



Case Studies In Diagnosing and Correcting Problematic Lyophilization Cycles and/or Formulations

ABSTRACT:

Commercial freeze-drying has improved significantly over the last 20 years both in terms of the engineering of the equipment, and in terms of the understanding of the science behind the process. Even though great strides have been made in lyophilization, occasionally there are problems that arise during the process that not only may leave scientists scratching their heads, but in a worst case scenario, may also bring manufacturing to a screeching halt until the problem is found and resolved.

In the case where manufacturing is halted, the scientists and engineers within the company are under extreme pressure to quickly diagnose the problem, resolve the issues, and get production up and running. In the case of freeze-dried products, it may be very difficult to identify the problem as there are many issues that may cause physical and or chemical damage to the product. Additionally, unless there is a scientist or engineer on staff who truly understands the science behind freeze-drying, diagnosing and fixing problems may be very problematic.

While some problems will require the expertise of a lyophilization expert to solve, other smaller problems, with some basic detective work, may be diagnosed and eventually corrected by a novice. Either way, following a precise line of questioning will help in understanding what is truly wrong with the product, why it is occurring (whether formulation or process based), and will give clues on how to solve the problem.