

Vaccine process. Recombinant antigen expressed in bacteria. Products. Services. Expertise.

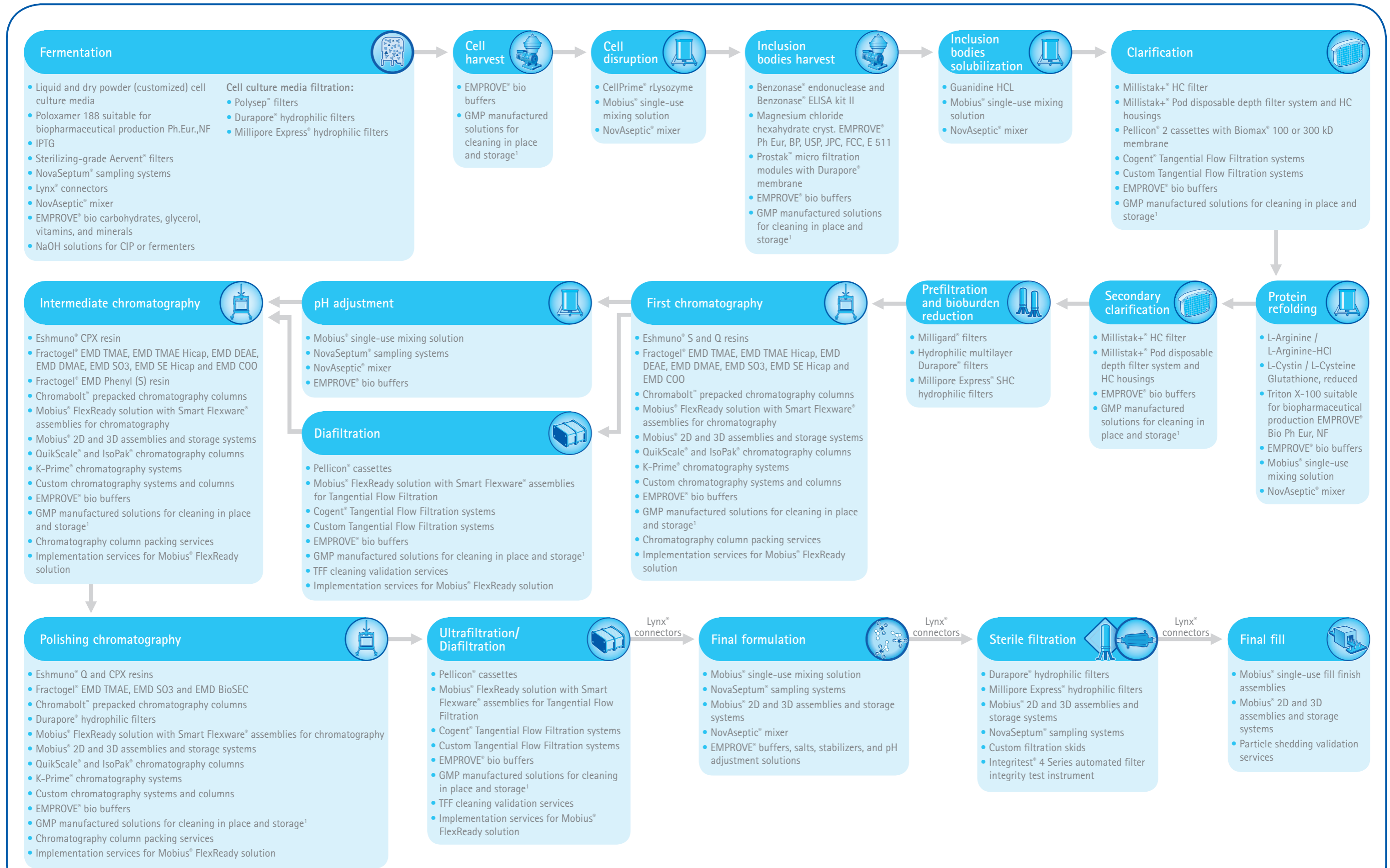
Most of the modern vaccine pipeline is based on bacterial expression, due to the ease of production and low manufacturing costs.

Bacterial production of vaccines does present challenges. While bacterial platforms are generally regarded as safe, there are process-related challenges with endotoxin removal and, as with any process, the goal of optimizing recovery and yield. With bacterial-produced proteins of all varieties, there is the additional challenge of assuring proper refolding of the protein following purification. Such challenges must be overcome during process development and implementation in order to assure high-quality product.

Given the challenges associated with bacterial expression of vaccine, it is critical to choose a partner with experience meeting and overcoming these types of issues. Merck Millipore's regulatory knowledge, integrated portfolio, and applications expertise can help you overcome your bacterial vaccine process challenges.

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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We provide information and advice to our customers on application technologies and regulatory matters to the best of our knowledge and ability, but without obligation or liability. Existing laws and regulations are to be observed in all cases by our customers. This also applies in respect to any rights of third parties. Our information and advice do not relieve our customers of their own responsibility for checking the suitability of our products for the envisaged purpose.

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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