Advanced Elemental Impurities Analysis (ICH Q3D) 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

The shift from the century-old ?Ç£heavy metals?Ç¥ test to the modern, risk-based approach defined by the ICH Q3D Guideline for Elemental Impurities represents one of the most significant updates in pharmaceutical quality control. Ensuring patient safety and global regulatory compliance is paramount, demanding that pharmaceutical companies possess specialized, advanced knowledge to effectively manage potential elemental contamination. This comprehensive training course provides a deep dive into the scientific, toxicological, and analytical intricacies required for successful ICH Q3D implementation across the entire drug product lifecycle. It moves beyond simple theoretical compliance to emphasize the practical application of advanced analytical techniques and robust Quality Risk Management (QRM) principles.

Advanced Elemental Impurities Analysis (ICH Q3D) Training Course is specifically designed to empower technical and quality personnel with the expertise to navigate the complex landscape of elemental impurity control. Key focus areas include mastering the calculation and application of Permitted Daily Exposure (PDE) values, executing systematic risk assessment methodologies for all sources, and optimizing state-of-the-art analytical methods such as ICP-MS and ICP-OES. Graduates will be able to develop and defend a comprehensive control strategy that not only meets but exceeds current global standards, leading to streamlined operations, reduced testing costs, and assurance of the highest level of pharmaceutical quality and supply chain control.

Programme Curriculum

Advanced Elemental Impurities Analysis (ICH Q3D) Training Course

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Course Duration

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Course Objectives

1. Master the principles of ICH Q3D(R2) and its global regulatory nexus with USP and Ph. Eur. requirements.
2. Conduct a definitive, systematic Quality Risk Assessment (QRA) for all potential elemental impurity sources.
3. Calculate and accurately apply Permitted Daily Exposure (PDE) values for all 24 elemental impurities based on different routes of administration.
4. Develop and defend a science-based Elemental Impurity Control Strategy across the product lifecycle.
5. Interpret the toxicological classification of elements and their relevance to the risk profile.
6. Identify and mitigate high-risk sources of contamination, including residual catalysts, excipients, and container/closure interactions.
7. Select, optimize, and validate appropriate ICP-MS and ICP-OES analytical methods for low-level trace element analysis.
8. Ensure Good Manufacturing Practice (GMP) compliance for elemental impurity testing and documentation in the QC laboratory.
9. Translate PDE limits into practical concentration limits for raw materials and final drug product specifications.
10. Address regulatory challenges and audit findings related to elemental impurities and Q3D documentation.
11. Implement robust vendor qualification and supply chain control measures for excipients and APIs.
12. Manage the lifecycle of the risk assessment, including handling process changes and unexpected excursions.
13. Apply the ICH Q9 principles of Quality Risk Management to maintain an ongoing state of ICH Q3D compliance.

Target Audience

1. Analytical and QC Chemists.
2. Quality Assurance (QA) Professionals.
3. Regulatory Affairs Specialists.
4. R&D and Formulation Scientists.
5. Laboratory and Technical Managers.
6. Supply Chain and Procurement Professionals.
7. Toxicologists.
8. Auditors and GMP Inspectors.

Course Modules

Module 1: The ICH Q3D Global Regulatory Framework

- Evolution from the legacy heavy metals test to the ICH Q3D mandate.
- Alignment and differences between ICH Q3D, USP, and Ph. Eur.
- Identifying which drug products, routes of administration, and packaging systems are covered.
- Detailed review of Class 1, 2A, 2B, and 3 elements based on toxicity and probability of occurrence.
- Case Study: Analyzing a recent FDA warning letter citing deficiencies in elemental impurities control strategy.

Module 2: Fundamentals of Permitted Daily Exposure (PDE)

- Understanding how No-Observed-Adverse-Effect-Levels are derived.
- Step-by-step methodology for calculating PDEs for different routes of administration
- Application of safety and adjustment factors in the PDE equation.
- Establishing the regulatory and internal control thresholds
- Case Study: Calculation exercise for Arsenic (As) and Lead (Pb) PDE limits in a pediatric liquid formulation.

Module 3: Comprehensive Elemental Impurities Risk Assessment (QRA)

- Applying the principles of Quality Risk Management
- Systematically mapping potential sources from API synthesis, excipients, water, and process equipment.
- Leveraging supplier data, literature, and internal historical testing for risk profiling.
- Developing a quantitative or qualitative risk matrix to prioritize control efforts.
- Case Study: Performing a QRA for a solid oral tablet focusing on high-risk excipients like Magnesium Stearate and Talc.

Module 4: Risk from Drug Substance and Residual Catalysts

- Controlling intentional elemental additives from synthesis.
- Estimating the maximum possible carryover of a residual catalyst into the final API.
- Establishing clear specifications and a data exchange process with API manufacturers.
- Justifying process controls versus finished product testing for catalyst residues.
- Case Study: Developing a control strategy for a drug substance synthesized with a Palladium catalyst, justifying why testing in the final drug product is not required.

Module 5: Risk from Excipients and Raw Materials

- Understanding the inherent elemental composition and geographical variability in excipients.

- Utilizing Q3D-compliant supplier data to determine high and low-risk materials.
- Modeling the maximum theoretical elemental intake from all excipients combined.
- Setting scientifically justified internal limits for high-risk excipients.
- Case Study: Evaluating a high concentration of Chromium and Nickel found in a Titanium Dioxide excipient, and the subsequent change in vendor.

Module 6: Risk from Container/Closure Systems (CCS) and Manufacturing Equipment

- Understanding the difference between Extractables and Leachables from CCS.
- Evaluating glass vials, rubber stoppers, and plastic bottles for elemental contribution.
- Assessing the potential for corrosion and leaching from Stainless Steel and other alloys during processing.
- Strategies for passivation, material selection, and routine maintenance to reduce equipment risk.
- Case Study: Investigating a process-related excursion where Iron (Fe) contamination was traced back to a specific manufacturing pump component.

Module 7: Developing the Control Strategy and Specification Setting

- Detailed review of the three main control options outlined in ICH Q3D
- Converting the PDE to Acceptable Concentration Limits for the final drug product and individual components.
- Determining when to rely on USP and when to apply a tighter, risk-based limit.
- Documentation and procedures for periodic review and updating the risk assessment.
- Case Study: Designing a Control Strategy for a multi-component drug product using Option 2b, allocating limits to different raw materials.

Module 8: Introduction to ICP-OES and ICP-MS Technology

- Operating principles and key differences between Inductively Coupled Plasma-Optical Emission Spectrometry and Mass Spectrometry.
- Choosing the appropriate technique based on required sensitivity, matrix complexity, and budget.
- Demonstrating that the selected method is sensitive and robust enough for the required PDE limits.
- Identifying and compensating for common plasma, mass, and matrix interferences in both techniques.
- Case Study: Comparing the analysis of a high-salt buffer using ICP-OES versus ICP-MS.

Module 9: Advanced Sample Preparation Techniques

- Alignment of sample preparation with USP and other compendial guidelines.
- Mastering Microwave Digestion for complete and safe dissolution of complex organic matrices.
- Best practices and safety considerations for traditional acid digestion methods.
- Using diluents and internal standards to manage matrix effects and ensure accuracy.
- Case Study: Optimizing a microwave digestion program for a difficult, high-fat soft-gel capsule matrix without losing volatile elements like Mercury

Module 10: Analytical Method Validation

- Defining and executing tests for Specificity, Linearity, Range, LOD, LOQ, Accuracy, and Precision.
- Determining appropriate spiking levels and matrix-matching to confirm accuracy.
- Establishing routine checks to ensure instrument performance before analysis.
- Evaluating the method's reliability against minor changes in analytical conditions.

- Case Study: Full method validation report review for an ICP-MS method targeting Class 1 elements in a tablet excipient.

Module 11: Data Interpretation, Reporting, and OOS Investigation

- Ensuring all analytical data meets ALCOA+ principles for regulatory scrutiny.
- Correctly calculating concentration based on dilution factors and dry weight.
- Implementing a robust OOS investigation procedure specific to elemental impurities.
- Establishing a program for monitoring elemental impurity levels over time and reporting to QA.
- Case Study: Conducting a mock OOS investigation for an elevated Cadmium (Cd) level, following the investigation from initial result to final conclusion.

Module 12: Special Considerations: Topical, Inhalation, and Biologics

- Specific PDE adjustments and risk assessment factors for Inhalation and Parenteral drug products.
- Elemental impurities in purified proteins, cell culture media, and unique process additives.
- Assessing the risk of absorption and unique exposure limits for skin contact.
- Procedures for assessing the toxicity and setting control limits for elements not explicitly in ICH Q3D.
- Case Study: Risk assessment for an Inhalation product (MDI), focusing on unique sources like the canister and valve components.

Module 13: Audit Preparedness and Regulatory Submission

- Best practices for organizing and maintaining the Q3D risk assessment documentation package.
- Content and format of the elemental impurity section in a CTD Module 3.
- Strategies for addressing common regulatory questions and deficiencies from the FDA and EMA.
- Creating compliant Standard Operating Procedures for QRA, testing, and control strategy maintenance.
- Case Study: Mock audit scenario where a regulator challenges the justification for not testing a Class 3 element.

Module 14: Advanced Topics in ICP-MS

- Utilizing advanced cell technology to remove challenging polyatomic interferences
- Understanding the benefits and applications for complex, high-matrix samples.
- Use of inert nebulizers and spray chambers for non-aqueous or challenging solvents.
- Choosing the optimal isotope for analysis to avoid isobaric overlaps.
- Case Study: Implementing a Collision Cell method to accurately quantify Vanadium (V) and Chromium (Cr) in a high-chloride API matrix.

Module 15: Future Trends and Q3D(R3) Updates

- Reviewing the latest updates from the Pharmacopeial Discussion Group (PDG) on elemental impurities.
- Exploring real-time monitoring and advanced in-process control of elemental impurities.
- Linking elemental control to broader environmental and quality initiatives.
- Strategies for integrating Q3D risk assessment into the overall Pharmaceutical Quality System (PQS).
- Case Study: Discussion on the emerging concern of Nitrosamine impurities and how the Q3D QRM approach can be adapted to other trace contaminants.

Training Methodology

This course utilizes an **Adult Learning Model** combining rigorous academic content with real-world application to ensure practical competency.

1. Interactive Lectures.
2. Hands-on Workshops.
3. Real-World Case Studies.
4. Group Exercises/Simulations.
5. Q&A/Consultation.

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

Start Date	End Date	Location	Price
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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