avantor™

Solutions for vaccine manufacturing

Solutions for vaccine manufacturing

Vaccination represents a viable and attractive strategy for the prevention and therapy of infectious and non-infectious diseases as well as for immuno-oncology applications.

Yet still the challenges are numerous: how to guarantee safety, efficacy, and quality assurance of the vaccine; achieve a sufficient immune response; and increase productivity while reducing the costs so that the vaccine is available to a broader population, at the time it is needed and for a reasonable cost.

As a trusted supplier for the top 20 biopharmaceutical companies, Avantor's portfolio and solutions address the complexity of vaccines manufacturing from the upstream process to downstream purification and final fill – maintaining the vaccine's integrity and activity throughout the entire process.

QUALITY & REGULATORY EXPERTISE

We are actively collaborating with customers while sharing the product and application expertise and regulatory know-how that is critical to our customers success.

- Full supply chain transparency
- Change notice programs
- cGMP manufacturing
- Meeting compendial specifications to address overall raw material safety
- GHS-compliant labels and Safety Data Sheets
- Documentation support and global electronic quality system

Supply chain risk management

Quality risk management
- Quality metrics monitoring and reporting
- Supplier evaluation and monitoring
- Business continuity planning
- Redundant manufacturing sites

CONTROL OF FINAL FILL PACKAGING

Cleanroom management
- Certified to ISO Class 5 and 7 environments
- Microbial environmental monitoring

Sterility validation
- Compliant to ANSI / AAMI / ISO 11137 (VDmax25)
- Sterile barrier packaging validation

Lot release testing
- Endotoxin testing (USP 85) and particulate testing (USP 788)
- Full compendia testing

Trust Avantor to help you overcome unique bioprocessing challenges

QUALITY & CHOICE	EXPERTISE	CONVENIENCE	CUSTOMIZATION
PRODUCTION CHEMICALS			
Avantor-manufactured and distributed products provide structured choice and risk mitigation Global cGMP manufacturing capabilities backed by global change notification programs for regulated materials Lot-to-lot consistency and comprehensive supportive testing from our brands of high-purity direct materials	Field-based specialists to help you select the most appropriate direct materials for your processes Data-driven answers to your toughest biopharmaceutical challenges – from gene to protein to final formulation	Global cGDP logistics footprint ensures product integrity and prompt delivery globally Special logistics and supply chain services, including: – Product certifications provided electronically and/or with shipments – Customer-reserved inventory to help enable assurance of supply – Custom pallet programs and barcode labeling Global e-commerce platform enables you to get what you need, when you need it	Custom cGMP manufacturing capabilities for direct materials for biopharma manufacturing– from small scale to high volume manufacturing biopharma Addressing your custom purity needs, new product development and synthesis from cell culture supplements, elemental impurity controlled buffers through to novel excipients Wide range of packaging alternatives to fit your process for both powder and liquid materials
SINGLE-USE SOLUTIONS			
Open architecture mode vertically integrated on bags, stoppers and fittings supporting system choice Comprehensive supplier management program with qualified first and second sources of key components Complete sterility validation program to mitigate risk	Extensive fluid handling connectivity knowledge: – Single-use facilities – Hybrid facilities – Conversion from self-assembled parts Collaborative approach to designing your solution	Local single-use experts Expedited design and approval process: – Designs <5 days – Validation packs <5 days Global logistics footprint 100+ standard products	Fully customized solutions designed for specific applications Ability to develop custom components and parts Customized skid systems with disposable fluid paths
SERA			
Proven sera performance & consistency Proprietary manufacturing methods result in lot-to-lot and bottle-to-bottle consistency Quality you can see in the crystal-clear, vibrant color of each bottle of sera	**Nutrtionally superior sera** – Unique collection and manufacturing techniques preserve more naturally occurring growth factors found in serum **Industry-leading traceability and quality** – Independent labs used for all lot release criteria – ISIA traceability certification confirms truth in labeling	**Sera supply stability** Strong supply partnerships and a vertically integrated, raw material supply chain provide long-term supply assurance	**Unmatched operational sera support and service** – Flexibility in meeting each customer's unique needs – Multiple lot sampling, large volume reserves, and storage solutions – Proven track record of operational excellence, support and on-time delivery

Develop and scale up your vaccines more efficiently with trusted cGMP chemicals and single-use solutions

AVANTOR BIOPHARMA PRODUCTION CORE OFFERING

Chemicals

Cell culture/fermentation media, reagents and supplements:

- Media and sera
- IPTG
- Transfection reagents
- Antifoam agents
- Amino acids and salts
- Biological buffers
- Biological detergents
- Cell dissociation agents (Trypsin)
- Cryoprotectants (DMSO)

Harvesting:

- Surfactants
- Endonuclease (Denarase)
- Biological buffers
- ph adjusters
- Products for recovery and purification of inclusion bodies

Purification:

- Biological buffers
- Cleaning reagents
- Salts
- Chromatography media

Excipients:

- Biological buffers
- Inorganic salts
- Proteins and amino acids
- HPLE sugars
- Surfactants

*Most chemicals and reagents are available in cGMP

Single-use products

Aseptic fluid transfer:

- Standard & customised products
- Integrated sensors
- Specialized connectors
- Tubing management

Filtration systems, e.g. TFF

Closed aseptic sampling:

- Conical tube sampling
- Sampling manifolds
- Micro sampling
- Syringe sample devices

Fluid collection and storage:

- Process bags
- BDS freeze bottles
- Collection bottles
- Closed transfer bottles

Ready-to-use single-use products:

- Customized reagents and buffers in ready-to-use bags and manifolds
- Media-mixing bags and hold bags

Final fill and delivery:

- Innovative delivery systems
- Single-use filling lines with needles
- Isolator multi-tube filling assemblies
- Pass-through manifold

AVANTOR PROVIDES SOLUTIONS THAT MATTER – FROM RESEARCH TO COMMERCIAL MANUFACTURING

We provide services, solutions and compliant materials needed for vaccine development and manufacturing to quickly move from small-scale bench, scaling up in the pilot plant, to full production that reaches the market faster with new scientific breakthroughs in medicine.

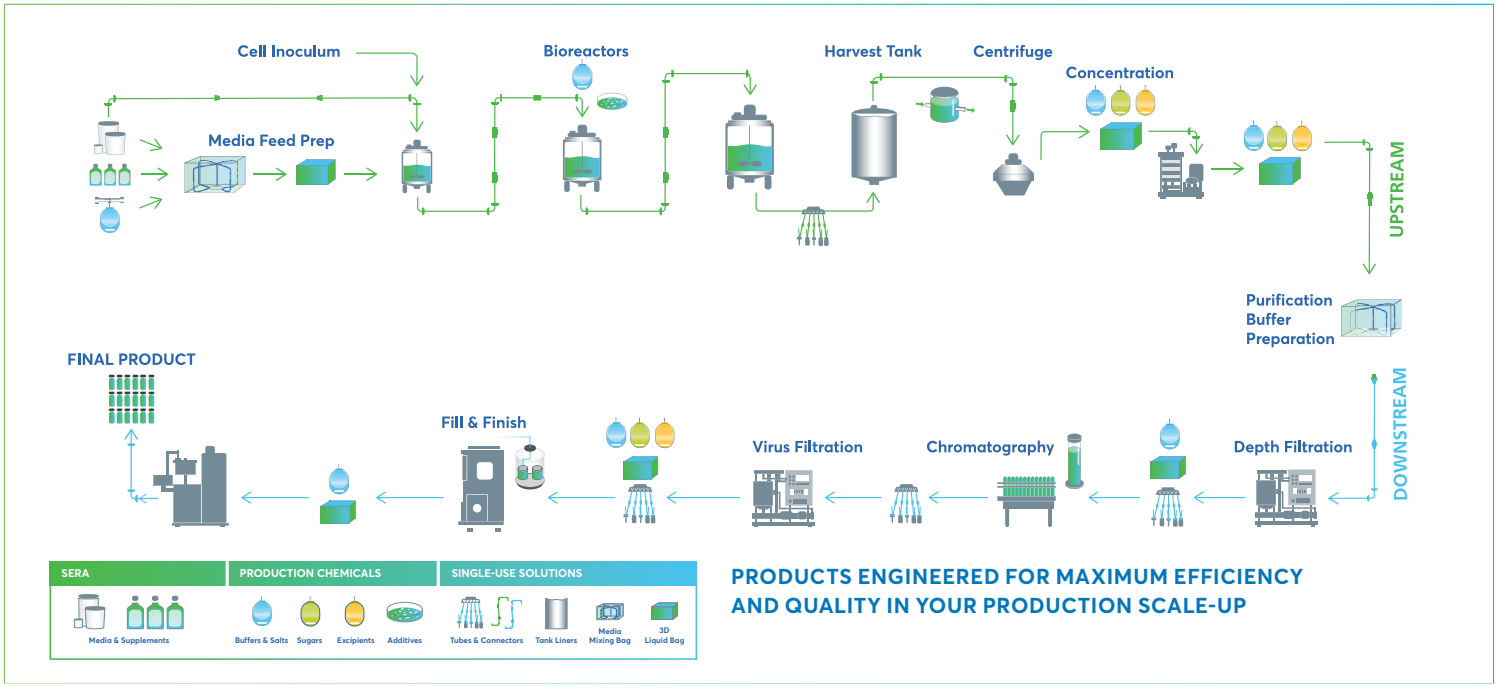
- Cell culture and fermentation media and supplements
- Amino acids and vitamins
- Biological buffers and salts
- Products for cleavage, lysis and DNA/RNA removal
- Products for inclusion body recovery and purification
- Chromatography resins
- Other high-purity production chemicals and excipients

Single-use fluid connectivity, sampling and sterile transfer systems

Single-use systems have proven to facilitate vaccine development while maintaining consistent and scalable performance.

Avantor single-use solutions is the only open-architecture provider to offer complete design, consultative engineering services plus manufacturing and logistics support to help create single-use fluid handling and aseptic sampling workflows that meet your needs of vaccine manufacturing.

CHEMICALS & SINGLE-USE TECHNOLOGY FOR VACCINE MANUFACTURING WORKFLOWS*[1]



PRODUCTS ENGINEERED FOR MAXIMUM EFFICIENCY AND QUALITY IN YOUR PRODUCTION SCALE-UP

1. General workflow showing Avantor's range. As vaccine manufacturing workflows can differ considerably, not every step of this workflow may apply.

When you need an experienced, trusted partner to accelerate your vaccines manufacturing processes, choose Avantor

PARTNERING WITH YOU ON INNOVATION

Avantor can work with you to develop solutions that help you overcoming your process challenges, such as:

Innovations in raw materials characterization:
- Enhanced use of data analytics tools
- Providing analytical e-data sets for customer product validation and transferring test methods to qualify incoming raw material

Achieve variability control:
- Supplying consistent high purity and cGMP raw materials from cell culture process to final fill

Innovations in material flow:
- Pre-weighed powders at different scales in direct dispense packaging, reducing the risk of clumping and dispensing to within 1% of fill weight

System risk reduction:
- Advanced single-use aseptic fluid transfer and closed system sampling

Yield improvement:
- Improved chromatography resins to increase selectivity

Formulation:
- Buffering and excipient strategies for stability and pre-blend, ready-to-use excipients for speed

COMPLEMENTARY SOLUTIONS FROM VWR, PART OF AVANTOR

Through our global channel, VWR, part of Avantor, you can also access a range of products, services and solutions from other industry-leading brands to supplement your development and manufacturing:

- Equipment
- Life science reagents and consumables
- Critical environmental and safety products
- Tailored services

Customization for your evolving needs – including tailored products, specifications and packaging – is through our product development team. Contact your Avantor Biopharma sales representative to learn more.

avantor™

AVANTORSCIENCES.COM

25854_JS_WH

ZPROAVTR25854-EN