

Category I

Continuing Medical Education (CME) 16



Certificate GCP-Basic-Training

GCP-Basic-Training including GCP-Update-Training

Zehui Bai

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

13. Oct 2020

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

- 1. Development of Drugs & Medical Devices
- 2. Principles of Biometry
- 3. Declaration of Helsinki & GCP Guidelines ICH GCP E6 (Revision 2)
- 4. Study Documents, Ethics Committees & Quality Requirements
- 5. Responsibilities of Investigators Part 1
- Responsibilities of Investigators Part 2, Responsibilities of Sponsors, Audits
- 7. Inspections and Reporting of Safety Related Events
- 8. Current Legislations & Regulations on Clinical Trials in Europe

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. 16 Continuing Medical Education (CME) points have been assigned. The course number is *2760402020013100002*.

D.Zh

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

