# Please join us for Celerion's Risk Management Workshop

## Risk Management in Global Clinical Trials Environment

**Programme Agenda:**

**15:30-16:00** Welcome, Networking and Refreshments

**16:00-16:10** Host Opening Remarks

**16:10-18:00** Dimensions of Risk Management in Global Clinical Trials Environment

- The Academia Perspective
  - What is risk management as perceived by a clinical trial site
  - How a clinical trial site would collaborate with a CRO and with a Sponsor to mitigate risks
  - Case studies
- The Sponsor Perspective
  - Sponsor oversight in clinical trials
  - Identify, assess, mitigate and review risks
- The Contract Research Organisation Perspective
  - Positioning the level of involvement of sponsor and CRO
  - How your vendor can help
  - Principles, Processes and Practicalities

**18:00-18:30** Q & A

**Event Details**

**Date:** Thursday, May 9, 2019

**Time:** 15:30-18:30

**Venue:** Steigenberger Hotel Herrenhof
Herrengasse 10,
1010 Wien, Austria

**RSVP**

## About the Host

**Celerion** is a global provider of outsourced clinical development services with the proven ability to address programs from first-in-human (FIH) through Phases I-III. We are the ideal partner for innovative biotech companies in an environment overwhelmed by tightening budgets, stricter regulations and more complex reimbursement. We assist biotech companies in getting their drugs to market faster and more cost effectively.

- With offices throughout Europe, the U.S. and Asia, we can address all of your requirements.
- We have specifically developed expertise in the areas of Renal/Hepatic impairment, Vaccines, Respiratory and Oncology.
- With our years of experience, Celerion has helped clients address their risk management challenges in the face of the increasing complexities of Phase I-III studies.

## Guest Speaker Biographies

### Prof. Dr. Michael Wolzt

- MD from the University of Vienna in 1991 and post-graduate research at the University College London, UK
- Professor of Medicine and internal medicine consultant at the Vienna General Hospital
- More than 20 years of experience in industry-sponsored and non-commercial clinical trials with human medicines and medical devices

### PD Dr. Ghazaleh Gouya Lechner, CEO and founder of Gouya Insights

- Austrian board certified in Internal Medicine, Cardiology and Clinical Pharmacology
- Leadership in clinical development for biotechnology companies
- Over 20 years of experience in the areas of clinical trials as Investigator (FIH to Phase IV)

**Space is limited. Please RSVP at marketing@celerion.com by Fri, May 3, 2019. For questions, please contact Alexandra Seifert at +491602612304.**