Advanced Analytical Chemistry in Drug Analysis 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

Advanced Analytical Chemistry in Drug Analysis Training Course is designed to equip pharmaceutical and chemical analysts with cutting-edge knowledge and practical expertise in Advanced Analytical Chemistry for Drug Analysis. The pharmaceutical industry is currently experiencing a rapid evolution, demanding a higher standard of data integrity, speed, and accuracy, particularly in complex areas like impurity profiling, bioanalysis, and method validation. Mastery of techniques like Ultra-Performance Liquid Chromatography (UPLC), High-Resolution Mass Spectrometry (HRMS), and the principles of Analytical Quality by Design (AQbD) is no longer optionalit is a critical requirement for ensuring regulatory compliance and accelerating the drug development lifecycle. This program bridges the gap between foundational chemistry and the latest industry trends, enabling participants to immediately implement robust, high-throughput analytical methods that stand up to the rigorous scrutiny of global regulatory bodies such as the FDA and EMA.

Participants will gain hands-on proficiency in optimizing and troubleshooting sophisticated hyphenated techniques like LC-MS/MS and GC-MS, which are essential for structural elucidation, trace-level quantification, and large molecule characterization. Furthermore, the curriculum emphasizes the practical application of chemometrics and AI/Machine Learning to enhance method development efficiency and interpret complex datasets, driving a culture of innovation and operational excellence. By focusing on real-world case studies from both small molecule and biopharmaceutical analysis, this course transforms theoretical understanding into applied analytical power, ensuring our graduates are prepared to solve the most challenging problems in pharmaceutical quality control (QC), research and development (R&D), and forensic toxicology.

Programme Curriculum

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Course Duration

10 days

Course Objectives

1. Master the principles of Analytical Quality by Design (AQbD) to develop robust and validated analytical methods.
2. Optimize and troubleshoot Ultra-Performance Liquid Chromatography (UPLC) and 2D-LC for high-resolution separation of complex drug mixtures.
3. Apply High-Resolution Mass Spectrometry (HRMS) and tandem MS/MS (MS2) for definitive structural elucidation and accurate mass measurement of drug candidates and metabolites.
4. Execute comprehensive Impurity Profiling and Forced Degradation Studies using hyphenated techniques to identify and quantify critical degradants.
5. Develop and validate Bioanalytical Methods for accurate quantification of drugs in biological matrices for Pharmacokinetics (PK) studies.
6. Ensure full adherence to Data Integrity principles, including 21 CFR Part 11 and cGMP guidelines, within the analytical laboratory workflow.
7. Characterize Biopharmaceuticals (e.g., monoclonal antibodies, ADCs) using advanced techniques like Peptide Mapping and Intact Mass Analysis.
8. Implement Green Analytical Chemistry (GAC) practices to reduce solvent usage and promote sustainability in laboratory operations.
9. Utilize Chemometrics and foundational AI/Machine Learning tools to optimize chromatographic parameters and analyze large-scale analytical data.
10. Navigate and apply key ICH Guidelines (Q2(R2), Q3, Q14) for method validation and lifecycle management.

11. Troubleshoot common issues in Gas Chromatography-Mass Spectrometry (GC-MS) for the analysis of volatile organic compounds and residual solvents.
12. Design and conduct an effective Out-of-Specification (OOS) investigation and implement corrective and preventive actions (CAPA).
13. Integrate Process Analytical Technology (PAT) tools for real-time monitoring and control of pharmaceutical manufacturing processes.

Organizational Benefit

- Accelerate Time-to-Market.
- Ensure Regulatory Compliance.
- Reduce Operational Costs.
- Enhance Product Quality & Safety.
- Future-Proof the Lab.

Target Audience

1. Analytical Chemists and Scientists
2. Lab Managers and Supervisors.
3. Bioanalytical Scientists.
4. Regulatory Affairs Specialists.
5. Method Development & Validation Specialist.
6. Forensic and Clinical Toxicologists.
7. Quality Assurance (QA) Auditors.
8. Recent Graduates.

Course Modules

Module 1: Foundational Principles of Modern Drug Analysis

- Review of chromatography and spectroscopy essentials.
- Understanding the role of analytical chemistry in the drug lifecycle
- Principles of quantitative vs. qualitative analysis and method selection.
- Introduction to Data Integrity concepts and regulatory requirements
- Selecting the right analytical strategy for small molecules vs. biopharmaceuticals.
- Case Study: Assessing a QC lab's system to identify 21 CFR Part 11 gaps in electronic data records.

Module 2: Analytical Quality by Design (AQbD)

- Defining the Analytical Target Profile (ATP) and quality attributes.
- Applying Design of Experiments (DoE) for method optimization.
- Establishing the Method Operable Design Region (MODR) and control strategy.
- Risk assessment for analytical variability.
- Documenting the Knowledge Management lifecycle for analytical methods
- Case Study: Using DoE to optimize HPLC column temperature, pH, and flow rate for a new API separation.

Module 3: Advanced High-Performance Liquid Chromatography (HPLC/UPLC)

- Theory and practice of Ultra-Performance Liquid Chromatography (UPLC) for speed and resolution.
- Advanced column chemistries, including sub-$\text{2\mu m}$ particles and superficially porous phases.
- Principles of Two-Dimensional Liquid Chromatography (2D-LC) for high peak capacity.

- Gradient optimization, flow programming, and mobile phase selection for complex matrices.
- Troubleshooting common HPLC/UPLC separation and hardware issues.
- Case Study: Developing a UPLC method to resolve 12 closely eluting process impurities in under 5 minutes.

Module 4: High-Resolution Mass Spectrometry (HRMS)

- Fundamentals of HRMS and accurate mass measurement.
- Different ionization techniques: ESI, APCI, MALDI for various analytes.
- MSn fragmentation techniques for definitive structural elucidation.
- Using isotopic pattern analysis to confirm elemental composition.
- Data processing for untargeted screening and identification of unknowns.
- Case Study: Using HRMS data and fragmentation to confirm the structure of an unexpected degradation product found in a stressed drug sample.

Module 5: Hyphenated Techniques

- Interface and optimization of LC-MS/MS for trace quantification.
- Setting up Multiple Reaction Monitoring (MRM) methods for high selectivity and sensitivity.
- GC-MS for analysis of volatile compounds, residual solvents, and genotoxic impurities.
- Selection of appropriate sample preparation for complex hyphenated methods.
- LC-MS data processing and quantitative analysis software workflows.
- Case Study: Quantifying a drug in plasma using LC-MS/MS with a MRM method for a PK study, including matrix effect evaluation.

Module 6: Impurity Profiling and Stability Studies

- Designing and executing Forced Degradation Studies according to ICH Q1A.
- Identification and quantification of process-related and degradation-related impurities
- Strategy for detection of low-level Genotoxic Impurities (GTIs).
- Developing and validating a stability-indicating assay.
- Handling complex chromatograms and managing peak purity determination.
- Case Study: Identifying and quantifying a novel impurity that only appears under hydrolytic stress and determining its ICH classification.

Module 7: Bioanalytical Chemistry and Pharmacokinetics (PK)

- Fundamentals of drug disposition: ADME
- Method development for drug and metabolite quantification in biological matrices.
- Matrix Effect assessment and mitigation strategies
- Regulatory expectations for Bioanalytical Method Validation
- Application of LC-HRMS in non-clinical and clinical PK studies.
- Case Study: Validating an LC-MS/MS method for a Phase I clinical trial, focusing on overcoming significant ion suppression from a plasma matrix.

Module 8: Biopharmaceutical Characterization

- Introduction to Large Molecule analysis
- Applying LC-MS for Intact Mass Analysis and subunit characterization.
- Performing Peptide Mapping and Post-Translational Modification (PTM) analysis.
- Characterization of aggregates and fragments using SEC-HPLC

- Analysis of Glycosylation and other critical quality attributes (CQA).
- Case Study: Using Peptide Mapping data to confirm the primary structure and identify a deamidation PTM site on a monoclonal antibody.

Module 9: Method Validation and Transfer (ICH Q2(R2))

- Detailed review of ICH Q2(R2) guidelines for validation characteristics.
- Statistical tools for determining linearity, limits of detection (LOD), and quantification (LOQ).
- Practical aspects of Specificity, Accuracy, and Precision testing.
- Protocols and challenges for successful Method Transfer between laboratories.
- Documentation and reporting requirements for regulatory submission.
- Case Study: Analyzing the validation data for a drug product assay and calculating the expanded uncertainty of the measurement.

Module 10: Chemometrics and Data Analysis

- Introduction to Chemometrics and its application in analytical chemistry.
- Multivariate data analysis: Principal Component Analysis (PCA) and clustering.
- Using software for advanced chromatographic deconvolution and peak purity.
- Statistical process control (SPC) for monitoring analytical system performance.
- Interpretation of complex LC-MS datasets using statistical models.
- Case Study: Applying PCA to HPLC data from multiple batches to identify and visualize subtle process-related variations.

Module 11: Laboratory Compliance and Quality Management

- In-depth review of Good Manufacturing Practice (cGMP) in the QC lab.
- Executing effective Out-of-Specification (OOS) and Out-of-Trend (OOT) investigations.
- Developing and managing robust CAPA programs.
- System suitability testing (SST) and instrument qualification (IQ/OQ/PQ).
- Preparing for and managing a regulatory audit of the analytical laboratory.
- Case Study: Conducting a mock OOS investigation after a drug product failed assay specifications, following the tiered investigation process.

Module 12: Emerging Trends: AI and Green Chemistry

- The role of AI/Machine Learning in optimizing method development and predicting retention times.
- Introduction to Process Analytical Technology (PAT) for real-time quality assurance
- Principles of Green Analytical Chemistry (GAC) and the 12 principles.
- Strategies for solvent reduction and substitution using SFC or alternative solvents.
- Miniaturization and portable analytical instrumentation.
- Case Study: Evaluating a new analytical method against the Green Analytical Chemistry metrics and proposing solvent-reduction alternatives.

Module 13: Forensic and Clinical Toxicology Applications

- Analytical strategies for Therapeutic Drug Monitoring (TDM).
- Sample preparation techniques for biological fluids
- Identification and quantification of New Psychoactive Substances (NPS) and drugs of abuse.
- Utilizing Multi-Analyte Screening methods for toxicology panels.
- Data interpretation for legal and clinical reporting.

- Case Study: Using LC-HRMS to screen and confirm the presence of a novel synthetic cannabinoid (NPS) in a forensic urine sample.

Module 14: Gas Chromatography (GC) and Headspace Analysis

- Advanced GC column selection and temperature programming.
- Principles of Headspace Gas Chromatography for Residual Solvents analysis
- GC detectors: FID, ECD, TCD and their applications.
- Addressing common GC issues like ghost peaks, baseline drift, and carryover.
- Validation requirements for GC methods in pharmaceutical testing.
- Case Study: Developing a Headspace-GC method to quantify Class 2 and 3 Residual Solvents in a solid API sample to meet ICH limits.

Module 15: Spectroscopy and Physical Characterization

- Application of NMR for purity and structural confirmation.
- FT-IR and Raman spectroscopy for raw material identification and PAT.
- X-Ray Powder Diffraction (XRPD) for solid-state characterization (polymorphism).
- UV-Vis Spectrophotometry for dissolution testing and assay.
- Thermal analysis (DSC/TGA) for characterizing drug substance thermal stability.
- Case Study: Using a combination of XRPD and DSC to investigate and differentiate between two polymorphic forms of an API.

Training Methodology

The course will employ a highly interactive, blended learning approach to ensure maximum knowledge retention and practical skill development:

1. Expert-Led Lectures.
2. Practical Demonstration
3. Hands-on Workshops.
4. Case Study Analysis.
5. Interactive Q&A and Discussion Forums.

Register as a group from 3 participants for a Discount

Send us an email: info@fineskilltrainingcenter.org 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
23 Nov 2026	04 Dec 2026	Online	$2,000
23 Nov 2026	04 Dec 2026	Physical	$3,000
23 Nov 2026	04 Dec 2026	Physical	$6,000
23 Nov 2026	04 Dec 2026	Physical	$6,000
23 Nov 2026	04 Dec 2026	Physical	$12,000
23 Nov 2026	04 Dec 2026	Physical	$9,000
23 Nov 2026	04 Dec 2026	Physical	$12,000
23 Nov 2026	04 Dec 2026	Physical	$12,000

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