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Enabling technologies for manufacturing thermostable and cost-effective vaccines

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ENABLING TECHNOLOGIES FOR MANUFACTURING THERMOSTABLE & COST-EFFECTIVE VACCINES

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Biopharmaceuticals are often intrinsically unstable and can rely on freeze-drying as a standard approach for stabilization. Although a standard, this process has long cycle times, is a batch drying process, and is incompatible with flexible manufacturing. There is need for advancing novel approaches that enable the vision for “a maximally efficient, agile, flexible, manufacturing sector that reliably produces high-quality drug products without extensive regulatory oversight;” (2004, FDA Pharmaceutical Quality for the 21st century).

This talk will provide an overview of two drying technologies that may enable semi-continuous manufacturing of vaccines: lyospheres and microwave drying. Lyospheres are freeze-dried spheres (approx. 5mm diameter) of consistent size obtained through bulk lyophilization and thus have a stability profile of a lyophilized product. While a packaging convenience comparable to liquid delivery that renders ease of making combination products, it also improves targeting through bead titration while simplifying technology transfers.

Alternatively, Microwave vacuum drying is a process like lyophilization except that heat transfer occurs by radiation (microwaves) into the entire frozen plug instead of by conduction from the bottom of the vial. Due to its short cycle time, ‘scale-out’ may be achieved by running smaller semi-continuous microwave dryers in campaign mode. This talk will provide an overview of these technologies and their comparative advantages and disadvantages over current drug product formulation methods.