LIGHTHOUSE

THE SCIENCE
OF PHARMACEUTICAL
MANUFACTURING

Compliance Program For EU Annex 1 Container Closure Requirements

The new EU GMP Annex 1 contains revised language for container closure requirements

- Emphasis on **appropriately validated methods**
- A container closure strategy that is **science-based** and **data-driven**
- Increased attention to **closure** during **transport** and **shipping**
- Emphasis on generating data in a **product life cycle** approach

The requirements in the new EU GMP Annex 1 represent an evolution to requiring a more robust science-based approach to container closure. We have designed a program to generate statistically relevant packaging data that enables compliance to regulatory requirements as well as justification of a container closure integrity (CCI) testing strategy in a holistic science-based approach.

A ROAD MAP WAS DEFINED FOR GENERATING ROBUST PACKAGING DATA DURING THE PRODUCT LIFE CYCLE THAT ENABLES COMPLIANCE TO EU ANNEX 1 REQUIREMENTS.

- Headspace gas ingress platforms for container closure integrity testing (CCIT)
- Primary Packaging Component Selection
- USP/EP Component Testing
- Worst-case Dimensional Fit CCIT

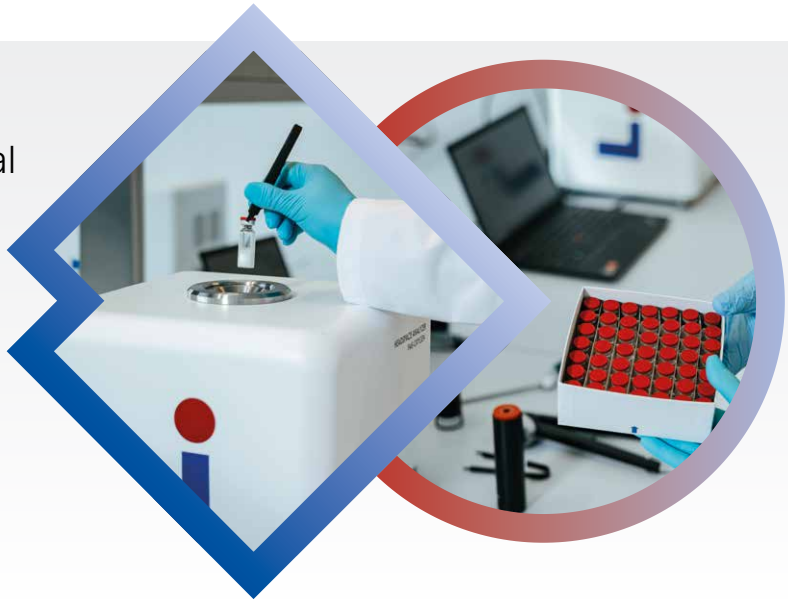
- CCIT Headspace Method Development
- CCIT Headspace Method Validation

- Seal Quality Characterization
- Capping Line Optimization & Qualification
- Qualification of raised stopper detection
- CCI Validation for transport and shipping

- Clinical Batch CCIT
- Stability CCIT
- Non-destructive headspace vacuum maintenance measurements

PLEASE CONTACT CCITEXPERTS@LIGHTHOUSEINSTRUMENTS.COM FOR SUPPORT

This flexible and scalable program comprehensively addresses critical regulatory and manufacturing concerns regarding CCI, while mitigating risks to the product, business and, most importantly, patient through collaboration with a team of experts.



- A program for container closure designed to enable compliance to EU Annex 1 requirements
- A one-stop-shop service model to ease administrative & quality vendor requirements
- A program developed by the world's leading experts who introduced the headspace technology and methods currently used for container closure integrity testing

ABOUT LIGHTHOUSE INSTRUMENTS

LIGHTHOUSE offers solutions for container closure integrity (CCI) testing, headspace oxygen monitoring, and moisture determination of freeze-dried product, sterile powders and solid dosage forms. LIGHTHOUSE delivers nondestructive laser-based headspace analysis platforms and analytical services to generate statistical process and product data in all stages of the product life cycle. LIGHTHOUSE application experts have gained incredible amounts of knowledge and expertise through their work with millions of finished sterile drug samples from pharmaceutical facilities around the world. The goal is to use this knowledge and expertise to support clients in ensuring the quality of your sterile products and processes.

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