



## ABSTRACT: Summary of Scale-Up of Freeze-Drying Cycles: Essential Factors and Transfer Strategies

This paper supports the webinar on the same topic and will discuss the scale-up procedure for freeze-drying processes with special consideration of critical product parameters and environmental factors. The rational development and optimization of freeze drying cycles in the laboratory should be based on knowledge of the critical formulation parameters, such as the collapse temperature. Once a recipe has been finalized that ensures acceptable product temperatures throughout the process, the transfer to manufacturing scale can be initiated. The aim of this scale up step should be to closely imitate the product temperature profile obtained in the laboratory to ensure comparable product quality. To achieve this, several important factors have to be taken into consideration.

The most important parameters such as nucleation behavior, differences in heat transfer, freeze dryer design and performance and their impact on product quality will be surveyed. Additionally, methods to evaluate and compensate differences between freeze dryers will be presented. Lastly, the use of placebo or fractional loads for preliminary studies will be evaluated.