



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

September 23<sup>rd</sup> – 24<sup>th</sup>, 2010

### GLP-Preconference Training

September 22<sup>nd</sup>, 2010



### Maritim Hotel Königswinter

Rheinallee 3  
53639 Königswinter / Germany

### Meeting Organization

CSM Congress & Seminar Management  
Industriestraße 35  
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Simultaneous translation in Joint-, GLP- and GCP-Sessions

### Program Organizing Committee

Holger Dittberner, Steffen König, Günther Stelzer (GCP),  
Ulrich Schepers (GLP), Helmuth Morgenthaler (IT),  
Andreas Henrichs (Analytics), Christian Schad (GMP)

### Registration Fees (plus 19% VAT)

#### International Meeting

##### Member

Registration until July 16<sup>th</sup>, 2010 400,00 €  
Registration after July 16<sup>th</sup>, 2010 450,00 €

##### Non-Member

Registration until July 16<sup>th</sup>, 2010 500,00 €  
Registration after July 16<sup>th</sup>, 2010 550,00 €

#### Group Discount Available for International Meeting!

- Register 4 individuals from the same company location and the 5<sup>th</sup> attends FREE!
- All 5 individuals must register at the same time!
- Substitutions of enrolled delegates may be made at any time, please notify CSM of any substitutions as soon as possible.

Info and Registration: [www.csm-congress.de/dggf/](http://www.csm-congress.de/dggf/)

### Sponsoring

If you are interested in sponsoring our international conference, please contact Steffen König (steffen.koenig@istgmbh.com)

#### GLP-Preconference Training

##### Member

Attendees of International Meeting 250,00 €  
Only GLP-Preconference Training 300,00 €

##### Non-Member

Attendees of International Meeting 350,00 €  
Only GLP-Preconference Training 400,00 €

#### Exhibition and Posters

Persons or companies who are interested in exhibiting (display stand 1.000 € plus VAT) or making poster presentations (300 € plus VAT) should contact the Meeting Organizer (CSM) or write to [tagung@dggf.de](mailto:tagung@dggf.de). We also offer the opportunity to include information materials or flyers in the conference folder (500 € plus VAT).

## Program Highlights (Draft)

### Wednesday, September 22<sup>nd</sup>, 2010

#### Preconference Training (only in German)

09.00 - 15.00 **GLP training for beginners**  
You just started your career as Junior Auditor or Assistant Study Director and do not know what issues you need to consider? You are working in a service department and do not understand why QA keep asking you for written documentation about your activities? For further information please click [GLP-Preconference-Training](#)

#### International Meeting

17.00 - 19.00 Registration for international meeting and welcome reception  
18.30 Wine tasting (optional)

### Thursday, September 23<sup>rd</sup> and Friday, September 24<sup>th</sup>, 2010

#### Joint GxP Session

Trends in GxP; KPI; GCLP; GxP compliance from the courier/ transportation perspective.

#### Joint IT Session

Information technology overview for medical science; Growing digitalization of the GxP world (from numerical values to digital images); The GAMP 5 message for the GxP World.

#### GLP Analytic Session

Feedback concerning implementation e-data in bioanalysis; Assay validation; Actual trends FDA / EMA.

#### GLP Session

GLP update - an international view; Overview of GLP monitoring systems (UK, CH); Archive transfer; Experiences of a CRO with study setup; Round table discussion, FDA Inspections; Contractor Audits – Practical Industry Experience.

#### GCP Session

**Pharmacovigilance:** Good vigilance practices; MHRA risk-based inspections; Compliance in pharmacovigilance – sources of errors, prevention of errors, PV systems, interfaces to clinical development and reg. authorities; Safety data management and signal detection; Handling of protocol violations. **Monitoring:** Targeted communication with study team; Pre-study visit, and study initiation visit – objectives, procedures, assessment; Source documents and SDV; Challenges when monitoring mega-trials.

#### GMP Session

Integrated risk management for quality & supply chain; Risk based training concept and performance review; Training practice in a biopharmaceutical company; Round table discussion.

<b>08.00</b>	<b>Registration</b>	<b>13.30 – 17.30</b>	<b>Parallel Sessions</b>	<b>17.30 – 18.15</b>	<b>DGGF Annual Meeting</b>	<b>19.00</b>	<b>Sparkling Wine Reception</b>
<b>08.50 - 09.00</b>	<b>Welcome 15<sup>th</sup> Annual Meeting</b> <b>DGGF President Holger Dittberner</b>					<b>20.00</b>	<b>Conference Dinner and More</b>

**GxP Stream I \***

<b>09.00 - 12.10</b>	<b>Joint Information Technology Session: IT Innovations Change our Life – Influences to the GxP World</b> Chairperson: Helmut Morgenthaler, BASF SE, Limburgerhof, Germany
09.00 – 09.40 (D)	<b>Innovations and Visions in Health Telematics</b> Klaus Juffernbruch, Cisco Systems, Düsseldorf, Germany
09.40 - 10.20 (E)	<b>Digital Pathology – Growing Digitalization, Technical Challenges</b> André Huisman, University Medical Center, Utrecht, The Netherlands
<b>10.20 – 10.50</b>	<b>Coffee Break</b>
10.50 – 11.30 (D)	<b>Digitalization of GxP Documents – Increasing Challenges</b> Thorsten Dunker, BioMedion, Henningsdorf/Berlin, Germany
11.30 – 12.10 (D)	<b>GAMP 5 – Helpful IT Answers for the GxP World?</b> Maxim Bothe, Nycomed GmbH, Konstanz, Germany
<b>12.10 – 13.30</b>	<b>Lunch</b>

\* Simultaneous translation English and German  
(E) presentation in English, (D) presentation in German

**GLP Stream I \***

<b>13.30 – 17.30</b>	Chairperson: Ulrich Schepers, BASF SE, Limburgerhof, Germany
13.30 - 14.15 (D)	<b>GLP update – an international view</b> Wolf Bulling, Bundesinstitut für Risikobewertung, Berlin, Germany
14.15 - 15.00 (E)	<b>Overview of the UK GLPMA's inspectorate policies and its approach to risk based inspections</b> Andrew Gray, MHRA, London, UK
<b>15.00 - 15.30</b>	<b>Coffee Break</b>
15.30 - 16.00 (E)	<b>The Swiss GLP Compliance Monitoring Program – National and International Activities</b> Olivier Depallens, DFI, Liebefeld, Switzerland
16.00 - 17.30 (E)	<b>Round Table Discussion – Questions and Answers</b> , Wolf Bulling, Andrew Gray, Olivier Depallens, Ulrich Schepers Moderator: Stephen Harston

**GCP Stream I \***

<b>13.30 – 17.00</b>	Chairperson: Kerstin König, ImClone Systems International GmbH, Heidelberg, Germany
13.30 - 14.00 (D)	<b>MHRA Risk-based Inspections</b> Ute Hoeffner, Novartis Consumer Health GmbH, Munich, Germany
14.00 – 14.30 (D)	<b>Good Vigilance Practices</b> Monika Pietrek, Pietrek Associates GmbH, Weinheim, Germany
14.30 – 15.00 (D)	<b>Compliance in Pharmacovigilance – Source of Errors, Prevention of Errors</b> Jürgen-Hans Schmidt, Sanofi-Aventis GmbH, Frankfurt, Germany
<b>15.00 - 15.30</b>	<b>Coffee Break</b>
15.30 - 16.30 (D)	<b>Pharmacovigilance in Clinical Trials – do's and don't's – Moderate, audience-interactive oral presentation on selected topics of pharmacovigilance in clinical trials</b> Uwe Ullmann, Drug Safety Consultant, Kreuzlingen, Switzerland Heinz Weidenthaler, MediGene AG, Munich, Germany
16.30 – 17.00 (D)	<b>Handling of Protocol Violations</b> Rita Hattemer-Apostel, Verdandi AG, Zurich, Switzerland

**GLP / Analytic Stream**

<b>13.30 – 16.00</b>	Chairperson: Andreas Henrichs, Sanofi Aventis, Hattersheim, Germany
13.30 - 14.10 (D)	<b>Feedback concerning implementation e-Data in Bioanalysis</b> Jörn Krause, Sanofi-Aventis, Frankfurt, Germany
14.10 – 14.50 (D)	<b>Assay Validation</b> Timo Kretzschmar, Pharm-Analyt Labor GmbH, Baden, Austria
<b>14.50 - 15.20</b>	<b>Coffee Break</b>
15.20 - 16.00 (E)	<b>Harmonization of Guidelines: FDA and EMEA</b> Gerd Paulus, Swiss BioAnalytics AG, Birmfelden, Switzerland

Friday, September 24<sup>th</sup>, 2010

<b>09.00 – 12.30</b>	<b>Parallel Sessions</b>	<b>12.30 – 13.30</b>	<b>Lunch</b>	<b>13.30 – 15.30</b>	<b>Joint Session</b>	<b>15.30</b>	<b>Closing Remarks</b>
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**GLP Stream II \***

<b>09.00– 12.30</b>	Chairperson: Frauke Hermann, Harlan Cytotest Cell Research GmbH, Rossdorf, Germany
09.00 - 09.45 (E)	<b>FDA GLP Inspections – Past, Present and Future</b> Kathleen Andrews, KD Andrews & Company, Cary NC, USA
09.45 - 10.30 (E)	<b>Contractor Audits – Practical Industry Experience</b> Leena Liimola-Luoma, Bayer Schering Pharma AG, Berlin, Germany
<b>10.30 - 11.00</b>	<b>Coffee Break</b>
11.00 - 11.45 (D)	<b>Experiences of a CRO with study setup</b> Erinita Fröhke, Covance Laboratories, Münster, Germany
11.45 – 12.30 (D)	<b>Archive transfer – A child's game?</b> Jürgen Sneikus, Bayer CropScience AG, Monheim, Germany

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**GCP Stream II \***

<b>09.00 – 11.00</b>	Chairperson: H. Günther Stelzer, Clinical Quality Consultants, Freiburg, Germany
09.00 - 09.45 (E)	<b>Quality Assurance at the Site when using ePRO</b> Valdo Arnera, PHT Corporation, Geneva, Switzerland
09.45 - 10.30 (D)	<b>Targeted Communication with Study Team</b> Petra Kammerer, Dipl.-Psych., Berlin, Germany
<b>10.30 - 11.00</b>	<b>Coffee Break</b>
<b>11.00 – 12.30</b>	Chairperson: Andreas Grund, GCP-Service International, Bremen, Germany
11.00 - 11.30 (D)	<b>Findings!...and what happens then?</b> Marianne Linsel-Nitschke, CTC North, MediGate GmbH, UKE, Hamburg, Germany
11.30 - 12.00 (D)	<b>Source Documents and Source Data Verification</b> Christiane Hartlieb-Wallthor-Sano, ProTS, Monheim, Germany
12.00 - 12.30 (E)	<b>Navigating Monitoring of mega-Trials in a Resource strained Environment and growing regulatory Pressures</b> Beat Widler, F. Hoffmann-La Roche Ltd, Basel, Switzerland

**GMP Stream**

<b>09.00 – 12.10</b>	Chairperson: Christian Schad, IS&S Informationstechnik GmbH, Aschaffenburg, Germany
09.00 - 09.40 (D)	<b>Integrated Risk Management for Quality &amp; Supply Chain</b> Thomas Zimmer, Boehringer-Ingelheim, Ingelheim, Germany
09.40 - 10.20 (D)	<b>The Risk Based Training Concept And Performance Review</b> Maria Brecht, PTS Training Service, Arnsberg, Germany
<b>10.20 – 10.50</b>	<b>Coffee Break</b>
10.50 - 11.30 (D)	<b>Training Practice In A Biopharmaceutical Company</b> Thomas Menne, Rhein Biotech GmbH, Düsseldorf, Germany
11.30 - 12.10 (D)	<b>Round Table Discussion</b> Moderation: Christian Schad, IS&S Informationstechnik GmbH, Aschaffenburg, Deutschland or Klaus Buchweitz, Micromet AG, Munich, Germany

**GxP Stream II \***

<b>13.30 – 15.30</b>	<b>Joint GxP Session:</b> Chairperson: Holger Dittberner, Nycomed GmbH, Barsbüttel, Germany
13.30 - 14.10 (D)	<b>How to measure quality?</b> Angelika Tillmann, Omnicare Clinical Research, Bad Soden, Germany
14.10 – 14.50 (D)	<b>Good Clinical Laboratory Practice – First experiences with GCLP as a new quality standard</b> Wolfgang Seidel, Merck KGaA, Darmstadt, Germany
14.50 – 15.30 (D)	<b>GxP compliance from the courier/transportation perspective – Finding the right balance between Regulators expectations and the real world</b> Rüdiger Lomb, World Courier Management Inc., Berlin, Germany

**15.30** **Closing Remarks**  
DGGF President Holger Dittberner