MEDIZINISCHE FAKULTÄTUNIVERSITÄTSKLINIKUM MAGDEBURG A. ö. R.

COORDINATION CENTER FOR CLINICAL STUDIES

Quality Assurance

Quality assurance primarily involves the maintenance, further development, and continued establishment of the quality management system (QM system). This standardizes processes within the framework of clinical trials and thus ensures high quality. For this purpose, the KKS Magdeburg has established an SOP system and provides these to individual trial centers. (PZ-SOP) available as fundamentals of work.

Furthermore, the QM system includes regular internal audits, which are performed by the quality manager in the context of clinical trials, but also in the context of the SOP system. This means that, as a rule, each IIT study can be audited once a year by the KKS Magdeburg until its completion.

External audits have so far been carried out exclusively by external providers.

The sponsor's QM system also includes Schulungen of employees of the UMMD. Regular courses are held by the KKS on the topic of Good Clinical Practice (AMG refresher course) for drug and medical device studies (MP supplementary course or MP refresher course if a basic GCP course is available). The KKS Magdeburg continues to be involved in the organization of the twice-yearly, through the Insitut für Biometrie und Medizinische Informatik (IBMI) conducted, 2-day basic GCP courses.

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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