethical Review, Ethics Committees and Informed Consent Process**  
*Dr. B. Wilffert*
- 12.30 p.m.     lunch
- 1.30 p.m.**     **Good Clinical Practice and Essential Documents**  
*Dr. B. Wilffert*
- 3.30 p.m.     coffee break
- 4.00 p.m.**     **European and German Clinical Trials Legislation**  
*Dr. I. Klingmann*
- 5.00 p.m.     end

## **Programme Oktober 26th, 2011**

- 9.00 a.m.     **Safety in Clinical Trials**  
- AEs/SAEs/SUSARs – Annual Safety Report – EudraVigilance – Risk-/ Benefit  
Analysis – 14. AMG Novella  
*Dr. Th. Sudhop*
- 11.00 a.m.     coffee break
- 11.30 a.m**     **Quality Management in Clinical Trials: from SOPs to Inspections**  
*Dr. I. Klingmann*
- 12.45 a.m.     lunch
- 1.45 p.m.**     **Clinical Trials in Vulnerable Populations –  
Women, Elderly, Children**  
*Dr. Th. Sudhop*
- 3.15 p.m.     coffee break
- 3.45 p.m.**     **Clinical Section of the Application Dossier, SPC and EPAR**  
*Dr. C. Arras-Reiter*
- 5.15 p.m.     end

**Information and organizational references**

**p.t.o.**

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**Date:**

Tuesday, October 25<sup>th</sup>, 2011

Start: 9.00 a.m.

Wednesday, October 26<sup>th</sup>, 2011

End: ca. 5.15 p.m.

**Venue:**

Hotel Bristol

Prinz-Albert-Str. 2

D-53113 Bonn

Phone: 0049-228-26980

Fax: 0049-228-2698-222

**Participation fees:**

For DGRA members and M.D.R.A. students  
course XIII: € 750

**Please note:**

Due to the limited number of available places,  
allocation will take in the order that we receive  
the registration.

The Casino is open for lunch (not included).

**Cancellation terms:**

Up to two weeks before the first day of the  
conference(October 11, 2011): € 50; up to one  
week before the first day of the conference  
(October 18, 2011): 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.

**Workshop language:**

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  
„DGRA“.

- Hotel Bristol, Bonn  
phone: 0049 –228 – 26980
- Hotel Königshof, Bonn  
phone: 0049 –228 – 26010

More available rooms for direct booking  
[www.bonnhotels.de](http://www.bonnhotels.de) (incl. public transport),  
[www.hrs.de](http://www.hrs.de)

**Registration:**

Please use the form at  
[www.dgra.de](http://www.dgra.de)

DGRA-Office

Schedestraße 9

D-53113 Bonn

Fax: 0049 - 228 - 368 26 47

E-mail: [info@dgra.de](mailto:info@dgra.de)