GCP-CERTIFICATES AND OTHER TRAININGS

According to the Pharmaceutical Products Act (12th amendment of the PPA), principal investigators must submit their **GCP certificates** to the ethics commission already at the beginning of a clinical study. Since the order of the German Medical Association in April 2013, principal investigators in all studies must prove to have completed a GCP training according to the PPA and MPA.

We carry out GCP courses which are individually tailored to your study (PPA or MPA). This can be carried out in a joint event of all principal investigators in a study – for example also in the course of an investigator meeting. Alternatively, the GCP training can also be carried out as in-house training and can be combined with an initiation – thus, the effort for principal investigator and study nurse is manageable and at the same time all GCP guidelines are adhered to.

The contents of our GCP trainings strictly comply with the regulations of the Pharmaceutical Products Act:

Content	**Description**
Methodical basics	Delimitations pharmaceuticals / medicinal products / foodstuff / cosmetics Definition clinical investigation, NIS and safety assessment Phases of pharmaceuticals development (I - IV) Types of studies, study design Biometric basics
Ethical principles	Historical development of clinical research Declaration of Helsinki Vulnerable groups
Legal basics	EU law, federal law Authorization procedures (higher federal authority, assessment by Ethics Commission - Ethics Commission vote)
Planning and preparation	Relevant documents: investigation plan, investigator´s brochure, patient information, CRF, etc. Responsibilities (sponsor, CRO, monitor, investigator) Resource planning Allocation of tasks within the team Investigation contract
Implementation	
Investigational Medical Products (IMP`s)	Definition, storage, dispensation

Screeening and recruitment	Strategies Inclusion and exclusion criteria Randomization
Information and consent Regular implementation	Prüfplankonformer Studienablauf, Abbruchkriterien, Dokumentation, Queries, Archivierung
Monitoring, audits, inspections Adverse Events, security	Definition AE, SAE, SAR, SUSAR, etc. , causality assessment Reporting obligation and reporting deadlines
Finalisation of clinical investigation	Close Out Visit
	Filing Final report and publication
Assessment of learning success	

Additionnally, we offer training to following other subjects:

- Introduction to data management
- Principles of statistical evaluations
- Explaining eCRF – instructions to all relevant programmes
- Carrying out literature research and introduction to Endnote
- Compiling Powerpoint presentations

Depending on our agreement, the trainings can take place in our training rooms, on your premises as in-house training or via internet.

Upon request further individual trainings are possible.

Which training do your team needs for your study?

SPEAKER AT YOUR SYMPOSIUM

We want to help you make your symposium symposium a great success! Here, we also gladly take on lectures and presentations on topics regarding clinical studies and statistics. Of course, the presentations can be held in German or English.

What is your symposium about?