MEDIZINISCHE FAKULTÄTUNIVERSITÄTSKLINIKUM MAGDEBURG A. ö. R.

COORDINATION CENTER FOR CLINICAL STUDIES

Explanation of Terms for Training Offers

The basic course as well as the AMG advanced course replace the 2-day GCP basic course from the previous years.

Basic course:? Day 1 in Magdeburg

This course is aimed in particular at physicians/scientists who have not yet worked as an investigator/deputy or member of an investigator group within the meaning of the AMG (Section 4 Para. 25 as well as Section 40 Para. 1a), as an investigator within the meaning of the CTR/EU Regulation for clinical trials with medicinal products (Article 2 Para. 2 No. 15) or as an investigator within the meaning of the MDR/EU Regulation for clinical trials with medical devices (Article 2 No.54).

Study nurses, MTAs or MDAs are also addressed as members of the review team for whose qualifications the investigator/principal investigator is responsible.

AMG Advanced Course: ? Day 2 in Magdeburg

Physicians/scientists who have the function of investigator/deputy investigator in the sense of the AMG (§ 4 para. 25) or principal investigator according to the CTR (Art. 2 para. 2 no. 16) require an advanced qualification, which must be completed building on the basic course (cf. curricular advanced training "Advanced course for investigators/deputies or principal investigators leading an investigator group or investigator team in clinical trials according to the AMG or the CTR").

The content specifically prepares for the special responsibility of the examiner/deputy or principal examiner according to CTR. The course builds on the basic course and therefore requires successful participation in a basic course.

MP supplementary course: also applies to performance studies with in vitro diagnostic devices in accordance with IVDR and MPDG.

The MP supplementary course, comprising at least 5 ½ UEs, is aimed at physicians/scientists who are to assume the role of principal investigator or investigator in a test center in accordance with MDR (Article 2 No.54) or MPDG (§30). The content specifically prepares for the special responsibility of the principal investigator/investigator according to MPDG (§ 30 para. 1-5). The course complements the above-mentioned courses and therefore requires successful participation in the above-mentioned courses.

The principal investigator is responsible for ensuring that all members of the test group are trained. Therefore, we also recommend here that all members of the group also attend an MP supplementary course.

Curriculum Aufbaukurs_AMG_CTR+MPDG+MDR_IVDR_2022

Curriculum Auffrischungskurs_AMG_CTR+MPDG+MDR+IVDR_2022 ☐

Curriculum Grundlagenkurs_AMG+CTR_MPDG_MDR+IVDR_2022 ☐

Curriculum Updatekurs_AMG_CTR_2022 ☐

AMG Refresher Course:

This refresher course, comprising at least 4 units, is aimed at physicians who have already completed a basic course, as well as other members of the examination group who also have prior knowledge.
According to current knowledge, we recommend that you attend a refresher course again after 3 years.

MP Refresher Course:
This refresher course of at least 4 units is aimed at physicians who have already completed a basic course, an AMG refresher course, and an MPG supplementary course, as well as other members of the examination group who also have prior knowledge. Training participants who have already successfully participated in a previous MPG training course from KKS-Magdeburg are entitled to book an MPG refresher course.
According to current knowledge, we recommend that you attend a refresher course after 3 years.

BÄK+AK Med. EK_Beschluss Curriculare Fortbildung_Auffrischungskurs_AMG_MPG_Oktober 2016 ☐