

Container Closure Integrity Testing (CCIT)

Container closure integrity is critical to maintaining product sterility, quality, and safety throughout its shelf life. As regulatory expectations evolve, deterministic CCIT methods are increasingly preferred for their sensitivity, reproducibility, and reliability. Solvias offers a comprehensive portfolio of deterministic and probabilistic CCIT methods, providing tailored solutions for diverse products and container closure systems in alignment with USP <1207>, EU GMP Annex 1, ICH Q5C, and PDA Technical Report 27.

Deterministic Methods

Vacuum/Pressure Decay Method

Solvias uses the NEO DPX system, combining vacuum decay, pressure decay, and the highly sensitive LFC Method® in one platform to support diverse product-container combinations and increase sensitivity. Backed by a long regulatory track record, these methods offer rapid testing, fast format changeovers, and high-throughput capabilities, making them ideal for multi-product QC environments and high volume testing.

Laser-Based CO_2 Headspace Analysis

Particularly valuable for dry-ice shipping qualification and long-term stability studies. Detects CO_2 ingress through transient leaks that may occur during ultra-low-temperature shipping but reseal upon warming. The container is never opened, pressurized, or thermally cycled during measurement, enabling repeated testing of the same vial throughout stability studies to monitor individual container integrity while preserving valuable samples.

Optical Emission Spectroscopy (OES)

An ultra-sensitive method suitable for diverse container formats, including opaque, flexible, and complex geometries. Uses gases already present in the container headspace, eliminating the need for tracer gases or extensive sample preparation. Its ability to detect air and water vapor leakage simultaneously, combined with exceptionally high sensitivity and multi-container testing capabilities, makes it particularly valuable for challenging container configurations and high-throughput testing.

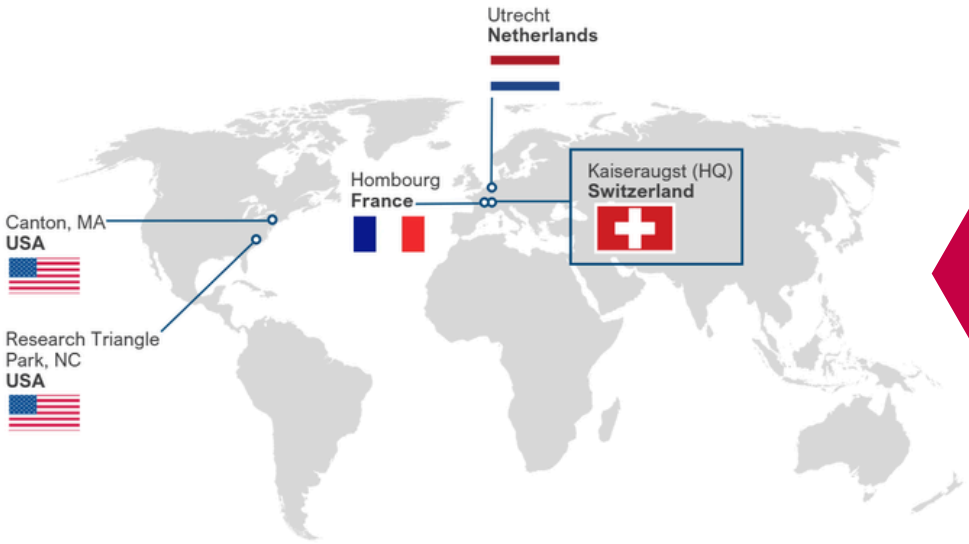
Probabilistic Methods

Microbial Ingress Test (MIT)
Tests the ability of container closures to prevent the entry of microorganisms by inoculating the external environment with a known microbe and monitoring for any microbial growth inside the container.

Dye Ingress Method
Tests the integrity of liquid-filled containers by submerging them in a dye solution and applying pressure or vacuum to detect any dye penetration, indicating leaks.

Why partner with us?

- CRO
- Founded in 1999
- 800+ team members
- 175+ PhD-level scientists
- GMP, GLP, ISO9001 certified
- 23K m^2 of lab capacity
- 700+ customers worldwide
- 5 centers of excellence



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