Issue
What precautions should be taken when loading and unloading multiple lyophilizers from a common corridor?

This guidance should address questions raised by lyophilization (freeze drying) facilities involving in using of automated loading and unloading systems for new lyophilizer installations. The options described in this guidance assume the use of such an automated system. Maximum operational flexibility and capacity with these systems is desired without compromising product quality. As such, it is desirable to simultaneously load and unload product from different dryers. This can be accomplished with a pass-through freeze dryer design or with appropriate control of the operation from a single-side freeze dryer design. A review of regulatory guidances and internal standards does not find any prohibition to the recommendations made in this guidnace. A review of the barriers to contamination is provided to support the recommendation that the loading and unloading of the same product can be conducted with a single transfer cart without cleaning or sanitization between each shelf loading cycle within a batch. Further, with separate carts dedicated to loading and unloading, different products can be simultaneously loaded and unloaded in the same transfer corridor.

A single cart should not be used to load and unload different products without cleaning between these uses. Cleaning and sanitization validation, airflow pattern studies, environmental monitoring program, as well as satisfactory sterile process simulations (media fills), are required to support any operating mode chosen. Products containing penicillin, cephalosporins, sex hormones, cytotoxic compounds or live biological agents are excluded from consideration and require more rigorous isolation thorough separate facilities or dedicated equipment.

Introduction
Generally, filling and primary packaging lines for lyophilized products are constructed to be separate from each other to avoid issues of cross contamination and product mix-up. The use of multiple freeze dryers and the extended nature of lyophilization cycles offer the possibility to run the filling line separate from the capping line to optimize the capacity of the workcenter.

One method to separate these functions is to use a pass-through dryer design, loading from one side and unloading from another. Regulatory and internal standards do not require this option and alternative options may be considered. The options described below address conditions using single and multiple transfer carts and situations with multiple lots of the same product as well as operations involving different products utilizing freeze dryers which involve loading and unloading from the same side.

For any option to be used successfully, the concerns of contamination (microbiological and chemical cross-contamination) as well as potential product mix-up must be addressed.
For the purposes of this discussion, the definition of same product includes different strengths of a product containing the same active ingredient.

Regulatory Guidance
The FDA, in its Guidance for Industry: Sterile Products Produced by Aseptic Processing – Current Good Manufacturing Practice requires that " … partially closed sterile product should be transferred only in critical areas. Facility design should ensure that the area between a filling line and the lyophilizer provide for Class 100 (ISO 5) protection. Transport and loading procedures should afford the same protection."
The FDA set similar requirements in their earlier Guide for Inspection of Lyophilization of Parenterals. Here, they state "The transfer and handling, such as loading of the lyophilizer,

