High-Performance Liquid Chromatography (HPLC) Introduction QC Training Course

Professional Development Training Course Outline

Category	Biotechnology and Pharmaceutical Development	**Duration**	10 Days
Base Fee	$4,000 USD	**Delivery Mode**	Online / On-site Hybrid

Course Introduction

High-Performance Liquid Chromatography (HPLC) is an essential analytical technique used in pharmaceutical quality control (QC) for the separation, identification, and quantification of compounds in various drug formulations. With the growing complexity of pharmaceutical products, HPLC has become indispensable for ensuring product purity, consistency, and regulatory compliance. In the rapidly evolving pharmaceutical industry, QC professionals must stay ahead of technological advancements and be well-versed in the best practices of HPLC to maintain high standards of drug safety and efficacy. High-Performance Liquid Chromatography (HPLC) Introduction QC Training Course is designed to equip professionals with the advanced skills and knowledge necessary to effectively use HPLC in pharmaceutical applications, ensuring compliance with industry regulations such as FDA, EMA, and ICH.

The course focuses on practical application and technical understanding, incorporating up-to-date techniques and trends in pharmaceutical quality assurance and analytical chemistry. It is aimed at helping pharmaceutical professionals master HPLC instrumentation, method validation, and data analysis. The training will provide comprehensive coverage of key areas, including column chemistry, sample preparation, and method development, all aligned with the latest industry standards. By the end of the course, participants will be able to apply their knowledge in real-world settings, thereby enhancing their contributions to pharmaceutical manufacturing and improving the quality assurance processes within their organizations.

Programme Curriculum

High-Performance Liquid Chromatography (HPLC) in Pharma QC Training Course

Introduction

High-Performance Liquid Chromatography (HPLC) is an indispensable **analytical technique** in the **pharmaceutical industry**, serving as the cornerstone for **Quality Control (QC)**. High-Performance Liquid Chromatography (HPLC) in Pharma QC Training Course provides professionals with the **practical skills** and **theoretical knowledge** necessary to excel in a **GMP-regulated laboratory environment**. Participants will gain a comprehensive understanding of **HPLC principles, instrumentation, and applications**, focusing on **drug substance analysis**, **impurity profiling**, and **stability testing**. By mastering this essential tool, trainees will be equipped to ensure **drug safety, efficacy, and quality**, adhering to stringent **regulatory guidelines** and **pharmacopoeial standards**.

This course is meticulously designed to bridge the gap between theoretical concepts and **real-world laboratory practices**. Through a **blended learning approach**, including **hands-on training** and **case studies** , participants will develop proficiency in **HPLC method development, validation, and troubleshooting**. The curriculum emphasizes **data integrity**, **Good Manufacturing Practices (GMP)**, and **Good Laboratory Practices (GLP)**, which are critical for **regulatory compliance** and **audit readiness**. Upon completion, graduates will be ready to contribute to **modern QC laboratories**, enhancing **operational efficiency** and **analytical productivity** in the rapidly evolving **biopharmaceutical landscape**.

Course Duration

10 days

Course Objectives

By the end of this **HPLC training course**, participants will be able to:

- Master the fundamental principles of chromatography and HPLC.
- Operate and maintain a range of HPLC instrumentation and software.
- Perform quantitative and qualitative analysis of drug substances and products.
- Develop and validate robust HPLC analytical methods per ICH guidelines.
- Conduct impurity and degradation product profiling with high accuracy.
- Execute stability studies and content uniformity testing.
- Troubleshoot common HPLC system issues and optimize parameters.
- Ensure data integrity and regulatory compliance (GMP/GLP).
- Document analytical procedures and results according to pharmacopoeial standards (USP/EP).
- Apply quality by design (QbD) principles to analytical methods.
- Analyze and interpret complex chromatograms and report results effectively.
- Transition from traditional HPLC to UHPLC (Ultra-High-Performance Liquid Chromatography) techniques.
- Utilize chemometrics and laboratory automation to enhance efficiency.

Organizational Benefits

- Trained staff perform analyses faster, with fewer errors, reducing sample backlog and turnaround times.
- Proactively meeting stringent **FDA, EMA, and ICH regulations** and guidelines, minimizing the risk of non-compliance, costly audits, and product recalls.
- Implementing robust practices to ensure **ALCOA+ principles** are met, safeguarding against data falsification and improving audit readiness.
- Empowering in-house staff to perform **preventive maintenance** and **troubleshooting**, reducing reliance on expensive external service engineers.

- Investing in professional development to upskill employees, improving job satisfaction and retaining skilled talent in a competitive market.
- Enabling chemists to design and validate **more robust and reliable analytical methods**, saving time and resources.
- Preparing the team to adopt **advanced techniques** like **UHPLC** and **hyphenated systems (LC-MS)**, staying at the forefront of pharmaceutical analysis.

Target Audience

- QC/QA Analysts & Chemists
- R&D Scientists
- Laboratory Supervisors & Managers
- Fresh Graduates in Chemistry, Pharmacy, or Life Sciences
- Regulatory Affairs Professionals
- Validation Specialists
- Method Development Scientists
- Chromatographers

Course Outline

Module 1: Fundamentals of Chromatography

- Chromatography theory: Principles of separation, stationary phase, mobile phase.
- Key chromatographic parameters: Retention time, peak area, resolution, selectivity.
- Types of chromatography: Normal phase vs. reversed phase.
- HPLC vs. UHPLC: Understanding the benefits and applications.
- **Case Study**: Separating a mixture of active pharmaceutical ingredients (APIs) using different mobile phase compositions to illustrate retention and selectivity.

Module 2: HPLC Instrumentation & Components

- System components: Pumps, autosamplers, columns, detectors (UV-Vis, PDA, RI, FLD).
- Function and calibration of each component.
- Solvent preparation and degassing techniques.
- System suitability testing.
- **Case Study**: Identifying a solvent delivery problem based on chromatogram anomalies like fluctuating retention times and baseline noise.

Module 3: Method Development Essentials

- Systematic approach to method development.
- Column selection: C18, C8, HILIC, and other stationary phases.
- Mobile phase optimization: pH, buffer strength, and organic modifier selection.
- Detector selection based on analyte properties.
- **Case Study**: Developing a new method for an API and its related substance, optimizing mobile phase pH to achieve baseline separation.

Module 4: Practical Method Validation

- Validation parameters: Specificity, linearity, accuracy, precision.
- Range, limit of detection (LOD), and limit of quantitation (LOQ).
- ICH Q2(R1) guidelines for analytical procedure validation.

- Writing a validation protocol and report.
- **Case Study:** Validating a newly developed assay method for a pharmaceutical tablet, demonstrating precision and accuracy at different concentration levels.

Module 5: Impurity & Degradation Profiling

- Forced degradation studies to generate degradation products.
- Separation and quantification of impurities.
- Setting acceptance criteria for impurities based on ICH Q3B.
- Stability-indicating methods.
- **Case Study:** Analyzing a stress-tested drug sample to identify and quantify degradation products, linking them to a specific degradation pathway.

Module 6: Stability Testing & Shelf-Life

- Regulatory requirements for stability studies (e.g., ICH Q1A).
- Long-term, intermediate, and accelerated stability conditions.
- Use of HPLC to monitor drug product stability over time.
- Establishing a shelf-life based on stability data.
- **Case Study:** Monitoring the potency of a liquid drug product stored under accelerated conditions, using HPLC to project its long-term stability.

Module 7: Quantitative & Qualitative Analysis

- External and internal standard calibration methods.
- Peak integration and data processing techniques.
- Assay determination and content uniformity testing.
- Qualitative analysis for identification.
- **Case Study:** Performing an assay on a batch of raw material API to ensure it meets pharmacopoeial purity standards.

Module 8: Advanced Troubleshooting

- Identifying common HPLC problems: High back pressure, tailing peaks, ghost peaks, baseline drift.
- Root cause analysis for instrument and method issues.
- Practical solutions for troubleshooting.
- Preventive maintenance strategies.
- **Case Study:** A comprehensive troubleshooting exercise where participants diagnose and fix a simulated HPLC system error, such as a clogged injector or column.

Module 9: Data Integrity & GMP Compliance

- ALCOA+ principles in a chromatographic environment.
- Electronic records and signatures (21 CFR Part 11).
- Audit trails and data security.
- Documentation best practices (logbooks, SOPs).
- **Case Study:** Reviewing a mock audit trail to identify and address a data integrity breach, such as an unrecorded change to a method.

Module 10: Column Chemistry & Selection

- Particle size, pore size, and column dimensions.

- Bonded phases: C18, C8, Phenyl, and specialty columns.
- Considerations for small molecule vs. large molecule analysis.
- Guard columns and their importance.
- **Case Study:** Selecting the optimal column for separating a complex mixture of pharmaceutical excipients.

Module 11: Hyphenated Techniques (HPLC-MS)

- Introduction to Mass Spectrometry (MS).
- Why couple HPLC with MS.
- LC-MS applications: Impurity identification, trace analysis.
- Basic MS data interpretation.
- **Case Study:** Using LC-MS data to conclusively identify an unknown impurity peak detected in a routine HPLC chromatogram.

Module 12: Good Laboratory Practices (GLP) & Safety

- GLP principles for pharmaceutical labs.
- Safety procedures in the lab: Handling solvents, waste disposal.
- Proper documentation and record-keeping.
- Instrument qualification (IQ/OQ/PQ).
- **Case Study:** Developing an SOP for safe handling and disposal of mobile phase solvents, ensuring compliance with GLP and environmental regulations.

Module 13: Pharma QC Lab Automation

- Automated sample preparation and injection.
- Robotics in the QC lab.
- Laboratory Information Management Systems (LIMS).
- Digital transformation in pharmaceutical QC.
- **Case Study:** Designing an automated workflow for high-throughput dissolution testing, using HPLC as the detection method.

Module 14: Regulatory Affairs & Audits

- Understanding regulatory bodies: FDA, EMA, Health Canada.
- Preparing for and participating in regulatory audits.
- Responding to Form 483 and warning letters.
- Compliance with pharmacopoeial monographs.
- **Case Study:** A simulated FDA audit where participants must present and defend their HPLC data and documentation.

Module 15: Advanced HPLC Applications

- Chiral chromatography for enantiomer separation.
- Ion-exchange and size-exclusion chromatography.
- GPC/SEC for polymer and protein analysis.
- Preparative HPLC for compound purification.
- **Case Study:** Developing a chiral HPLC method to separate the active and inactive enantiomers of a drug, a critical step in drug development.

Training Methodology

The training is delivered through a highly interactive and practical methodology, designed to maximize learning and retention.

- Lectures & Presentations.
- Hands-on Practical Sessions.
- Case Studies & Group Exercises.
- Q&A and Discussion Forums.
- Pre- and Post-Course Assessments.

Register as a group from 3 participants for a Discount

Send us an email: info@fineskilltrainingcenter.com or call *+254769199797*

Certification

Upon successful completion of this training, participants will be issued with a globally- recognized certificate.

Tailor-Made Course

We also offer tailor-made courses based on your needs.

Key Notes

a. The participant must be conversant with English.

b. Upon completion of training the participant will be issued with an Authorized Training Certificate

c. Course duration is flexible and the contents can be modified to fit any number of days.

d. The course fee includes facilitation training materials, 2 coffee breaks, buffet lunch and A Certificate upon successful completion of Training.

e. One-year post-training support Consultation and Coaching provided after the course.

f. Payment should be done at least a week before commence of the training, to FINESKILL TRAINING CENTER account, as indicated in the invoice so as to enable us prepare better for you.

Upcoming Scheduled Sessions

Start Date	End Date	Location	Price
07 Sep 2026	18 Sep 2026	Online	$4,000
14 Sep 2026	25 Sep 2026	Online	$4,000
21 Sep 2026	02 Oct 2026	Online	$4,000
28 Sep 2026	09 Oct 2026	Online	$4,000
05 Oct 2026	16 Oct 2026	Online	$4,000

Start Date	End Date	Location	Price
12 Oct 2026	23 Oct 2026	Online	$4,000
19 Oct 2026	30 Oct 2026	Online	$4,000
26 Oct 2026	06 Nov 2026	Online	$4,000

Ready to enroll or request a customized program? Book online or contact us:

Register Online Now

Email: info@fineskilltrainingcenter.com | Website: www.fineskilltrainingcenter.com