Advanced Container Closure Integrity Testing (CCIT) 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 Container Closure Integrity Testing (CCIT) Training Course is designed to equip pharmaceutical and biotechnology professionals with cutting-edge expertise in Advanced Container Closure Integrity Testing (CCIT). As the industry faces increasingly stringent regulatory compliance, the transition from traditional, subjective methods to modern, deterministic and non-destructive technologies is paramount. This course dives deep into the science, validation, and practical application of advanced CCIT methods, ensuring product sterility assurance and safeguarding patient safety for high-value parenteral products, including biologics and advanced therapy medicinal products (ATMPs). Mastering these advanced techniques, such as High Voltage Leak Detection (HVLD), Laser-Based Headspace Analysis (HSA), and Helium Leak Detection, is crucial for establishing a robust Quality by Design (QbD) approach throughout the entire drug product lifecycle.

This program focuses on providing a holistic CCIT strategy, moving beyond basic leak detection to full method development and validation according to global compendial standards. Participants will gain the critical skills needed to implement 100% in-line inspection, define the Maximum Allowable Leakage Limit (MALL) using a risk-based approach, and effectively troubleshoot complex container-closure systems, including pre-filled syringes, vials, and blow-fill-seal (BFS) containers. By integrating data integrity and automation principles, this training transforms compliance into a competitive advantage, significantly enhancing operational efficiency and quality control in the sterile manufacturing environment

Programme Curriculum

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Course Objectives

Upon completion, participants will be able to:

1. Strategically Select the most appropriate Deterministic CCIT Method for diverse container-closure systems
2. Define and Justify the Maximum Allowable Leakage Limit (MALL) using a Quality by Design (QbD) and Risk-Based Approach.
3. Master Method Development and Validation protocols compliant with USP and international regulatory guidance.
4. Apply High Voltage Leak Detection (HVLD) principles for liquid-filled products, optimizing parameters for low-conductivity formulations.
5. Perform Headspace Analysis (HSA) using Tunable Diode Laser Absorption Spectroscopy (TDLAS) for lyophilized products and moisture ingress monitoring.
6. Understand and utilize Helium Mass Spectrometry and Mass Extraction techniques for ultra-sensitive Micro-Leak Detection.
7. Integrate Advanced Automation and 100% In-Line Inspection solutions into high-speed manufacturing lines.
8. Establish and maintain Data Integrity and 21 CFR Part 11 Compliance for all CCIT electronic records.
9. Troubleshoot common container integrity defects and CCIT system errors for continuous process improvement.
10. Develop a comprehensive CCIT Control Strategy across the entire Drug Product Lifecycle, from R&D to commercial stability.
11. Compare and contrast the limitations of Probabilistic Methods versus the superiority of Deterministic Testing.

12. Prepare for and successfully manage Regulatory Audits and inspections related to Sterility Assurance and CCIT documentation
13. Leverage emerging trends, including Artificial Intelligence (AI) and Machine Learning in predictive CCIT maintenance and data analysis.

Target Audience

1. Quality Assurance (QA) and Quality Control (QC) Personnel.
2. Packaging Development and Engineering Professionals.
3. Process and Validation Engineers.
4. R&D Scientists and Formulation Experts.
5. Regulatory Affairs Specialists.
6. Lab Managers and Technicians.
7. Automation and Metrology Engineers.
8. Project Managers.

Course Modules

Module 1: Regulatory Foundation and CCIT Strategy

- Global Compendial Requirements.
- Understanding the regulatory preference for quantitative, non-destructive technologies.
- Defining the Critical Quality Attribute (CQA).
- Risk-Based Approach (QbD).
- Case Study: Developing a CCIT Control Strategy for a new Biologic parenteral product, justifying the MALL and method selection.

Module 2: Maximum Allowable Leakage Limit (MALL)

- MALL Definition and Derivation.
- Microbial Ingress Testing (MIT)
- Physical Leak Rate Correlation.
- Container Closure System (CCS) Vulnerability Assessment.
- Case Study: Calculating and validating the MALL for a Pre-Filled Syringe based on drug viscosity and fill-volume.

Module 3: Method Development Essentials

- Test Sensitivity and Reproducibility
- Positive Control Defect Preparation
- Detection Limits (LOD).
- Parameter Optimization.
- Case Study: Optimizing Vacuum Decay parameters to achieve a 5-micron LOD for a specific glass vial and rubber stopper combination.

Module 4: High Voltage Leak Detection (HVLD)

- Working Principles.
- Evaluating the benefits of reduced voltage exposure on product integrity.
- Selection criteria based on product conductivity, container type, and fill level.
- Addressing common challenges like air bubbles, product foaming, and low-conductivity buffers.

- Case Study: Developing an HVLD method for a low-conductivity Ophthalmic Solution in a plastic bottle, optimizing for sensitivity without degrading the drug product.

Module 5: Laser-Based Headspace Analysis (HSA)

- TDLAS Principles.
- Applications for Lyophilized Products.
- Headspace Gas Tracer Techniques.
- Implementing HSA for high-speed in-line monitoring of seal quality.
- Case Study: Using HSA to monitor Oxygen Ingress in a lyophilized vaccine vial during an accelerated Stability Study.

Module 6: Tracer Gas Methods: Helium Leak Detection

- Helium Mass Spectrometry.
- Test Modes.
- Helium Charging and Conditioning.
- Quantitative Leak Rate Measurement.
- Case Study: Applying Helium Leak Detection to validate the integrity of a complex Medical Device Combination Product with multiple sealing points.

Module 7: Pressure/Vacuum Decay and Mass Extraction

- Vacuum Decay (ASTM F2338).
- Pressure Decay Principles.
- Mass Extraction Technology.
- Applications and Limitations.
- Case Study: Implementing Mass Extraction for 100% In-Line Inspection of a high-speed production line for Blow-Fill-Seal (BFS) ampoules.

Module 8: Method Validation in Detail

- Validation Protocol Development.
- Key Validation Parameters.
- Validation Report Generation.
- System Suitability Testing (SST).
- Case Study: Designing and executing a full validation for an HVLD method, including a multi-operator R & R study.

Module 9: Container Closure Systems (CCS) and Components

- Vial and Stopper Interactions.
- Pre-filled Syringe Integrity.
- Specialized Containers.
- Materials Science.
- Case Study: Investigating a CCIT failure on a Freeze-Dried Vial lot, tracing the root cause back to an inadequate crimping process.

Module 10: CCIT in the Product Lifecycle

- Early Stage Development (R&D).
- Process Validation (PV).

- Stability Testing.
- Routine Manufacturing.
- Case Study: Designing a CCIT testing plan for a new drug from Phase I clinical trials through commercial launch, ensuring consistency.

Module 11: Automation and 100% In-Line Inspection

- Integrating Deterministic CCIT.
- Statistical Process Control (SPC).
- Automated Handling Systems.
- Reject Management.
- Case Study: Evaluating the ROI of upgrading from a Dye Ingress Test to a fully automated HSA system for 100% inspection.

Module 12: Data Integrity and Regulatory Audit Preparedness

- Ensuring CCIT data is Attributable, Legible, Contemporaneous, Original, Accurate and readily available.
- Validating CCIT instrument software for electronic records and signatures.
- Audit Trail Review.
- Standard Operating Procedures (SOPs).
- Case Study: Preparing a comprehensive CCIT data package in response to a 483 observation regarding insufficient method validation data.

Module 13: Troubleshooting and Failure Investigation

- Root Cause Analysis (RCA).
- Common Failure Modes.
- Non-Conformance Management
- Forensic Package Analysis.
- Case Study: Conducting an RCA for recurring micro-leaks in a BFS container lot, leading to a process parameter change.

Module 14: Emerging Technologies and Future Trends

- AI and Machine Learning.
- Advanced Spectroscopic Techniques.
- Non-Contact Sensing.
- Ultra-Cold Storage CCIT.
- Case Study: Implementing a Predictive Maintenance model using AI to analyze historical HVLD data and anticipate sensor drift.

Module 15: Practical Hands-On and Strategy Workshop

- Instrument Calibration and Setup.
- Positive Control Testing
- Method Development Group Exercise.
- Q&A with Industry Experts.
- Case Study: Group simulation: Defending a newly validated Headspace Analysis method to a mock regulatory auditor panel.

Training Methodology

The course employs a highly interactive and practical methodology:

- Expert-Led Lectures.
- Case Studies and Group Discussions.
- Hands-On Instrument Demonstrations
- Interactive Workshops.
- Q&A and Peer-to-Peer Learning.

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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