

Category I

Continuing Medical Education (CME) 18



Certificate ISO14155-Basic-Training

Good Clinical Practice in Medical Device Studies

Zehui Bai

has attended the ISO14155-Basic-Training according to the curricular trainings by the German Medical Association (published in "Deutsches Ärzteblatt", 07. October 2016) on

07. Oct 2020

The training course lasted 8 hours and consists of the following 8 training modules:

- 1. Development of Drugs & Medical Devices
- 2. Basics of Biometry
- 3. European legislation on MD clinical trials
- 4. Declaration of Helsinki & ISO14155:2011
- 5. Responsibilities of Investigators 1
- 6. Responsibilities of Investigators 2 & Sponsors
- 7. Study Documents
- 8. Quality control of a Case Report Form

The attendee has passed the training exam(s) with at least 80% of the maximum possible points. The training course has been accredited by the Medical Association of Bremen. 18 Continuing Medical Education (CME) points have been assigned. The course number is *2760402020013140008*.

D.Zh

Dr. Andreas Grund Activity Provider / Organizer GCP-Service International Ltd. & Co. KG

