

## Medigen shows the way to low cost vaccine production

13 July 2012 | Analysis | By BioSpectrum Bureau

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At a time when there is a need to reduce the cost of vaccination and meet the huge demand, Taiwan-based Medigen has shown the way through its Vero cell-based vaccine production platform. The platform features high cell culture density, high purity and high yield of the vaccine product, resulting in low production cost. The core technology of the platform lies in its patent-protected tidal nutrition or oxygen supply system and dissolvable matrix system, which enables maximum cell-media-air interactions with minimum disruptions and damages to cells.

Medigen has demonstrated that this technology can be used in the production of high-quality H1N1 and H5N1 vaccines with excellent efficiency and reproducibility and, in future, can be applied to the production of EV71 and other virus vaccines. Medigen's HD Tide Cell culture System allows tide flow of the medium between the bioreactor and the supply, assuring better exchange of air and nutrients and, therefore, increasing the efficiency of production system.

Tide cell culture system's 10-liter capacity is equal to 100 liters of conventional bioreactors and allows high production quality for manufacturing H1N1 and H5N1 vaccines. This innovation has put Medigen in competition with Novartis and Roche in China for better production capacity. Medigen possesses an in-house proprietary up-stream cell-based vaccine production technology. With this technology and experience in other aspects of vaccinology, Medigen is looking for international collaboration with partners in the development of vaccine products and enhancing the production process.

Medigen has completed the manufacturing of phase I clinical lots of MDCK cell-based H1N1 vaccine and is conducting its preclinical animal testing. Currently, the vaccine team is working on the manufacturing of H5N1 clinical lots using the cGMP facility at the Vaccine Center of Taiwan's National Health Research Institutes. The quality and efficiency of this high density cell production system have been validated through the confirmation of several batches of H1N1 and H5N1 virion antigen, produced by certified MDCK cell line at a semi-industrial scale production (60~500L). Medigen is now looking for potential collaborators to co-develop a series of prophylactic or therapeutic vaccine projects, which will significantly diminish public concerns about emerging infectious diseases in the Asia Pacific region.

Speaking about the potentials of tide cell culture system, Mr Stanley Chang, chairman, Medigen, said, "This production system allows low installation, production and manufacturing cost and since it is a closed system, it reduces the concerns of contamination." Medigen has achieved key global patent on tide cell production technology. "One can develop flu vaccine using this technology in future and is proven to be efficient."

Medigen is now looking at developing EV71 vaccine using this technology and demonstrate the effectiveness of the system. It has successfully achieved proof-of-concept and small-scale production of EV71 vaccine using the BelloCell high density cell culture system and is further progressing on technical optimization and production scale-up.