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GLP Training in China

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WHY IS GOOD LABORATORY PRACTICE (GLP) TRAINING IMPORTANT?

The international OECD (Organization for Economic Co-Operation and Development) standard of a Good Laboratory Practice (GLP) is a GLP quality system that should be applied (mandatory) to the non-clinical safety testing of test items contained in pharmaceutical products, pesticide products, cosmetic products, veterinary drugs as well as food additives, feed additives, and industrial chemicals. The purpose of these OECD Principles of Good Laboratory Practice is to promote the development of quality test data. Comparable quality of test data forms the basis for the mutual acceptance of data among countries. If individual countries can confidently rely on test data developed in other countries, duplicative testing can be avoided, thereby saving time and resources. The application of these Principles should help to avoid the creation of technical barriers to trade, and further improve the protection of human health and the environment.

The non-clinical health and environmental safety studies are performed by laboratories with the aim of registering or licensing pharmaceuticals, pesticides, food and feed additives, cosmetic products, veterinary drug products and similar products, and for the regulation of industrial chemicals.

It is important that the actors involved in the GLP process understand and interpret correctly the content of these Principles before they produce reliable data that complies with regulatory agencies' good laboratory practice guidelines, specifications, and regulations. Therefore, participation to a thorough and intensive GLP training course of five days is recommended before starting non-clinical health and environmental safety studies. This GLP training course is programmed and managed by **Mr. Hedwig Beernaert, a Belgium GLP inspector from EuroQAM Ltd.** who shares his knowledge in an enthusiastic, interactive manner. The program of this GLP training course includes **presentations, discussions, individual exercises and group problem-solving case studies** to assure the actors to apply the OECD Principles of GLP correctly in order to be GLP certified and to submit data for scientific evaluation by regulatory authorities.

TRAINER PROFILE

Hedwig Beernaert

Consultant and GLP expert, General Manager of EuroQAM Ltd,

Hedwig Beernaert is the quintessential GLP expert, author or coauthor of some 100 peer reviewed publications, Chairman of the EU's mutual joint visit program steering group, organizer and developer of multiple GLP courses and vice president of Belgium's GLP accreditation board are just a taste of the accolades that decorate his outstanding career.

During his 20 year tenure, Mr. Beernaert racked up an impressive list of achievements specifically relating to implementation of OECD principles of GLP, and personally was involved in more than 200 OECD sanctioned inspections. A figure of global reputation, Mr. Beernaert started his own consultancy firm "EuroQAM" in 2009, providing quality and dependable advice and consultancy on all things GLP.

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Training Overview and COURSE SCHEDULE

The training program is an intensive and interactive exercise.

COURSE SCHEDULE

SCHEDULE	MORNING SESSION (9:00 am-1:00pm)	AFTERNOON SESSION (2:00-6:00pm)
DAY 1	· Introduction · General GLP aspects · What is GLP? · Interrelation between Receiving and Monitoring Authority · Scope of GLP: trends in the OECD GLP Principles · Legal Framework (Differences between OECD, USA and Japan) · Inspection preparation: how to survive an inspection? **Questions (trainees) and answers (trainer)** **Individual exercise:** general GLP aspects	· Critical points concerning responsibilities of √ Sponsor √ Test Facility Management (TFM) √ Study Director (SD) √ QA staff √ Archivist √ Study personnel **Questions (trainees) and answers (trainer)** · Master schedule of GLP studies: **Group exercise : set-up and deficiencies of a master schedule**
DAY 2	**· Critical points QA Program** **· What is a processed based inspection?** **Questions (trainees) and answers (trainer)** **Group exercise : preparation of test-facility inspection**	**Group exercise : performance and reporting a test facility inspection**
DAY 3	· Critical points of facilities: floor plan, separation of activities, environmental conditions, waste disposal, housekeeping **Questions (trainees) and answers (trainer)** **Individual exercise: facilities** · Critical points apparatus, materials and test systems : purchase, use of terms maintenance, calibration and validation **Questions (trainees) and answers (trainer)** **Individual exercise : equipment**	· Critical points computerized systems · IT policy: responsibilities, training, security, SOPs, archiving · Master validation plan (DQ, IQ, PQ, OQ) of computerized systems **Questions (trainees) and answers (trainer)** **Group exercise : computerized systems**
DAY 4	· Critical control points of test and reference items **Questions (trainees) and answers (trainer)** · Critical points standard operating procedures (SOPs) **Questions (trainees) and answers (trainer)** · Critical points archives **Questions (trainees) and answers (trainer)** **Individual exercise : test and reference items, SOPs, archiving**	· Critical points performance of a study **Group exercise: case study set up (SD) and audit (QA) of a study plan**
DAY 5	**Group exercise: open discussion results case study plan** · Critical points reporting of a study **Questions (trainees) and answers (trainer)** **Group exercise: case study set up (SD) and audit (QA) of a final report (QA)**	**Group exercise: open discussion results case study final report**

TARGET GROUP

A GLP training course is successful and efficient if the number of participants is limited to 20 persons. This group should be interested and involved in the field and interactive during the training. It is recommended that the participants have communicative skills and understand and talk the English language. Simultaneous translation can be an alternative.

The GLP training course can be attended by

- **Sponsor:** responsible for the organization commissioning and submitting GLP work
- **Management:** responsible for providing adequate resources to run GLP studies and designates a study director prior to study initiation and replace, if necessary
- **Study Director:** is the single point of the GLP study and is responsible for the overall conduct of the study and its final report
- **Study Personnel:** should follow protocols, SOPs, analytical methods and are obliged to communicate any deviation concerned to the study director
- **Principal Investigator:** responsible for test site supervision
- **Quality Assurance Unit (QAU):** responsible for the independent inspection and study audits to assure regulatory agencies that the work was conducted and reported according to good laboratory practice regulations

PRICE

To negotiate between the organization of the training course and the trainer.

The GLP training course can be organized by a laboratory, industry, public or private organizations. The course can be followed by participants of the same or different organizations of laboratories, industry, public or private organizations

REGISTER or INQUIRE

Interested to attend the training? Contact us to register or inquire about the details at:

Email: contact@chemlinked.com
Phone: 86 571 8609 4444