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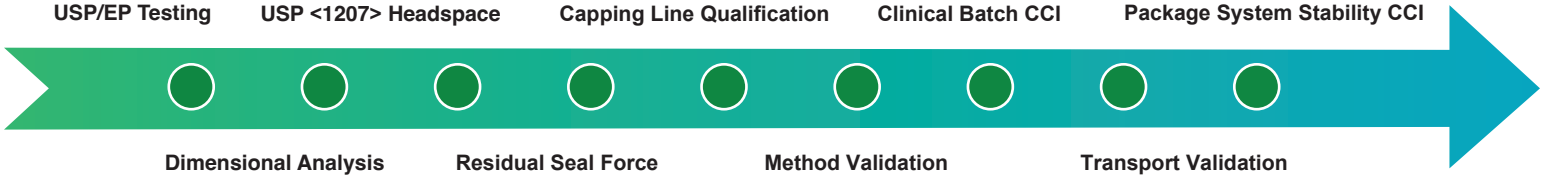
CONTAINING QUALITY

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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