



Cycle Development and Scale-Up Issues for Freeze Dried Products, from Small Molecules to Proteins

ABSTRACT:

Historically, many freeze-drying cycles have been arrived at on an empirical basis. However, it is now widely accepted that cycles should be developed on a formulation-specific basis.

The first step in the development process involves the characterization of a formulation's behavior, critical temperatures and events, which may be achieved using a wide range of methodologies including freeze-drying microscopy (FDM), thermoanalytical techniques and electrical impedance analysis. The second - and arguably equally important - step is to fully interpret such analytical data and to understand how such information can be used directly when developing a cycle, while also taking into account as many scale-up factors as reasonably practicable.

This Webinar will outline how various methods of formulation characterization, laboratory scale trials and approaches to robustness testing can contribute to the achievement of a quality lyophilized product that will also survive the scale-up process.