ONE-DAY COURSE, Sunday only

17 Introduction to GLP Regulations and Bioanalytical Method Validation by LC-MS/MS

Instructor

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Course Description

Good laboratory practice (GLP) is a set of regulations intended to assure the quality and integrity of non-clinical laboratory studies that are intended to support research or marketing permits for products regulated by government agencies.

“Guidance for Industry - Bioanalytical Method Validation” published in May 2018 provides general recommendations for bioanalytical method validation using advanced technologies. This one-day short course will focus on the introduction to GLP regulations and bioanalytical method validation using LC-MS/MS. It will help audiences to comply with the regulations for drug discovery and development in the pharmaceutical industry and CROs. The short course will also reflect the recently published white papers regarding bioanalytical method validation using LC-MS/MS.

Intended Audience:

This one-day short course will benefit the analytical chemists, lab supervisors, QA/QC managers, regulators, GLP auditors and CRO consultants who work in the GLP-regulated labs and the pharmaceutical industry. This course will also benefit all levels of management as a refresher course to stay current with the GLP regulations.

Detailed Outline:

1. Introduction to GXPs

- Good Clinical Practice (GCP)
- Good Laboratory Practice (GLP)
- Good Manufacturing Practice (GMP)
- IBT incident and GLP
- What is a nonclinical study for
- The key requirements for GLP-type work

2. Bioanalytical Method Validation

- Full, partial, and cross validation
- The fundamental parameters of a validation
- Requirements for accuracy, precision, recovery, selectivity and specificity

- Calibration curve – how to define LLOQ and ULOQ
- Stability tests
- Principles of bioanalytical method validation
- Specific recommendations for standards and QCs
- Acceptance criteria for standards and QCs

3. Bioanalytical Sample Analysis

- Application of a validated methods to routing drug analysis
- Recommendations for routine drug analysis
- Design an analytical run/batch
- How to arrange samples - by subject or by period
- Evaluation of LLOQ, ULOQ and QCs
- Criteria to approve or reject results
- Evaluation of unknown study samples
- Deviations and remedial actions
- Re-assay selection
- How to report bioanalytical results

4. Case Study and White Paper Discussion

- Validation bottleneck and challenges
- How to measure and minimize matrix effects
- How to harmonize the various global bioanalytical guidance documents
- How to deal with urine samples
- How to improve the throughput

Instructor Qualification and Experience

Dr. Perry G. Wang worked in the pharmaceutical and medical-device industry from 2000 to 2008. He received his Ph.D. degree at Oregon State University. Dr. Wang currently works at FDA as a chemist. In addition to over twenty peer-reviewed publications, he has edited and co-edited five books: "High-Throughput Analysis in the Pharmaceutical Industry", "Monolithic Chromatography and Its Modern Applications", "Hydrophilic Interaction Liquid Chromatography (HILIC) and Advanced Applications", "Counterfeit Medicines", and "High-Throughput Analysis for Food Safety". His expertise focuses on high throughput analysis and validation by LC-MS. He prepares and teaches this course in his own capacity but not as an employee of the FDA. He has been invited to teach this course at ASMS since 2015.