



Container Closure Selection for Lyophilized Drug Products

Presenters: Eugene T. Polini, III and Ronald L. Mueller, Ph.D.

ABSTRACT

The selection of a primary parenteral package significantly influences the stability of lyophilized drug products. Moisture ingress can cause degradation of those products. Several chemical and physical attributes to minimize moisture ingress and manufacturing issues will be discussed.

- Understanding the importance of the relationship between the elastomeric stopper equilibrium moisture content, the moisture vapor transmission rate and the steam sterilization process is important in selecting the appropriate elastomeric formulation and the sterilization/drying cycle for that stopper.
- Selecting optimal components for the lyophilization process should also be considered prior to manufacturing to eliminate vacuum loss, resulting in the reduction of discarded product and potential risks when bringing product to market. A novel screening approach evaluating the ability of various container closure systems to maintain vacuum prior to capping.
- Further functionality attributes will also be considered as they relate to the final product and how designing unique features into the stopper configuration will minimize manufacturing issues, *e.g.*, “popup” during the lyophilization process, stopper tackiness and penetration forces.

[Click Here to Register](#)