



# MEDIZINISCHE FAKULTÄTUNIVERSITÄTSKLINIKUM MAGDEBURG A. Ö. R.

## COORDINATION CENTER FOR CLINICAL STUDIES

### Good Clinical Practice - GCP

GCP's guiding principles are:

- the compatibility of the clinical trial with the law, ethical principles and their concretization in the Declaration of Helsinki
- the start of the clinical trial with a minimum of risk and with the least possible burden for the trial subjects and society
- the rights, safety, and well-being of the trial subjects take precedence over the interests of science and society
- the design of the clinical trial must be reasonable in light of the available preclinical and clinical data
- an appropriate, detailed protocol/CIP must be available
- the clinical trial is conducted in accordance with the protocol/CIP previously "approved" by the Ethics Committee
- adequate care of the trial subjects by a qualified physician is ensured
- all participating persons are qualified by education and training for the tasks they are to perform
- the written consent of the subject is obtained after proper informed consent has been obtained
- proper documentation of the clinical trial for the purpose of ensuring and verifying its usefulness is ensured
- confidentiality and data protection regulations for the protection of the trial subjects are observed
- the use of the trial medication is in accordance with the protocol
- the manufacturing, handling and storage of the investigational medicinal product is performed in accordance with the applicable Good Manufacturing Practice (GMP)
- the medical device is used in accordance with the CIP
- a quality management system is in place, which is applied according to the written specifications

Kontakt & Anschrift

**Dr. rer. nat. Antje Wiede**

Leiterin des KKS

Tel.: 0391/67-21 838

Fax: 0391/67-15 898

[kks@med.ovgu.de](mailto:kks@med.ovgu.de)

Otto-von-Guericke-Universität

Medizinische Fakultät,

KKS Magdeburg

Leipziger Str. 44

39120 Magdeburg

Haus 1, Ebene 4, rechts

[Anfahrt und Lageplan](#)

KKS-Nutzungsordnung\_ZMF

KKS Beratungsanfrage

Hinweisblatt Studienplanung

Kurzleitfaden Eine Studie-Ein Votum

## **Schulungsangebote intern NEU**

## **Regularien**

### **Links**

KKS-Netzwerk

BfArM

BfS

Paul-Ehrlich-Institut **PEI**

Bundesministerium für Gesundheit

European Medicines Agency **EMA**

Registrierung **DRKS**

Ethikkommission **AKEK**

**ICH**

