

# Solutions for monoclonal antibody manufacturing

Each stage of bioprocessing is influenced by the steps preceding it. In the production of monoclonal antibodies (mAbs), manufacturing challenges such as reducing variability, increasing yields, effective separation of impurities in downstream purification or achieving high protein concentration in formulation and drug product stability must be effectively managed in order to successfully complete regulatory review processes and bring new, life-altering medicines to market.

As a trusted supplier for the top 20 biopharmaceutical companies, Avantor's expertise and solutions address the complexity of mAbs manufacturing. From process development and scale-up, through commercial manufacturing, we offer the products and support you need to help maintain mAbs quality, activity and stability throughout the entire process.

## QUALITY AND REGULATORY EXPERTISE

We actively collaborate with customers, sharing the product and application expertise and regulatory know-how that is critical to their 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

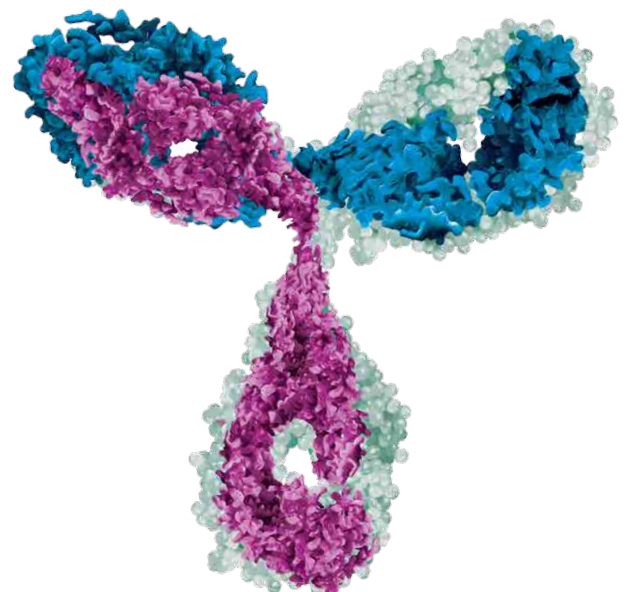
- Certified to ISO Class 5 and 7 environments
- Microbial environmental monitoring

### 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 your unique mAbs manufacturing 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 barcoded 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

Addressing your custom purity needs, new product development and synthesis from cell culture supplements, elemental impurity controlled buffers, through novel excipients

Wide range of packaging alternatives to fit your process for both powder and liquid materials

### SINGLE-USE SOLUTIONS

Open Architecture Model vertically integrated on bags, stoppers & fittings supporting choice of your systems

Comprehensive Supplier Management Program with qualified 1st and 2nd 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 & approval process:

- Designs < 5 days
- Validation Packs < 5 days

Global logistics footprint

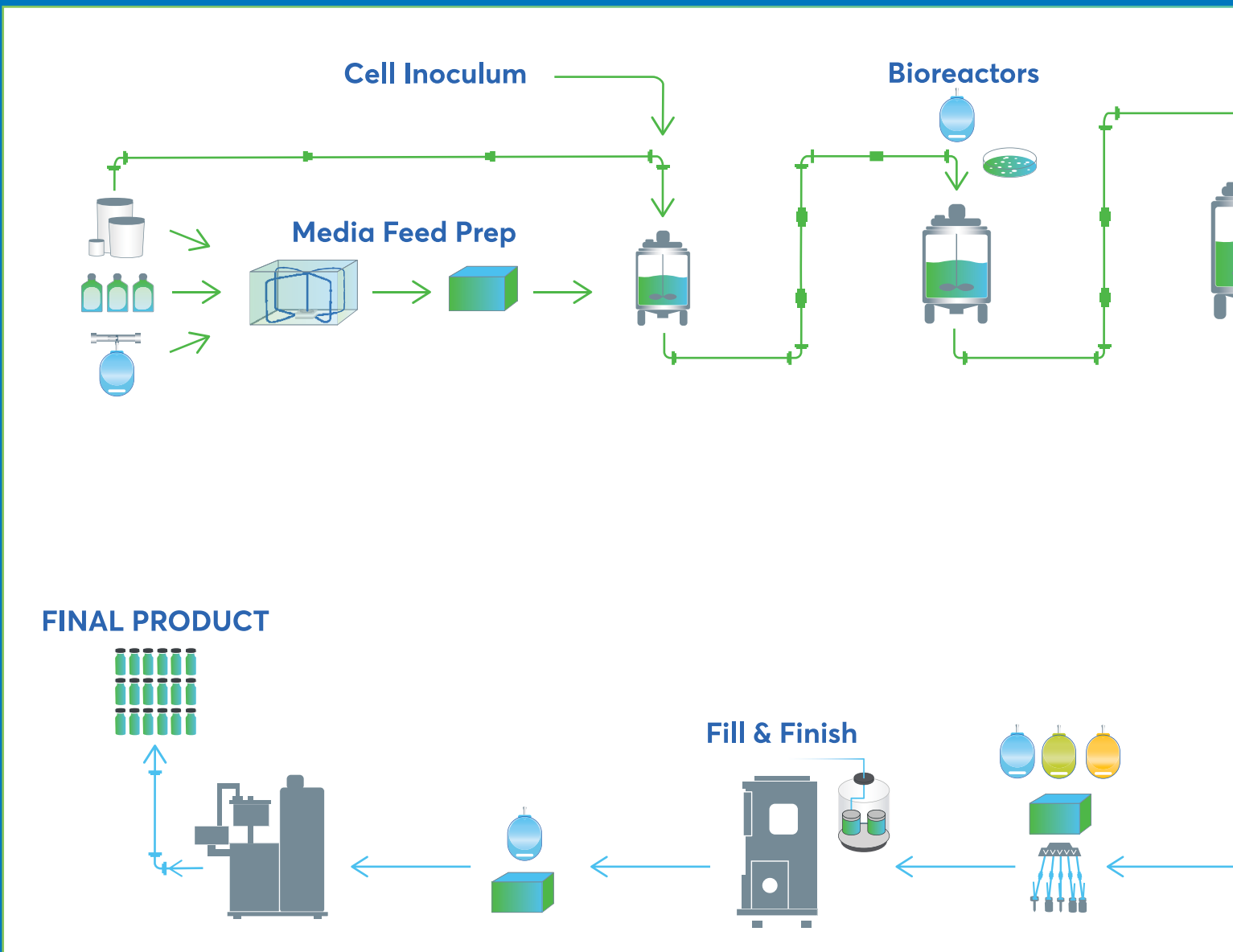
100+ standard products

Fully custom solutions designed for specific applications

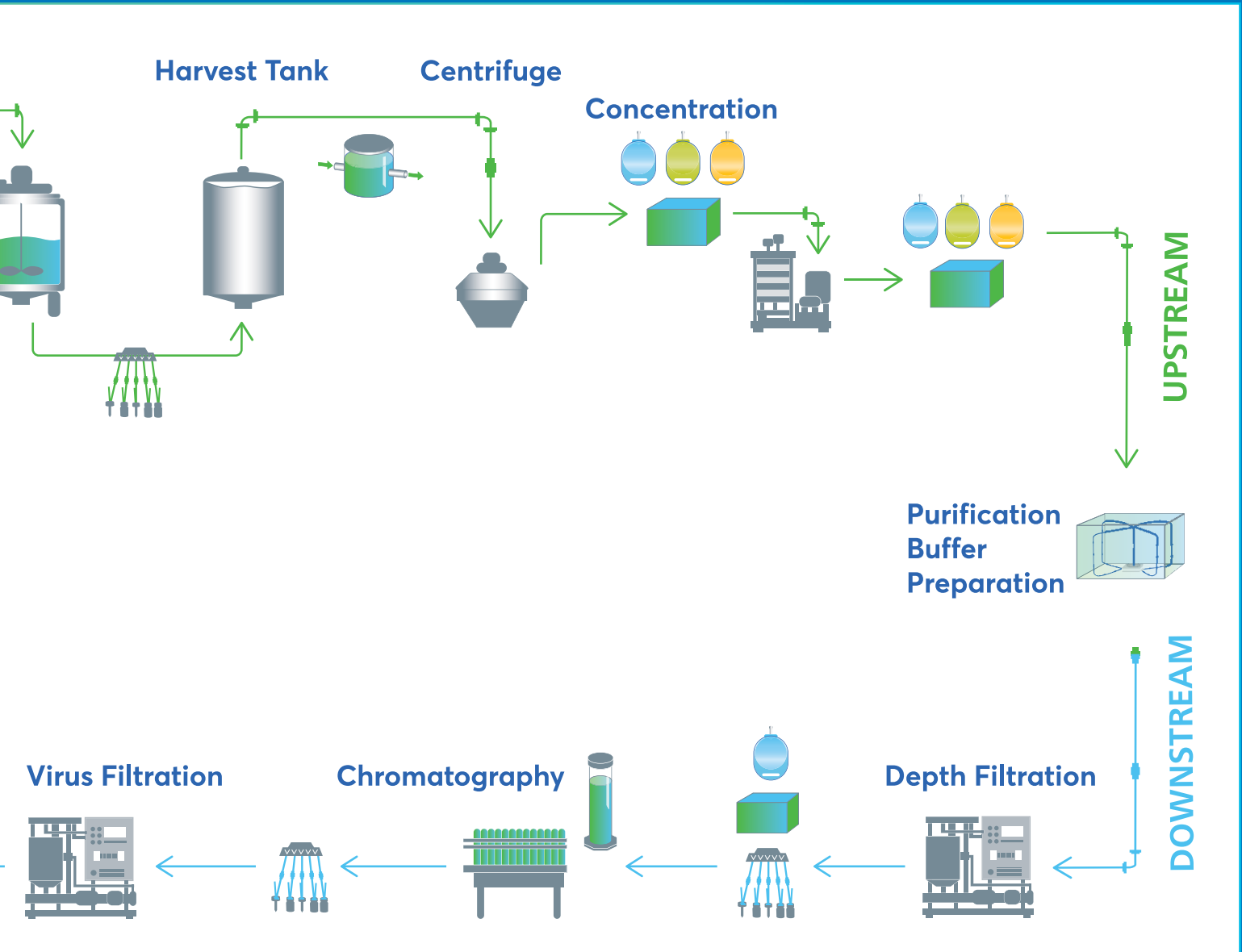
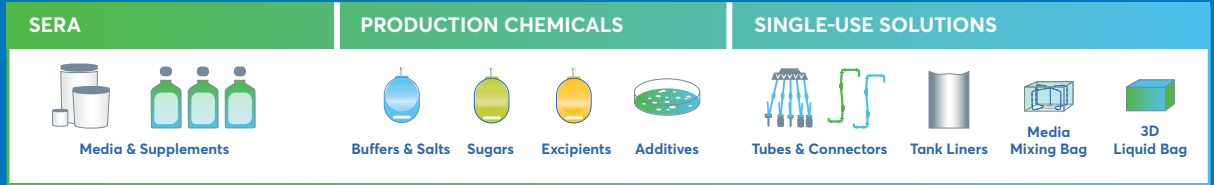
Ability to develop custom components & parts

Customized skid systems with disposable fluid paths

# cGMP chemicals and single-use technology for the mAbs manufacturing workflow



# PRODUCTS TO SUPPORT QUALITY AND STABILITY OF YOUR TARGET PROTEIN THROUGHOUT THE PURIFICATION PROCESS



# Scale-up your mAbs more efficiently with trusted cGMP materials and single-use solutions

Trust our portfolio of cGMP chemicals, excipients and chromatography resins to help you move from the small-scale bench, to the pilot plant, and to full production—reaching the market with new breakthroughs in medicine faster, safely and effectively.

Additionally, Avantor is an open-architecture provider of single-use fluid connectivity, sampling and sterile transfer products. We offer complete design, consultative engineering services, manufacturing and logistics support to help create single-use fluid handling and aseptic sampling workflows that meet your needs of mAb manufacturing.

## AVANTOR BIOPHARMA PRODUCTION CORE OFFERING

Chemicals	Cell culture supplements:	Harvest:	Purification:	Formulation, Fill & Finish: <sup>1</sup>
<ul style="list-style-type: none"> <li>– Buffer supplements</li> <li>– pH adjusters</li> <li>– Proteins and amino acids</li> <li>– Minerals and vitamins</li> <li>– Sugars</li> <li>– Antibiotics</li> </ul>	<ul style="list-style-type: none"> <li>– Surfactants</li> <li>– Denaturants</li> <li>– Biological buffers</li> <li>– pH adjusters</li> <li>– Salts and disulfide reducing agents</li> <li>– Virus inactivation detergents</li> </ul>	<ul style="list-style-type: none"> <li>– Biological buffers</li> <li>– Cleaning reagents</li> <li>– Inorganic salts</li> <li>– Chromatography media</li> <li>– Media storage buffers</li> <li>– Sanitization agents (e.g. Guanidine, NaOH)</li> </ul>	<ul style="list-style-type: none"> <li>– Biological buffers</li> <li>– Inorganic salts</li> <li>– Proteins and amino acids</li> <li>– Sugars</li> <li>– Surfactants (e.g. Polysorbates)</li> <li>– Lyophilization reagents (e.g. Trehalose)</li> <li>– pH adjusters</li> </ul>	
<p>Learn more by visiting <a href="http://vwr.com/bioprocessing">vwr.com/bioprocessing</a></p>	<p>1. Pre-weighed powdered raw materials and excipients in J.T.Baker® Direct Dispense</p>			

1. Direct Dispense comment in table above applies only to Cell Culture, Harvest and Purification; it does not apply to Final Fill.

Single-use products	Aseptic fluid transfer:	Closed aseptic sampling:	Fluid collection & storage:	Ready-to-use single-use products:	Final fill & delivery:
<ul style="list-style-type: none"> <li>– Standard products</li> <li>– Customised products</li> <li>– Integrated sensors</li> <li>– Filtration, TFF</li> <li>– Specialized connectors</li> <li>– Tubing management</li> </ul>	<ul style="list-style-type: none"> <li>– Conical tube sampling</li> <li>– Sampling manifolds</li> <li>– Micro sampling</li> <li>– Syringe sample devices</li> </ul>	<ul style="list-style-type: none"> <li>– Process bags</li> <li>– BDS freeze bottles</li> <li>– Collection bottles</li> <li>– Closed transfer bottles</li> </ul>	<ul style="list-style-type: none"> <li>– Media mixing devices and holding bags</li> <li>– Customized reagents &amp; buffers in ready-to-use bags and manifolds</li> </ul>	<ul style="list-style-type: none"> <li>– Innovative delivery systems</li> <li>– Single-use filling lines with needles</li> <li>– Isolator multi-tube filling assemblies</li> <li>– Pass-through manifolds</li> </ul>	
<p>Learn more by visiting <a href="http://vwr.com/single-use">vwr.com/single-use</a></p>					



## PARTNERING WITH YOU ON INNOVATION

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

- Raw materials characterization, with improvements made through the use of data analytics tools and e-data sets for product validation and transferring test methods to qualify incoming raw materials.
- Achieving variability control by utilizing cGMP raw materials of consistent high-purity and quality in cell culture processing steps all the way to final fill steps.
- Improvements in material flow with the implementation of the Avantor J.T.Baker® Direct Dispense packaging system—a solution for pre-weighed powdered materials and excipients that dispenses to within +/- 1% of fill weight and reduces the risk of clumping.
- Reducing system risk with the use of advanced single-use aseptic fluid transfer and closed system sampling.
- Improving yield through the use of J.T.Baker® chromatography resins to increase separation efficiency.
- Optimizing materials used in formulation, such as excipients and buffers, influencing pH, viscosity and concentration of final formulations.

## 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 including:



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

Tailored services and solutions for your evolving needs—tailored products, specifications and packaging are available.

When you need an experienced, trusted partner to accelerate your mAbs manufacturing processes, choose Avantor. Contact your sales representative today to learn more.



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