Advanced Extractables and Leachables (E&L) Testing 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 Extractables and Leachables (E&L) Testing Training Course addresses the critical need for specialized expertise in controlling chemical contamination throughout the pharmaceutical and medical device lifecycle. In today?ÇÖs stringent regulatory environment driven by evolving global guidelines a basic understanding of E&L is no longer sufficient. Drug and device manufacturers must transition from standard testing to sophisticated, proactive risk assessment and material characterization. This training delivers the deep dive required, focusing on complex product types like Single-Use Systems (SUS), combination products, and biologics, where container-product interaction is highly critical. Graduates will gain the scientific rigor and regulatory intelligence to defend their E&L programs to global health authorities.

The industry's current focus is shifting from simply identifying extractables to establishing a robust, validated chemical linkage between extractables and subsequent leachables under real-time and accelerated stability conditions. This course emphasizes mastering Good Identification Practices (GIP), managing the challenges of Non-Intentionally Added Substances (NIAS), and applying advanced toxicological risk assessment to safeguard patient health. By integrating real-world case studies from nitrosamine control in drug products to medical device biocompatibility this program equips professionals with the practical expertise to streamline development, accelerate regulatory submissions, and ensure product quality and supply chain resilience in an increasingly complex manufacturing ecosystem.

Programme Curriculum

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Course Duration

10 days

Course Objectives

The successful participant will be able to:

1. Strategically Design robust, risk-based E&L protocols for complex systems.
2. Master the application of High-Resolution Mass Spectrometry and advanced analytical screening techniques
3. Implement USP and ISO 10993-18 methodologies for comprehensive medical device chemical characterization.
4. Apply ICH M7 and PQRI recommendations to assess the genotoxic and mutagenic potential of identified leachables.
5. Establish a clear, auditable chemical linkage between Controlled Extractables Studies and long-term Leachables Stability Data.
6. Accurately calculate and apply the Analytical Evaluation Threshold and Safety Thresholds for unknown compounds.
7. Develop and validate leachable-specific quantitative methods that meet cGMP and regulatory expectations.
8. Identify, characterize, and manage the risk associated with Non-Intentionally Added Substances, including degradation products and adducts.
9. Formulate a Supplier Quality Agreement (SQA) that ensures batch-to-batch consistency and E&L control for critical materials.
10. Critique and interpret toxicological risk assessments (TRA), including the application of read-across and in-silico models.
11. Implement E&L lifecycle management protocols for post-approval changes and material changes across the supply chain.
12. Design simulation studies and accelerated extraction conditions that accurately mimic real-world drug-product contact.

13. Drive process validation by evaluating the impact of Single-Use System leachables on biopharmaceutical stability and performance.

Target Audience

1. Analytical R&D/QC Scientists
2. Toxicologists
3. Regulatory Affairs Specialists
4. Packaging/Material Engineers
5. Quality Assurance (QA)/Auditors
6. Bioprocess/Manufacturing Engineers
7. Program/Project Managers
8. Contract Research/Testing Organization (CRO/CTO) Staff

Course Modules

1. Advanced E&L Regulatory Landscape & Strategy

- Deep dive into USP for Single-Use Systems and ISO 10993-18:2020 for Medical Devices.
- Integrating ICH Q3D and E&L inorganic testing
- Establishing a Risk-Based Threshold Strategy and its regulatory justification.
- Post-approval E&L lifecycle management and Change Control strategies.
- Case Study: Justifying reduced E&L testing frequency for a high-risk parenteral due to robust initial Material Qualification.

2. Single-Use System (SUS) E&L Mastery

- Understanding BPOG and BPSA guidelines for SUS qualification and worst-case scenario definition.
- Challenges of complex SUS assemblies and defining the final drug contact surface area.
- Impact of sterilization methods on SUS material degradation and E&L profiles.
- Designing Process Simulation Studies to mimic bioprocessing conditions
- Case Study: Evaluating a high-profile antioxidant leachable from an SUS bioreactor bag and its effect on a monoclonal antibody stability.

3. Advanced Analytical Screening Techniques

- Mastering LC-HRMS and GC-HRMS for Non-Targeted Screening and confident E&L identification.
- Strategies for maximizing mass spectrometry confidence: Accurate Mass, Isotope Ratios, and MS/MS Fragmentation.
- Effective use of High-Performance Liquid Chromatography and advanced detection
- Best practices for Analytical Evaluation Threshold calculation and method sensitivity adjustment.
- Case Study: Identifying an unknown extractable in a drug product's primary packaging using GC-QTOF and advanced spectral library matching.

4. Non-Intentionally Added Substances (NIAS)

- Defining and classifying NIAS.
- Source identification of NIAS
- Developing specific analytical methodologies for trace level detection of high-risk NIAS.
- Strategies for quantitative risk ranking and toxicological assessment of low-level NIAS.
- Case Study: Investigating a carcinogenic NIAS found in an elastomeric closure and tracing its origin to the curing process.

5. Toxicological Risk Assessment (TRA) for E&L

- In-depth application of Threshold of Toxicological Concern and Permitted Daily Exposure concepts.
- Advanced TRA for Genotoxic Impurities and compounds with structural alerts.
- Using (Q)SAR computational toxicology tools and read-across methodologies to estimate toxicity.
- Integrating E&L analytical data with toxicology results for final safety determination.
- Case Study: Performing a TRA for a carcinogen leachable identified at trace levels and justifying its safety margin for a high-volume parenteral drug.

6. Validation of Leachable Methods (GMP)

- Designing a Leachable Stability Study to reflect shelf-life and real-world conditions.
- Implementing cGMP-compliant method validation parameters
- The critical process of establishing the Chemical Linkage between extractables and subsequent leachables.
- Developing Targeted Quantitative Methods for high-risk leachables identified in the extractables screen.
- Case Study: Validation of an LC-MS/MS method for a specific leachable in a complex drug matrix.

7. Container Closure Systems (CCS) E&L

- Material science deep dive: Polymer, Elastomers, and Glass.
- E&L considerations for Pre-Filled Syringes (PFS), Vials, and Blister Packs.
- Addressing E&L challenges specific to biologics.
- Advanced testing for Glass Delamination and evaluation of tungsten or metal impurities.
- Case Study: Assessing E&L for a PFS combination product where silicone oil and tungsten residuals are potential leachables.

8. Combination Products & Drug Delivery Systems

- Navigating the regulatory overlap between medical device and pharmaceutical E&L requirements.
- Specific E&L strategies for complex delivery systems
- Designing Simulated Use Studies that accurately reflect patient administration and contact time.
- Addressing E&L for materials with brief or transient patient contact
- Case Study: E&L testing strategy for an Orally Inhaled Nasal Drug Product (OINDP) and the impact of propellants and drug deposition.

9. Material Qualification & Supplier Management

- Developing robust Material Specifications and initial Risk Ranking based on composition and contact.
- Auditing and vetting suppliers based on their E&L Data Packages and change control protocols.
- Defining and enforcing the Supplier Quality Agreement regarding component sourcing and manufacturing process.
- Managing Material Equivalency and justifying E&L waivers for minor material changes.
- Case Study: Evaluating two different suppliers for the same plastic resin and comparing their E&L profiles to ensure equivalency and minimize risk.

10. Extractables Study Design & Optimization

- Optimizing Controlled Extraction Study conditions for worst-case prediction.
- Selecting appropriate Extraction Solvents to maximize material component breakdown and coverage.
- Advanced techniques for Extractables Sample Preparation and matrix simplification prior to analysis.
- Interpreting Extractables Profiles and prioritizing compounds for subsequent leachable monitoring.

- Case Study: Designing a worst-case CES for a multi-layered blister packaging system using a tiered solvent approach.

11. Data Interpretation & Reporting for Submissions

- Applying Good Identification Practices (GIP) and calculating Relative Response Factors (RRFs) for accurate quantitation of unknowns.
- Statistical tools for Comparing Extractables Profiles
- Structure and content requirements for the E&L Technical Report for regulatory submission.
- Strategies for responding to Regulatory Agency Questions on E&L data.
- Case Study: Developing a concise and defensible E&L Summary Document for a BLA submission based on a five-year stability study.

12. Elemental Impurities & Inorganic E&L

- Compliance with ICH Q3D and USP for elemental impurities.
- Advanced ICP-MS/OES techniques for trace metal analysis in complex matrices
- Sources of elemental leachables: Catalyst Residues, Glass Erosion, Pigments, Metal-containing Additives.
- Establishing and justifying Acceptance Criteria for elemental leachables based on PDE.
- Case Study: Tracing a transient elemental impurity in a pre-filled syringe back to the manufacturing process.

13. E&L in Biologics and Advanced Therapies

- Protein Aggregation, Denaturation, Potency Loss due to leachables.
- E&L requirements for Cell and Gene Therapy (CGT) processing and final product containers.
- Strategies for E&L testing of process-contact materials
- Assessing the functional impact of leachables on bioprocess performance
- Case Study: Determining the effect of a plasticizer leachable from a cell culture bag on the viability of a CHO cell line.

14. Troubleshooting & Failure Investigation

- Systematic investigation protocols for an unexpected Leachable Excursion
- Differentiating between Lab Artifacts, NIAS, and True Leachables from the product contact material.
- Advanced isolation and structural elucidation techniques for hard-to-identify leachables.
- Developing Remediation Strategies
- Case Study: Investigating a new leachable peak observed during accelerated stability testing and tracing it back to a subtle change in the secondary packaging material.

15. The Future of E&L: Standardization & Automation

- Review of emerging standards and the path to global E&L Harmonization
- Adoption of Automated Data Processing and specialized E&L Spectral Databases for faster identification.
- Integrating E&L into Quality by Design and material selection at the earliest development stages.
- Application of Digital Tools and Machine Learning in predictive toxicology and risk modeling.
- Case Study: Utilizing a specialized E&L software platform to automatically compare an extractables profile against a library of known toxic compounds for rapid risk scoring.

Training Methodology

This course utilizes an **Experiential Learning Model** focused on translating advanced theory into practical, defendable workplace strategies:

- Interactive Lectures.
- In-Depth Case Studies.
- Hands-on Workshops.
- Group Problem-Solving.
- Expert Q&A Panels.

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

Start Date	End Date	Location	Price
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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