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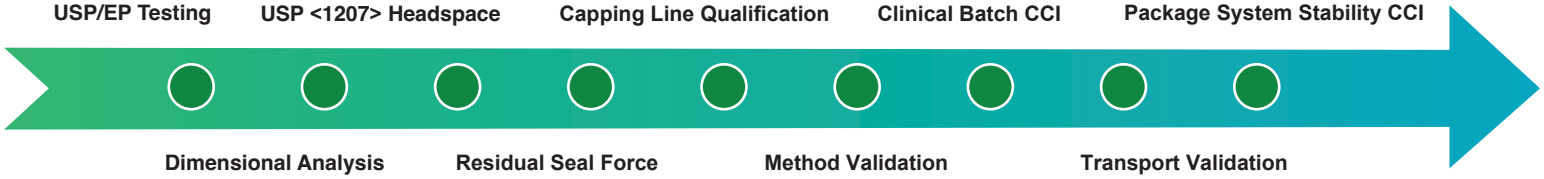
Cold Storage Package System Qualification

Cold Storage (< -60˚C) of Sterile Pharmaceutical Products can introduce risk to pharmaceutical primary packaging system integrity [1-3]

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

The risk to the Container Closure Integrity of cold storage products caused by temperature induced changes to elastomeric viscoelasticity and component shrinkage for glass vials, rubber stoppers and crimp seals can be mitigated by robust development and qualification activities based on quality-by-design principles.



A defined a road map for generating appropriate packaging data for cold storage product that ensures good CCI during cold storage and transport that meets all expected regulatory requirements.

Changes to Rubber Closure Due to Cold Storage

Stopper Shrinkage due to Cold Temperature Exposure

A holistic science-based approach that has been developed that enables coordinated, regulatory-ready and robust packaging data generation across all stages of the product lifecycle [4]

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"This flexible and scalable program will comprehensively address critical concerns for product manufacturers while mitigating risk to the product, business, and most importantly, the patient through collaboration with a single, expert service provider team."

About CS Analytical

CS Analytical is the only cGMP, FDA-regulated laboratory exclusively designed and built to serve the container and package testing needs of the pharmaceutical, biotechnology, and medical device industries.

The CS Analytical Team is comprised of the world's leading experts when it comes to regulated container qualification testing. The comprehensive package system testing services offered cover complete USP <1207> CCI method development, validation, and analysis, as well as USP/EP/JP physical performance tests, ASTM 4169 and ISTA distribution testing and physicochemical / functional tests for all common or unique primary packaging components and systems.

- **A strict cGMP program designed to meet all Regulatory qualification requirements – all work is performed in an FDA regulated facility**
- **A custom-designed program that meets the specific needs of your cold storage package system across the lifecycle**
- **A quality by design program developed by the world's leading experts on container integrity and cold storage package system qualification**

The CS Analytical Mission

Share their experience, knowledge, and commitment to regulatory compliance with each client.

REFERENCES

[1] Zuleger, B.; Werner, U.; Kort, A.; Glowienka, R.; Wehnes, E.; Duncan, D. Container/Closure Integrity Testing and the Identification of a Suitable Vial/Stopper Combination for Low-Temperature Storage at –80 °C. PDA J. Pharm. Sci. Technol. 2012, 66 (1), 453–465.

[2] Presentation 'Ensuring container closure integrity of a gene therapy cancer vaccine needing deep cold storage', Josine Wilmer, 2019 PDA Parenteral Packaging Conference, Venice, Italy

[3] Presentation 'Correlating Vial Seal Tightness to Container Closure Integrity at Various Storage Temperatures', Derek Duncan and Roger Asselta, 2015 PDA Parenteral Packaging Conference, Frankfurt, Germany

[4] Presentation 'Mitigating Risk to Container Closure Integrity of a COVID 19 Vaccine Product During Ultra Cold Chain Storage and Distribution', Derek Duncan, Michael Edey, Anna Rozentsvayg, 2021 PDA/FDA Joint Regulatory Conference