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## **Four years of the International DDI Workshop in Marbach Castle – a real success story**

The organisation team of the international Drug-Drug Interaction (DDI) Workshop in Marbach Castle on Lake Constance is happy to report the great acceptance and success of the events series in its fourth year. More than 70 drug development experts and representatives of health authorities participated in the scientific event "[DDI 2013 – 4<sup>th</sup> International Workshop on Regulatory Requirements and Current Scientific Aspects on the Preclinical and Clinical Investigation of Drug-Drug Interactions](#)". Feedback from participants has been overwhelmingly positive and has motivated the organisation team to start making preparations for next year's anniversary event immediately. The date for the fifth international DDI Workshop has been set for 25th – 27th May 2014.

The fourth DDI Workshop (26<sup>th</sup> – 28<sup>th</sup> May) was once more represented internationally. In attendance were nine speakers from the USA, three from Great Britain, three from Germany and one from Switzerland and Sweden respectively. The participants came from 10 countries in total.

"We are delighted with the international character of the DDI Workshop. Having speakers and participants from the USA, Europe and Asia has provided stimulating scientific discussions and a fruitful exchange of ideas on the topic of drug interactions across the continents for the last four years. Propositions for a further harmonisation of the guidelines and of the investigation of drug-drug interactions were also an important topic in this year's DDI Workshop," explained Robert Hermann from the organisation team.

The focal points in the workshop were emphasized by its keynote speakers. Bernd Meibohm reported on the huge advances in the study of drug interactions where therapeutic proteins (biologics) are involved. In the last few years, therapeutic proteins and associated interactions have gained much more attention, both in drug development and from the authorities. Our understanding of molecular mechanisms is better today, and so we are able to develop practical investigation programmes for the clinical development of therapeutic proteins. Eva Gil Berglund once again summarised the development of the European guideline and compared the contents of the EMA and FDA guidelines. A draft copy of the latter is currently being discussed. She emphasized that the authorities must follow scientific discussion and keep up to date with new findings, and also acknowledged the demand for further harmonisation of guidelines between Europe and the USA. Keith A. Rodvold provided an excellent overview of drug interactions for anti-infective agents, including the important field of HIV and new hepatitis therapeutic agents. In his speech, David J. Greenblatt introduced the important topic of specific patient populations and their consequences for drug interactions. It once more became clear that studies of young and healthy volunteers are not sufficient in every case when evaluating drug

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interactions. Further studies or simulations are necessary to meet requirements for other important patient groups, such as children for instance.

The DDI Workshop once again afforded the participants a unique opportunity for scientific exchange and intensive networking across the boundaries of companies and organisations, which was cited by the participants as an important feature of the workshop. The comprehensive responses from the participating experts on the structure and quality of the workshop, in addition to further fields of interest which should be discussed in future, will influence the preparations for the next DDI Workshop.

### **About the DDI Workshop**

The DDI Workshop is an initiative of cr.appliance in cooperation with Hartmut Derendorf, Amin Rostami-Hodjegan, and Oliver von Richter. The meeting takes place in Marbach Castle Conference Centre, located at the Lake Constance, Germany.

The organisers of the DDI Workshop are:

- Hartmut Derendorf, PhD FCP; College of Pharmacy, University of Florida, USA
- Robert Hermann, MD FCP; cr.appliance, Germany
- Amin Rostami-Hodjegan, PhD FCP; Faculty of Medical and Human Sciences, University of Manchester, UK
- Oliver von Richter, PhD FCP; Dept. Exploratory Medicine, Merck Serono, Germany

### **About cr.appliance**

cr.appliance is an independent team of experts that supports its clients in the healthcare industry with counseling, development concepts and services during the early stages of clinical drug development and throughout the licensing process.

cr.appliance uses its well-documented, recognised expertise to the benefit of its clients.

The team of experts has undertaken successful project work in the pharmaceutical industry as well as work in the service sector (CROs), hospitals and academia. The team has a wealth of well-founded, up-to-date expertise. This, combined with many years of professional experience in a number of specialist fields and areas of work, enables them to provide high-quality consultancy, create sustainable and viable development concepts and offer customer-specific services in various aspects of drug development.

More information about cr.appliance: <http://www.cr-appliance.com>

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