

Cold Storage Package System Qualification

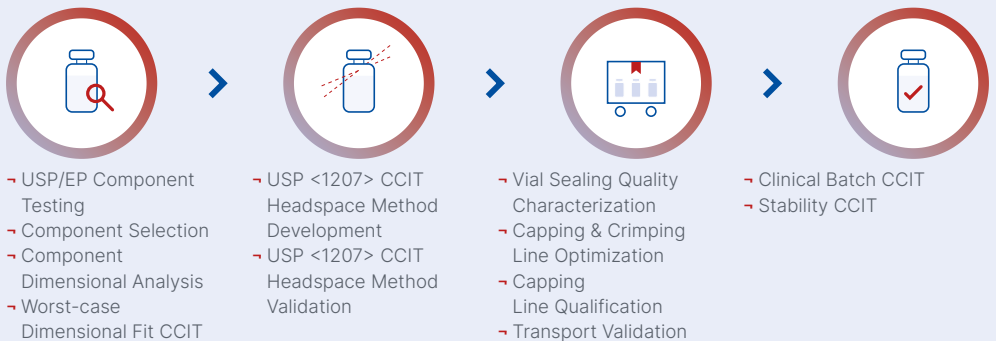


Cold storage and transport temperatures (< -60°C) introduce risk to the container closure of sterile pharmaceutical products (1-4).

- Active Cell Products
- Gene Therapies
- Live Viral Vaccines
- Messenger RNA

Changes to the elastomer viscoelasticity and shrinkage of the packaging components during cold storage increase the risk of losing Container Closure Integrity (CCI). Using quality-by-design principles, this risk can be mitigated by robust development, validation and qualification activities. Our holistic science-based approach generates a body of statistically relevant packaging data that enables compliance to regulatory requirements.

A ROAD MAP WAS DEFINED FOR GENERATING ROBUST PACKAGING DATA DURING THE PRODUCT LIFE CYCLE THAT ENABLES COMPLIANCE AND ENSURES GOOD CCI DURING COLD STORAGE AND TRANSPORT.



This flexible and scalable program comprehensively addresses critical concerns of product manufacturers while mitigating risk to the product, business, and most importantly, patient through collaboration with an expert service provider team.



- A custom-designed program for your cold storage package that meets all regulatory qualification requirements
- A one-stop-shop service model to ease administrative & quality vendor requirements
- A program developed by the world's leading experts with a decade of experience in cold storage CCI testing

REFERENCES

- [1] Container/Closure Integrity Testing and the Identification of a Suitable Vial/Stopper Combination for Low-Temperature Storage at -80 °C; Zuleger, B.; Werner, U.; Kort, A.; Glowienka, R.; Wehnes, E.; Duncan, D., PDA J. Pharm. Sci. Technol. 2012, 66 (1), 453-465.
- [2] Ensuring container closure integrity of a gene therapy cancer vaccine needing deep cold storage, J. Wilmer, 2019 PDA Parenteral Packaging Conference, Venice, Italy.
- [3] Correlating Vial Seal Tightness to Container Closure Integrity at Various Storage Temperatures, D. Duncan and R. Asselta, 2015 PDA Parenteral Packaging Conference, Frankfurt, Germany.
- [4] Mitigating Risk to Container Closure Integrity of a COVID-19 Vaccine Product During Ultra Cold Chain Storage and Distribution, D. Duncan, M. Edey, A. Rozentsvayg, 2021 PDA/FDA Joint Regulatory Conference

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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