Controlling Nucleation on Production Freeze Dryers

SP Scientific has announced that *ControLyo Nucleation On-Demand Technology* can now be retrofitted to a wide range of previously installed production freeze dryers.

The *ControLyo technology*, patented by Praxair Inc., was licensed by SP Scientific in 2010 for use on development freeze dryers with shelf surface areas < 1.0 sq.-m. The technology was incorporated into the SP Scientific Lyostar 3 freeze dryer.

Since that time, considerable research has been done at the development scale with controlled nucleation. *ControLyo technology* offers many benefits to freeze drying in the biotech and pharmaceutical industries including improved vial-to-vial uniformity, reduced cycle times, easier process scale-up, reduced protein aggregation and better conformance to the Food & Drug Administration's Process Analytical technology (PAT), and Quality by Design (QBD) Initiatives.

In order for the benefits demonstrated in development work to offer economic benefits to companies, the technology has to be scalable to production freeze dryers. SP Scientific and Praxair have demonstrated that many commercial production dryers can be relatively quickly and easily retrofitted to benefit from the advantages offered by *ControLyo technology*. It has also been demonstrated on production freeze dryers as large as 300 sq.-ft. (27 sq.-m), that controlled nucleation was achieved in nearly 9000 vials, ranging in size from 20ml to 100ml with fill volumes of ¼ and ½. Economical retrofits and scalability of the technology open opportunities to significantly improve production cycles of lyophilized products, with concomitant reduction in costs.

SP Scientific, 845-255-5000, www.spscientific.com [1]

Source URL (retrieved on *12/08/2013 - 6:14pm*):
http://www.biosciencetechnology.com/product-releases/2012/12/controlling-

nucleation-production-freeze-dryers

Links:
[1] http://www.spscientific.com