Vaccine process. Conjugated polysaccharide.
Products. Services. Expertise.

The global conjugated polysaccharide vaccine market is expected to experience continued expansion with the new requirements in emerging countries, such as higher number of doses; changing national immunization programs in developed countries; and the inclusion of many conjugated polysaccharide vaccines in the WHO priority lists.

From a manufacturing perspective, vaccines manufacturers are concerned with balancing speed to market and cost containment, while maintaining product safety. This implies many process challenges such as:

- increasing process efficiency and product recovery
- achieving higher product yield
- ensuring process safety and reproducibility of multi-strain products

Merck Millipore's regulatory know-how, integrated portfolio, and applications expertise can help you overcome your vaccines 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.

Vaccines process. Conjugated polysaccharide. Products. Services. Expertise.

Media and inoculum preparation

- Polysep™ filters
- Millipore Express® hydrophilic filters

Lynx® connectors

Fermentation

- Liquid and dry powder (customized) cell culture media
- Media ingredients and supplements
- Sterilizing-grade Aervent® filters
- NovaSeptum® sampling systems
- NovAseptic® mixer
- EMPROVE® bio carbohydrates, vitamins and minerals

Centrifugation

- EMPROVE® bio buffers
- GMP manufactured solutions for cleaning in place[1]

Secondary clarification

- Millistak+® Pod disposable depth filter system or Millistak+® HC filter, C0HC, and B1HC media
- Mobius® FlexReady solution for clarification
- Customized clarification systems
- EMPROVE® bio buffers
- GMP manufactured solutions for cleaning in place[1]

Bioburden reduction

- Durapore® hydrophilic filters
- Millipore Express® hydrophilic filters

Ultrafiltration/ Diafiltration

- Pellicon® cassettes with Biomax® 300/100 kD membrane
- Mobius® FlexReady solution with Smart Flexware® assemblies for Tangential Flow Filtration
- Cogent® Tangential Flow Filtration systems
- Custom Tangential Flow Filtration systems
- EMPROVE® bio buffers
- GMP manufactured solutions for cleaning in place[1]
- Implementation services for Mobius® FlexReady solution
- TFF cleaning validation services

Multi-steps precipitation

- Ethanol absolute* EMPROVE® exp Ph Eur, BP, JP, USP
- 2-Propanol* EMPROVE® exp Ph Eur, BP, JP, USP
- Sodium acetate trihydrate** EMPROVE® bio Ph Eur, BP, JP, USP

*suitable for use as excipient **suitable for biopharmaceutical production

Centrifugation

- EMPROVE® bio buffers
- GMP manufactured solutions for cleaning in place[1]

Secondary clarification

- Millistak+® Pod disposable depth filter system or Millistak+® HC filter, B1HC /X0HC media or Polygard®-CR filters
- Mobius® FlexReady solution for clarification
- Customized clarification systems
- EMPROVE® bio buffers
- GMP manufactured solutions for cleaning in place[1]

Anion-exchange chromatography

- Eshmuno® Q resin
- Fractogel® EMD TMAE, TMAE Hicap, TMAE Medcap, DMAE, and DEAE resins
- Chromabolt™ prepacked chromatography columns
- Mobius® FlexReady solution with Smart Flexware® assemblies for chromatography
- QuikScale® and IsoPak® chromatography columns
- K-Prime® chromatography systems
- Custom chromatography systems and columns
- EMPROVE® bio buffers
- GMP manufactured solutions for cleaning in place[1]
- Chromatography column packing services
- Implementation services for Mobius® FlexReady solution

Activated carbon filtration

- Millistak+® CR filters
- Custom clarification systems
- EMPROVE® bio buffers
- GMP manufactured solutions for cleaning in place[1]

Precipitation

- Ethanol absolute* EMPROVE® exp Ph Eur, BP, JP, USP
- 2-Propanol* EMPROVE® exp Ph Eur, BP, JP, USP
- Sodium acetate trihydrate** EMPROVE® bio Ph Eur, BP, JP, USP
- Potassium iodide*** EMPROVE® api Ph Eur, BP, JP, USP
- CTAB

*suitable for use as excipient
**suitable for biopharmaceutical production
***suitable for use as an active pharmaceutical ingredient

Ultrafiltration/ Diafiltration

- Pellicon® cassettes with Biomax® 100 kD membrane
- Mobius® FlexReady solution with Smart Flexware® assemblies for Tangential Flow Filtration
- Cogent® Tangential Flow Filtration systems
- Custom Tangential Flow Filtration systems
- EMPROVE® bio buffers
- GMP manufactured solutions for cleaning in place[1]
- Chromatography column packing services
- Implementation services for Mobius® FlexReady solution
- TFF cleaning validation services

Bioburden reduction

- Durapore® hydrophilic filters
- Millipore Express® hydrophilic filters

Conjugation with carrier protein

- Sodium hydroxide solution* EMPROVE® bio
- Sodium acetate anhydrous* EMPROVE® bio USP
- Sodium acetate trihydrate* EMPROVE® bio Ph Eur, BP, JP, USP
- Adipic dihydrazide for synthesis
- Cyanogen bromide for synthesis
- Hydrazin hydrate for synthesis
- Dimethyl sulfoxide dried (max. 0.025% H2O) SeccoSolv®
- N-Hydroxysuccinimide for synthesis
- Sodium metaperiodate for analysis EMSURE® ACS, Reag. Ph Eur
- Sodium cyanoborohydride for synthesis
- EMPROVE® exp raw materials for use as excipients
- Mobius® single-use mixing solution
- NovAseptic® mixer

*suitable for biopharmaceutical production

Ultrafiltration/ Diafiltration

- Pellicon® cassettes with Biomax® 300 KD membrane
- Mobius® FlexReady solution with Smart Flexware® assemblies for Tangential Flow Filtration
- Cogent® Tangential Flow Filtration systems
- Custom Tangential Flow Filtration systems
- EMPROVE® bio buffers
- GMP manufactured solutions for cleaning in place[1]
- Implementation services for Mobius® FlexReady solution
- TFF cleaning validation services

Chromatography

- Fractogel® EMD Phenyl (S) resin
- Mobius® FlexReady solution with Smart Flexware® assemblies for chromatography
- QuikScale® and IsoPak® chromatography columns
- K-Prime® chromatography systems
- Custom chromatography systems and columns
- EMPROVE® bio buffers
- GMP manufactured solutions for cleaning in place[1]
- Chromatography column packing services

Ultrafiltration/Diafiltration

- Pellicon® cassettes with Biomax® 100, 300 or 500 KD membrane
- Mobius® FlexReady solution with Smart Flexware® assemblies for Tangential Flow Filtration
- Cogent® Tangential Flow Filtration systems
- Custom Tangential Flow Filtration systems
- EMPROVE® bio buffers
- GMP manufactured solutions for cleaning in place[1]
- Implementation services for Mobius® FlexReady solution
- TFF cleaning validation services

Lynx® connectors

Final formulation

- Mobius® single-use mixing solution
- NovaSeptum® sampling systems
- Mobius® 2D and 3D assemblies and storage systems
- NovAseptic® mixer
- EMPROVE® buffers, salts, stabilizers and pH adjustment solutions

Lynx® connectors

Sterile filtration

- Hydrophilic single layer Durapore® filters
- Hydrophilic multilayer Durapore® filters
- Millipore Express® SHC hydrophilic filters
- Mobius® 2D and 3D assemblies and storage systems
- NovaSeptum® sampling systems
- Custom filtration skids
- Integritest® 4 series automated filter integrity test instrument

Lynx® connectors

Final fill

- Mobius® single-use fill finish assemblies
- Mobius® 2D and 3D assemblies and storage systems
- Particle shedding validation services

Provantage® services include process development, process validation, equipment qualification and GMP drug production | Merck Millipore biopharmaceutical courses

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.

To place an order or receive technical assistance

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Italy: 848 845 645
Spain: 901 516 645 Option 1
Switzerland: 0848 645 645
United Kingdom: 0870 900 4645

For other countries across Europe,
please call: +44 (0) 115 943 0840

Or visit **www.merckmillipore.com/offices**

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

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