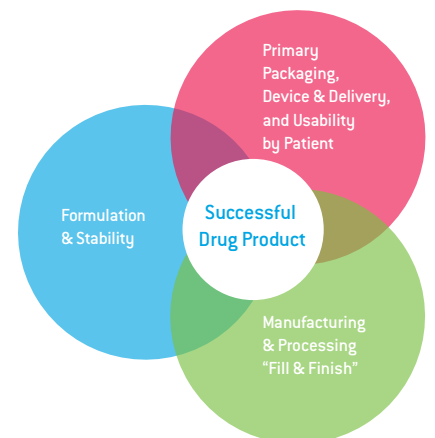**Lonza**

Container Closure Integrity Testing

Lonza's Drug Products Services Group Brings World-Class Expertise to Container Closure Integrity Testing

Successful drug product development should integrate formulation, manufacturing process, primary packaging, device and delivery to the patient. Lonza's Drug Product Services (DPS) offering delivers a holistic approach to DP development that anticipates and prevents problems early, and ensures the result is a product that is fit for purpose.

Container Closure Integrity

Sterility of parenteral drug products is a regulatory requirement and must be assured during the complete product life cycle. In addition to protection against possible microbial ingress, some drug products may require maintenance of gas impermeability. Assessment of Container Closure Integrity (CCI) is performed during container closure system qualification, drug product manufacture, release, storage and shipment until the end of shelf life. Numerous container closure integrity testing (CCIT) methodologies exist, but there is no preferred method by regulatory authorities. With the revision of USP Chapter <1207>, deterministic approaches are generally favored in order to be independent of the drawbacks of probabilistic testing.

Primary Packaging, Device & Delivery, and Usability by Patient

Formulation & Stability

Successful Drug Product

Manufacturing & Processing "Fill & Finish"

www.lonza.com/drugproduct

Container Closure Integrity Testing at Lonza

Helium Leak Test

Currently, the Helium Leak Test, a deterministic method, is being established as the gold standard for its sensitivity and versatility. Helium gas leakage from samples is detected by mass spectrometry. The ion counts are proportional to the leak rate and can thus be quantified. This test is available for qualifying vials, syringes and other drug product formats and is a destructive method.

At Lonza, we can conduct the Helium Leak Test for products at a variety of temperatures. We are the only company that currently offers this method for frozen conditions down to -80°C.

Container Closure Integrity Testing – Traditional Methods

A complete range of traditional methods is available at Lonza to accommodate specific setups for our customers, including:
- Dye Ingress (probabilistic)
- Laser-based Head Space Analysis
- Residual Seal Force and Capping Process Characterization

Leveraging Our Experience and Expertise

Lonza DPS brings world-class expertise to bear in support of the technical as well as strategic aspects of your drug product development program. The DPS team has gained experience from multiple years of actual product development, worldwide filings and approvals, with a combined current total of more than 200 INDs/IMPDs and more than 30 BLAs/MAAs resulting in at least 25 approved products. Capitalizing on this experience allows us to go beyond a typical drug product development offering. We include key specialized services supported by a comprehensive analytical toolbox to meet increased regulatory requirements for safe and efficacious products.

DPS's combination of unparalleled experience, a strong scientific track record, and state-of-the-art instrumental infrastructure provides industry best practices to successfully advance your drug product development programs.

Visit Lonza's Drug Product Showcase Page on LinkedIn:
www.linkedin.com/company/lonza-drug-product-services
For more information, contact us at: drugproduct@lonza.com
www.lonza.com/drugproduct