# **Organisation**





#### Venue

The  $20^{\text{th}}$  International Meeting will be held in the Maritim Hotel Ulm, Basteistrasse 40, 89073 Ulm, Germany. For room reservation (special rates) please follow the link https://www.csmcongress.de/congresses/dggf/ or call 0049 731 923-1791 or fax to 0049 731 923-1000 or e-mail to info.ulm@maritim.de.

### **Participation Fees**

DGGF International Meeting
 September 24<sup>th</sup>, 2015, 9:00 a.m. until 5:30 p.m.
 September 25<sup>st</sup>, 2015, 9:00 a.m. until 3:30 p.m.

	DGGF members	non-members
early bird discount until July 17 <sup>th</sup> , 2015	400 €	500€
registration after July 17 <sup>th</sup> , 2015	450 €	550€

There is substantial discount for delegates from the same company location: If all members of the group register on the same day, one in five persons and two in ten persons attend for free. Substitutions of enrolled delegates may be made at any time; please keep us informed. All prices are subject to value added tax (if applicable).

GLP Preconference Training
 September 23<sup>rd</sup>, 2015, 9:00 a.m. until 3:00 p.m.

	DGGF members	non-members
for attendees of International Meeting	250 €	350€
only Preconference Training	300 €	400€

### Registration

To register for the International Meeting and/or the Preconference Training please contact our event partner CSM online at www.csm-congress.de/congresses/dggf/ (for registration forms or direct online registration) or by fax at 0049 8142 54 73 5.

After registration you will receive a password which will enable you to download the available presentation slides from our website for 10 days before and for 3 months after the conference.

### Sponsorship and Advertising Opportunities

Would you like to arouse attention in a high-class environment? Then you might consider sponsoring the International Meeting or placing an advertisement. There are various ways to do so, be it within the conference dinner, the meeting brochure, or otherwise. Please feel free to contact us for more detailed information at tagung@dggf.de or visit our homepage www.dggf.de

#### **Exhibitors**

Companies interested in exhibiting or presenting posters are requested to contact either DGGF (tagung@dggf.de) or our event partner CSM (info@csm-congress.de).

For additional information, including continuous updates of the conference program, please visit our website at www.dqgf.de.



# 20<sup>th</sup> DGGF International Meeting

Maritim Hotel, Ulm September 23<sup>rd</sup>, 2015: Preconference Training September 24<sup>th</sup>-25<sup>th</sup>, 2015: Conference



# The DGGF International Meeting

# Program 2015

# Program 2015

The DGGF International Meeting is a convention of quality management professionals in the chemical and pharmaceutical industries. Every autumn, it brings together several hundred experts from industrial companies, contract research organizations, hospitals and government agencies. The meeting's wide range of topics allows attendees to update their professional knowledge, to gather valuable ideas for their day-to-day work, and to benefit from excellent net-working opportunities.

On the day before the DGGF International Meeting we offer a Preconference Training. This popular course – held in German – aims at professionals new to the field of Good Laboratory Practice (GLP) and will introduce students to the conditions, the set-up, the sequences and the documentation of GLP-studies.



The German Society for Good Research Practice (DGGF) is Germany's largest, and Europe's second largest, association dedicated to quality management in the chemical and pharmaceutical industries. Our work focuses on assuring optimum quality with regard to research and development of chemical, pharmaceutical and agrochemical substances. Good research practice helps in assuring high quality and safety through the finished product – and hence, for man and the environment.

#### GxP (Good Research Practice - cross-sectional issues)

- Personality psychology: People are different How to handle with them in Business Situations
- ISO-News
- No Chance of Product Piracy Anti-Counterfeit Packaging
- EU Regulator`s Viewpoint as why Regulatory Guidelines should NOT be followed

### **GCP (Good Clinical Practice)**

- Revision ICH E6 GCP
- Do you want to know what the future EU GCP inspection findings will be?
- The PUEKS project Process Optimization in Clinical Trial Monitoring
- A survey on risk-based monitoring Where does Germany Stand?
- A Novel Concept of Improving Quality of Sponsor-Investigator's Compliance with GCP for University Hospitals hosting Sponsor-Investigators

### Pharmacovigilance

- Quality Systems in Pharmacovigilance
- Management of PV Interfaces in Clinical Studies -Authorities perspective
- PV in Clinical Studies CRO Perspective

### **GLP (Good Laboratory Practice)**

- A glimpse into the global CRO market from an industrial sponsor perspective
- OECD IT Advisory Document
- GLP Round Table Discussion
- GLP vs. GMP
- GLP system in Brazil
- How to get the business started
- Keeping Conformity and Compliance to Analytical Part of GLP / GCP in Borderline Cases - QA Experience in a Bioanalytical CRO

#### IT

- Current status of using apps in the regulated environment, the potential difficulties, the general restrictions, and mobile devices
- Mobile Apps in the regulated Pharma R&D environment
- Electronic Archiving

### **GMP (Good Manufacturing Practice)**

- Qualification of a central warehouse for the interfaces:
  Sample transport, storage, and identity determination
- GxP meets Logistics
- Trending and Investigation of invalid tests
- Round Table Discussion

## Key-Note Speaker Regine Heiland

### People are different - How to handle them in Business Situations

The Lecturer: Regine Heiland is a graduate psychologist and has more than 20 years experience as a training teacher at the Institute of Schulz von Thun, author of the famous standard text book "Miteinander Reden" (Talking with Each Other). She facilitates team workshops and is an expert in the area of conflict clarification.

The Presentation: starting point of the lecture is the well-known fact that people are different and will assess the same issue differently. This is for good reasons which are resulting mainly from personal experience of life. Understanding and respecting this and adapting to it by use of skillful and appropriate communication is the main focus of the lecture. Involvement of the audience during the presentation is guaranteed.



Most papers will be presented in German. Simultaneous translation (German/English and English/German) will be available in the GxP. GCP and GLP sessions.