Valentia Analytical

Technical Education Series

Course in HPLC Theory and CGMP Testing Principles

Theory

Chemical Principles Review

Reversed-Phase

Size-Exclusion

Ion-Exchange

Affinity

Hydrophilic Ion

Detection

Instrumentation

Pump

Gradient

Sampling

Detector

Quality Principles

System Suitability

Method Validation

Regulatory Guidance (ICH, USP)

CGMP Testing Principles (FDA)

Course Fees

$799 per person. Additional costs may be applied for customized courses.

Discounts available for current students, groups, return attendees, or individuals self-funding their continuing education.

Document Version: C0011903

Length and Location

2 days in Hayward, CA

Chromatographic Theory with Quality Testing Principles

With classroom lecture, you will be taught chromatographic theory bringing together chemical principles you learned in school and the fulfillment of CGMP requirements for IND, NDA, or BLA submissions. The review of Quality Principles applicable to testing can carry into other methodologies beyond HPLC.

Learning with State-of-the-Art Instrumentation

Laboratory experiments will be performed utilizing state-of the art instrumentation capable of HPLC and UPLC. It is paired with a modern chromatographic data system developed for full compliance with 21CFR11.

Customized Courses are Available

Request a customized course session to focus on specific methodologies or other areas of choice.

HPLC emerged as one of the most critical tools to demonstrating product Safety, Identity, Strength, Purity and Quality. It is used all through product development of pharmaceutical and biologics from characterization, GLP studies, raw material qualification and testing, and testing for in-process, release, and stability testing under CGMP.

The course begins with theory. The class will then generate HPLC data using state-of-the-art HPLC instrumentation coupled with chromatographic software designed to be fully compliant with 21CFR11. The instrument is also designed for Ultra Performance Liquid Chromatography.

Objectives:

Learn how it is used in testing for identification, purity, potency, and degradation products and where such procedures are influenced by regulatory requirements.

Learn about reporting impurities and potency, and which chromatographic parameters and ICH guidance must be considered in development and optimization of methods.

There will be a review an HPLC test method to understand and improve methods at the workplace to reduce risk.

This course is designed with an emphasis on preparing personnel in the performance, review, and analysis of HPLC data to be executed under CGMP as well as cover method validation principles.

For those involved with the following:

- Method Development
- Method Validation
- Method Transfer
- Characterization
- Quality Control
- Quality Assurance
- Data Review
- Regulatory Filings

Valentia Analytical

717 Sandoval Way, Hayward, CA 94544
www.ValentiaAnalytical.com
Kenneth.Gomez@ValentiaAnalytical.com