PROCESS ECONOMICAL EFFECTS OF IMPLEMENTATION OF READY-TO-USE MICRO CARRIERS IN CELL-BASED VIRUS VACCINE PRODUCTION

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Micro-carriers are used as support for the growth of adherent cells. By providing a large cultivation surface in bioreactor cultures, micro-carriers have replaced, to a great extent, cultivation in Cell Factory™ systems or roller bottles over the last decades.

At Sanofi Pasteur, one of the world leaders in human vaccines, Cytodex™ 1 microcarriers have been used in the production of viral vaccines on Vero cells for several years. In accordance with the supplier's recommendation, the microcarriers that are delivered dry are swollen in buffer, washed, and heat-sterilized before use. Since October 2016 a ready-to-use Cytodex™ 1 alternative, delivered presterilized by gamma irradiation, is available.

Before implementing the change, the presterilized alternative was first evaluated with regards to reduced preparation time and cost. With a two-year shelf-life, the presterilized alternative reduced utility cost and added flexibility to operations by decreasing the need for steam and stainless steel materials in viral production facilities, and in alignment with extended use of single-use bioreactors equipment.

The second step was to compare the cell growth and viral productivity using this ready-to-use alternative with that of the prior referenced product in place. Both cell growth and viral productivity were comparable between the two products, which supported further the documentation for the implementation of this ready-to-use alternative in GMP manufacturing for new R&D vaccine projects. The qualification process covered technical, quality, and analytical aspects based on the supplier documentation, and internal analyses and justification regarding our requirements in upstream vaccine production.

While the presterilized Cytodex™ 1 microcarriers are now implemented in process development for new vaccines and qualified for manufacturing of clinical batches of new vaccine products, the next step will be to evaluate the benefits and impacts of replacing the microcarrier reference product with the gamma sterilized alternative on industrial products.