NOVARTIS

Cell-Culture Process for Influenza Vaccine Production

– *Innovative cell-culture technology potentially allows for quick, efficient production*
– *Production of cell-derived vaccine requires little advanced planning and may provide rapid response in the event of pandemic*

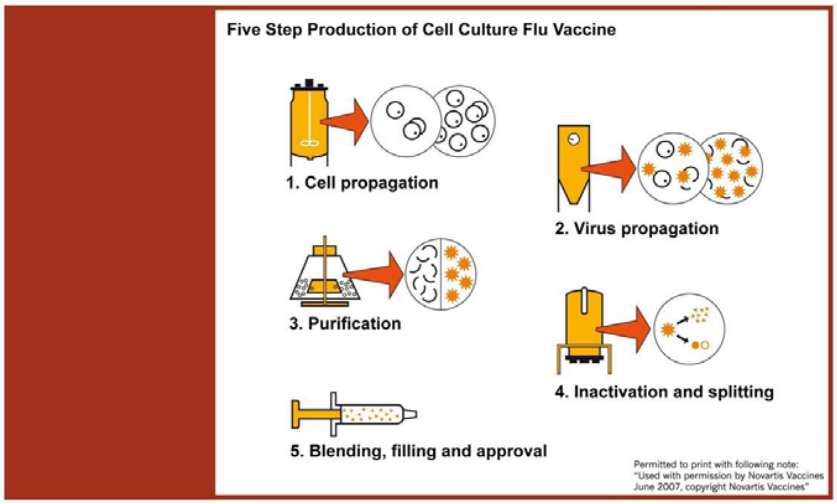
The severity of the influenza season is highly unpredictable, making vaccination the most effective way to prevent the spread of seasonal influenza[1].

Cell-culture process is an innovative and alternative production technique for influenza vaccine manufacturing. This is the first major innovation in influenza vaccine production in more than 40 years.

Traditionally, influenza vaccines are produced through the use of chicken eggs from qualified facilities, in which viruses are grown and harvested. This method needs millions of eggs, requiring orders to be placed about a year prior to production. Once manufacturing activities begin, egg-derived vaccines can take anywhere between 6 and 9 months to be produced before they are ready for distribution[2].

Cell-Culture Technology

The cell-culture-based vaccine production takes place in closed and sterile bioreactors, production of cell-culture influenza vaccine amplifies the virus production in MDCK cell lines[3,4]. From start to finish, the production process involves five fundamental steps.



Cell Propagation: The MDCK cell line is grown in suspension for flu vaccine production, facilitating scalability[3]. The process begins with a small volume of cells, which then increases at a relatively rapid rate.

Virus Propagation: Once a high number of cells have been produced, the three virus strains selected for that season are separately introduced to their own set of cells. The virus infects these cells and is then released to continue cell infection and multiplication.

Purification: Using a centrifuge, the virus is then separated from the cells and removed from the solution.

Inactivation and Splitting: A chemical process is used to inactivate the virus, stripping it of its ability to infect. Through a technology called "splitting," the surface antigens are separated and extracted from the virus.

Blending, Filling, and Approval: In the final stages of formulation, the three sets of antigens, each from one of the 3 previously identified strains, are combined. The vials are then filled, packaged, and ready for shipment.

References

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