## Keynote

# Wir würfeln uns eine Studie (We dice a study)



Key Note Speaker

## Prof. Björn Christensen

#### The Lecturer

Prof. Björn Christensen is Professor for Statistics and Mathematics at the University of Applied Science Kiel and has more than 15 years of experience as teacher, author and expert in Data Mining, Predictive Analytics, Big Data Analytics. Prof Björn Christensen published numerous scientific papers and publishes periodic columns such as "Angezählt" (Spiegel online) and "Achtung: Statistik - Alltagsthemen der Statistik zum Nachdenken und Schmunzeln".

#### The Presentation

Statistics are considered to be a deadpan topic and difficult but are present at every turn during education, profession and above all in the media, however not easily understandable to everyone. In the course of his lecture Prof. Björn Christensen will demonstrate that everyone can gain interesting and astonishing insight into the world of statistics even without previous knowledge. The lecture will enable everyone in the future to critically judge statistical results presented in public science and media and to view statistics in a new light.

## **Topics** GxP goes digital

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

- OECD Advisory Document No.17

   Advantages, Disadvantages
   and Challenges
- Managing the Big Data Tsunami in the Life Sciences Lab
- Quality Management in the Digital Age
- Roll-out and implementation of a globally harmonized eQMS

#### **Risk Management**

- Practical Examples for Risk Management
- ISO 9001:2015 within clinical trial management – an approach for risk based quality management

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

- Laboratories are going "paperless": Electronic Raw Data Archiving in practice
- Is our GLP system suitable for the challenges of recent developments? GLP News, especially focusing on New Techniques and Challenges
- GLP Round Table Discussion
- e-LC/MS-MS Data
- Bioequivalence Studies / Bioanalytics at the interface of GCP-GLP

#### **Pharmacovigilance**

 E2B (R3) Implementation and associated requirements

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

- Electronic Informed Consent
- eArchiving (TMF)
- e-Data Regulatory Expectations
- GCP Round Table Discussion

# GMP (Good Manufacturing Practice)

 Finding the path to data integrity in a GMP environment

#### **GDP (Good Distribution Practice)**

 The last mile of drug supply in clinical trials

Most papers will be presented in German. Simultaneous translation will be available in GLP and joint sessions.

## Venue

The 22<sup>nd</sup> International Meeting will be held in the



Maritim Hotel Würzburg Pleichertorstraße 5 97070 Würzburg Germany.

For room reservation (special rates) please follow the **▶link** or

**call** +49 931 3053-830 **fax** +49 931 3053-900

e-mail info.wuerzburg@maritim.de

## Registration

To register for the International Meeting and/or the Preconference Training please contact our event partner **CSM** (for registration forms or direct online registration) or by fax at +49 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.

## **Participation Fees**

## **GQMA International Meeting**

Sept. 21<sup>st</sup>, 2017, 9:00 until 17:30 Sept. 22<sup>nd</sup>, 2017, 9:00 until 15:30

## **GOMA** members

- 4	
until July 31st, 2017	450,- €
after July 31 <sup>st</sup> , 2017	500,-€
Non-members	
until July 31st, 2017	550,-€
after July 31st, 2017	600,- €

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).

# Sponsorship and Advertising

Would you consider sponsoring the International Meeting or placing an advertisement? There are various ways to do so. Please feel free to contact us for more detailed information at info@csm-congress.de or visit www.gqma.de

## **Exhibitors**

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

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

## Contact

## CSM Congress & Seminar Management

Industriestr. 35 82194 Gröbenzell

 Phone
 +49 8142 57 01 83

 Fax
 +49 8142 547 35

 E-mail
 info@csm-congress.de

 Web
 www.csm-congress.de



# Preconference Training

## **GLP Basistraining**

Sept. 20th, 2017, 9:00.until 15:30

#### **GQMA** members

until July 31st, 2017	450,- €
after July 31st, 2017	500,- €
Non-members	
until July 31st, 2017	550,-€
after July 31st, 2017	600,-€

## Kommunikationsstrategien im Audit

Sept. 20th, 2017, 9:00.until 17:30

## Auditor in der Pharmakovigilanz

Sept. 20th, 2017, 9:00.until 17:30

## **About**

The **GQMA 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 networking opportunities.

Three Preconference Trainings on September 20<sup>th</sup>, 2017, will complete the program of the GQMA International Meeting.

The German Quality Management Association (GQMA), formerly known as Deutsche Gesellschaft für gute Forschungspraxis e.V. (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 environment.

For further Information about the society please visit www.ggma.de

