ANALYTICAL METHOD VALIDATION, VERIFICATION AND TRANSFER

AGENDA

DAY 01

- Seminar objectives review, expectations and scope.
- Drug Approval Process and Regulatory (FDA) Requirements (private standards)
- Pharmacopeias and Compendial (USP) Approval Process (public standards)
- Compendial Harmonization Process
- Chromatography System Suitability Requirements
- Allowed Adjustments of Chromatographic System Parameters
- Analytical Instrument Qualifications
- Instrument Categories
- Qualification Phases (DQ, IQ, OQ, PQ)
- Analytical Method Validation (typical validation parameters)
- Specificity
- Precision/Accuracy
- Linearity/Range
- LOD and LOQ
- Analytical Method Verification
- FDA and USP Requirements
- Factors to Consider
- Analytical Method Transfer
- Different Approaches
- Summary and Review

DAY 02

- Analytical Procedure Life Cycle
- Setting Specifications FDA regulations and ICH guidelines (Q6A)
- Out-of-Specification (OOS)
- Out of Trend (OOT)
- How to handle OOS and OOT?
- Summary and Review

OVERVIEW

In this course, general guideline for the determination of the analytical characteristics for different types of validation procedures is highlighted for the analysis of both the drug substance and drug product. The factors to consider for verification of the compendial procedures will also be discussed. In addition, different approaches for the transfer of analytical procedure from one lab (transferring) to other lab(s) (receiving) under different circumstances will be covered. Other related topics for obtaining reliable data will also be discussed. These topics include analytical instrument qualification as well as how to set, handle and monitor specifications.

LEARNING OBJECTIVES

- Drug Approval Process and Regulatory Requirements (private standards)
- Pharmacopeias and Compendial Approval Process (public standards)
- Compendial Harmonization Process
- Chromatography System Suitability Requirements
- Allowed Adjustments of Chromatographic System Parameters
- Analytical Instrument Qualifications including DQ, IQ, OQ, PQ
- Analytical Method Validation
- Analytical Method Verification
- Analytical Method Transfer
- Alternative to Official procedure and options
- Analytical Procedure Life Cycle
- How to Set Specifications and how to handle out-of-specification (OOS) and out-of-trend (OOT) results

WHO WILL BENEFIT

- Analytical/Chemists
- Formulation Chemists
- Lab Supervisors and Managers
- QC Managers and Personnel
- QA Managers and Personnel
- Regulatory Personnel
- Compendial Liaisons
- Pharmaceutical scientist/Pharmacists working in Industry
- Senior or Graduate students (chemistry, pharmaceutical, pharmacy)

FACULTY

KELLY THOMAS

Ms. Thomas has over two decades of cGMP hands-on industry experience in both pharmaceutical and medical device manufacturing operations. Her experience covers all Quality Systems as well as, all areas of validation; including, process/product validation, facilities validation, CSV and 21 CFR Part 11, test method validation, equipment/automated processes and cleaning validation