



LyoLearn Webinars

Process Development and Scale-Up Issues in Freeze Drying

ABSTRACT:

This webinar will discuss heat and mass transfer issues during freeze drying process development and scale-up.

The main objective of a rational design of the freeze drying process is to obtain a stable and elegant product with minimal intra- and inter-batch variability. In addition, the designed freeze drying process should be robust and easily scaleable and transferable from one lyophilizer to another. The critical product quality attributes for freeze dried product are elegance (i.e. no collapse), low residual moisture, short reconstitution time, in process stability and adequate shelf life.

During process development, there exist a number of manufacturing challenges such as differences in loading room environment, atypical radiation effects, load/batch size, equipment design and capacity, which needs to be taken into consideration during lyophilization cycle development and scale-up. An understanding of heat and mass transfer issues is critical to the design and development of a rational freeze drying process.