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. The term GLP is most commonly associated with the pharmaceutical industry and the required non-clinical animal testing that must be performed prior to approval of new drug products.

"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 GLP regulations and the bioanalytical method validation for drugs and metabolites in biological matrices 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 with regard to 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. Brief History of Food & Drug Laws

- Pure Food and Drug Act
- The Elixir Tragedy and Food, Drug, and Cosmetic Act (FDC)
- Kefauver-Harris drug amendments

2. Introduction to GXPs

- Good Clinical Practice (GCP)
- Good Laboratory Practice (GLP)
- Good Manufacturing Practice (GMP)
- Laws, regulations, and guidance

3. Good Laboratory Practice (GLP)

- History of GLP regulations
- GLP driven by harm to the public – IBT incident
- Specifications of GLP-type work
- What is a nonclinical study for
- Component of nonclinical study
- The key requirements for GLP-type work

4. Guidance for Industry – Bioanalytical Method Validation

- 2001 version and 2018 version
- GLP regulations vs. guidance
- Effect of guidance
- Full, partial, and cross validation
- The fundamental parameters of a validation
- Requirements for selectivity, accuracy, precision and recovery
- 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

5. Bioanalytical Sample Analysis

- Application of a validated method 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 for clinical studies
- How to report bioanalytical results

6. 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. at Oregon State University. Dr. Wang currently works at FDA as a research 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 in the pharmaceutical field focuses on high throughput drug 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 American Society for Mass Spectrometry (ASMS) since 2015.