PHARMA AKADEMIE

CERTIFICATE

Roman Botow

has successfully completed an

ICH GCP Training

International Council on Harmonisation Good Clinical Practice

as part of training for Clinical Research Associate (CRA).

The ICH GCP-Training consisted of 16 hours of professional training and a two hour workshop with focus on the following topics:

- Development of pharmaceutical products (history & phases)
- Overview of clinical studies (study design)
- Legal essentials (current versions AMG, ICH GCP, EU-directives, GCP-regulation), MPG, non-interventional studies
- Study site duties (current version 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

Leipzig, 03 December 2018

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