



Improving Lyophilization Manufacturing and Development with ContoLyo™ Nucleation On-Demand Technology

ABSTRACT:

It is highly desirable that pharmaceutical development and manufacturing personnel have complete, reproducible control over the operation, scale-up, and transfer of lyophilization processes. This presentation examines the fundamental problem of random nucleation during the freezing step that has historically prevented such control and introduces ContoLyo™ Technology as a practical method for resolving the nucleation problem. Case study results will be presented showing the impact of nucleation behavior on important process and product attributes, including pore size, drying rate, protein aggregation, vial cracking, product uniformity, and cake elegance.

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