

Vaccine process. Virus-Like Particles (VLP). Products. Services. Expertise.

Virus-like particles (VLPs) represent an appealing model for vaccine development, as they resemble native viruses but are not infectious. VLP-based vaccines are in high demand and being actively pursued by many vaccine companies worldwide.

VLPs can be produced by various methods such as mammalian cell culture, insect cell culture, and bacterial and yeast-based systems. While these systems can result in good production yields, purification requires particular attention.

Regulatory bodies are concerned about the level of the process-related impurities and their overall impact. For this reason, key impurities such as host cell proteins (HCP), host cell DNA (hcDNA), and baculovirus must be removed during the VLP production processes. The challenge is to develop a scalable upstream process, together with clarification steps and effective purification, while ensuring product quality and reproducibility.

When designing a manufacturing process for VLP vaccines, it is important to work with a partner who understands these challenges. Merck Millipore's regulatory expertise, integrated portfolio of development and manufacturing solutions, and proven applications experience can help you overcome challenges in your VLP vaccines process.

No guide will replace the need to conduct process development and optimization experiments. The unique nature of every process stream combined with application and regulatory requirements play a part in determining the optimum process solutions. Use this selection guide as a starting point for selecting and sizing the most appropriate Merck Millipore solutions.

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The holder of the manufacturing authorization shall ensure that the excipients are suitable for use in medicinal products by ascertaining the appropriate good manufacturing practice.

This is particularly true if the material in a certain application is regarded as high risk excipient, for example in parenteral dosage forms.

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¹ based on IPEC - PQG GMP guide for pharmaceutical excipients 2006.

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