CENTER OF EXCELLENCE IN CLINICAL RESEARCH

70-72, Dionisie Lupu Str.
Bucharest, Romania

Powered by ARENSIA Exploratory Medicine GmbH
Merowingerplatz 1, 40225 Düsseldorf, Germany

ICH GCP E6 (R2) Training

30/31 May, 2019 Bucharest, Romania

SCOPE OF TRAINING

Good Clinical Practice (GCP) course is designed to prepare research staff in the conduct of clinical trials with human participants.

It is a standard within clinical research business to hold an up-to-date GCP certificate.

The training offers the opportunity to refresh your GCP knowledge and provide you an update on current changes in EU legislation and related guidelines.

TRAINING LOCATION

OPERA HALL, 2ND floor, INTERCONTINENTAL HOTEL, BUCHAREST
Coffee and lunch breaks included

REGISTRATION FEES

250 RON (VAT included)
10% discount for groups of more than three participants from the same company

BENEFITS FOR PARTICIPANTS

- GCP Training Certificate of Attendance valid for two years

- The training curricula is compliant with TransCelerate Minimum Criteria of GCP Training Courses, as necessary to enable mutual recognition of GCP training among trial sponsors.

PARTICIPANT'S PROFILE

Professionals working in clinical trials (Investigators, clinical study teams or referrals, i.e. clinicians, GPs, study coordinators, study nurses), Clinical Research Coordinators, Clinical Research Organizations (CROs), IRB or CA Members, Researchers or other Research Staff

TRAINING AGENDA

Course Trainer: Dr. Peter M Kaiser –GxP auditor-Germany

- History of GCP (USA and Europe)
- Definition of Clinical Trial, Investigator, Subinvestigator, Sponsor
- The Principles of ICH-GCP
- Introducing new section "Quality Management" into ICH-GCP (section 5.0)
- Ethics
- Responsibilities of Sponsor (transfer to CRO) + Investigator
- Monitoring
- Pharmacovigilance / Reporting of Safety Data
- Drug Handling + GMP
- Source Data: Definition and SDV Check
- Validation of Computerized Systems
- Practical aspects, QA problems, examples of Audit findings

For registration please contact us at phone no **+40 725 200 692** or email **alexandra.stirbu@arensia-em.com**