



# CERTIFICATE

**Dr. Nicole Leib**

has successfully completed an

## ICH GCP Training

International Council on Harmonisation Good Clinical Practice

as part of our Medical Manager/MSL training programme.

The ICH GCP training included a written examination and contained the following main topics:

- Development of pharmaceutical products (history & phases)
- Overview of clinical studies (study design)
- Legal essentials (AMG, ICH-GCP, EU-directives, Clinical Trial Regulation EU No 536/2014), [MPDG](#), non interventional studies
- Study site duties (ICH-GCP E6 Guidelines)
- GCP documents, submissions to the relevant authorities, study protocol, patient's consent, testing medication, documentation & data management
- Pharmacovigilance (definition, registration requirements, annual safety report, documentation)
- Audits and inspections

*Andrea Ross*

Pharmaakademie



Leipzig, 02.12.23

