LATEST ADVANCEMENTS IN PROCESS INTENSIFICATION TO SUPPORT GLOBAL DEMAND FOR AFFORDABLE VACCINES

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Vaccines have a profound impact on global health, preventing illness, death, and improving the quality of life across the globe. However, the current costs of vaccine manufacturing and distribution often prevent the poorest segments of the world's population from accessing these critical medicines.

Vaccine manufacturing for global distribution typically requires large and expensive manufacturing facilities that result in high vaccine Cost of Goods and impede developing countries from initiating or expanding in-country manufacturing capabilities.

One of the strategies to address this is to intensify vaccine production processes. This presentation will give an overview of a project funded by the Bill & Melinda Gates foundation that focusses on applying the latest process intensification technologies to develop a platform that dramatically increases process efficiency, decreases production scale and reduces vaccine COGs to a price of $0.15 per dose or less.
This vaccine manufacturing platform combines Vero cell lines optimized for virus propagation and media capable of supporting high cell density cell growth, high cell density single-use bioreactors and high efficiency and single step purification technologies.

Together, these technologies enable vaccine yields to be significantly increased, which in turn allows commercial manufacturing in a small-footprint, low cost "micro-facility" capable of delivering >40M doses of vaccine per year for a CAPEX of not more than $10M and low operational costs. Such "micro-facilities" can be rapidly and inexpensively commissioned, drastically reducing vaccine COGs, facilitating rapid response and resulting in commercial manufacturing at lab scale.

The platform is currently being established using Sabin IPV as the target vaccine. Current status is that Vero cell lines expressing 2-4 fold higher cell specific virus titers have been selected. These have been successfully cultured in high cell density, single-use bioreactors up to 40 million cells per mL. Following infection with Sabin poliovirus vaccine strains, a single chromatographic step using a novel membrane has resulted in 90% recoveries at 95% purity.

For IPV, these yield intensifications mean that the entire commercial scale process can be operated in isolators in a footprint of ±30 m^2. Combination of four of these manufacturing units in a single "micro-facility" would be capable of delivering >40 million doses of trivalent sIPV per year.

Performance of the manufacturing process in isolators also allows the manufacture of viral vaccines that currently require high biological safety containment in an inexpensive facility design. This presentation will discuss the technologies used in the vaccine manufacturing platform and data obtained to date on Sabin IPV in more detail.