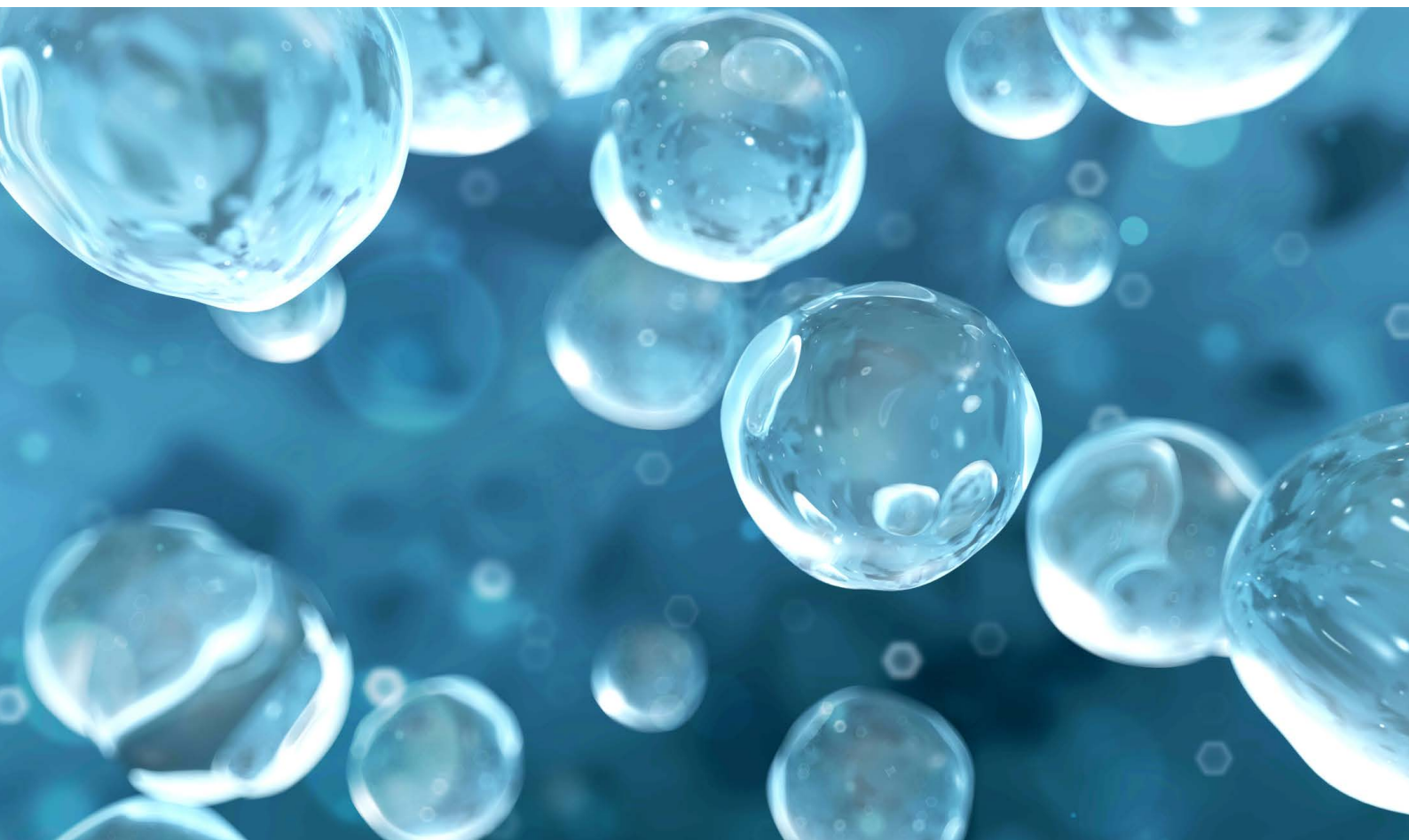


Avantor Custom Hydration Management:

Buffers, reagents and cell culture media



Optimizing your buffer and culture media management across biopharma workflows

Hydrated solutions, such as buffers and culture media, are critical material in biopharmaceutical manufacturing, as they are used from the earliest upstream processes to fill and finish.

Established practice is for buffers and culture media to be prepared in-house using USP or WFI grade water to hydrate powders in stainless steel or single-use tanks. However, there are significant hurdles and costs involved for preparation and scaling to commercial manufacturing.

In-house preparation of biopharma reagents and cGMP buffers requires the management of supply and quality of the numerous raw materials used as well as infrastructure, such as weighing and dispensing areas, mixing systems, analytical space and warehousing.

The workflows of newer modalities such as cell, gene, and nucleic acid-based therapies often require smaller batches

and smaller packaging, further increasing the burden of this infrastructure.

Considering the cost and complexity of in-house solutions preparation, the adoption of supplier provided premade solutions, buffers and buffer concentrates are a cost-, time- and resource-saving alternative for end-to-end bioprocessing.

Whether you are an R&D lab that needs a steady supply of Biotech Reagents or a GMP commercial manufacturing site that requires large volumes of solutions in different fill sizes, Avantor can provide:

- Ready-to-use critical reagent grade and cGMP solutions
- cGMP buffer concentrates to be used in conjunction with buffer stock blending skids or inline dilution systems
- Custom media preparations

Avantor can work with you to find the most appropriate solution to clear bottlenecks across your development and manufacturing processes.

Avantor enables rapid supply of biopharma reagents and buffered solutions, as well as outsourcing of your single- and multi-component buffer preparation. Utilizing Avantor's in-house production of J.T.Baker® chemicals, custom single-use assemblies, external sourcing of components that are optimized for your process and warehousing capabilities allows you to free up valuable space in your facility while realizing cost, time and labor savings, and to focus on your core activities.

CONTACT US FOR CUSTOM SOLUTIONS AND PACKAGING

Reduce total cost of buffer prep and management by leveraging Avantor's media and buffer preparation capabilities

Leveraging Avantor's manufacturing capabilities as well as our quality, supply chain and logistics expertise, you can concentrate on your core product development and manufacturing work. Depending on which buffer management strategy you choose, benefits from outsourcing your buffer preparation include:

Time and cost savings

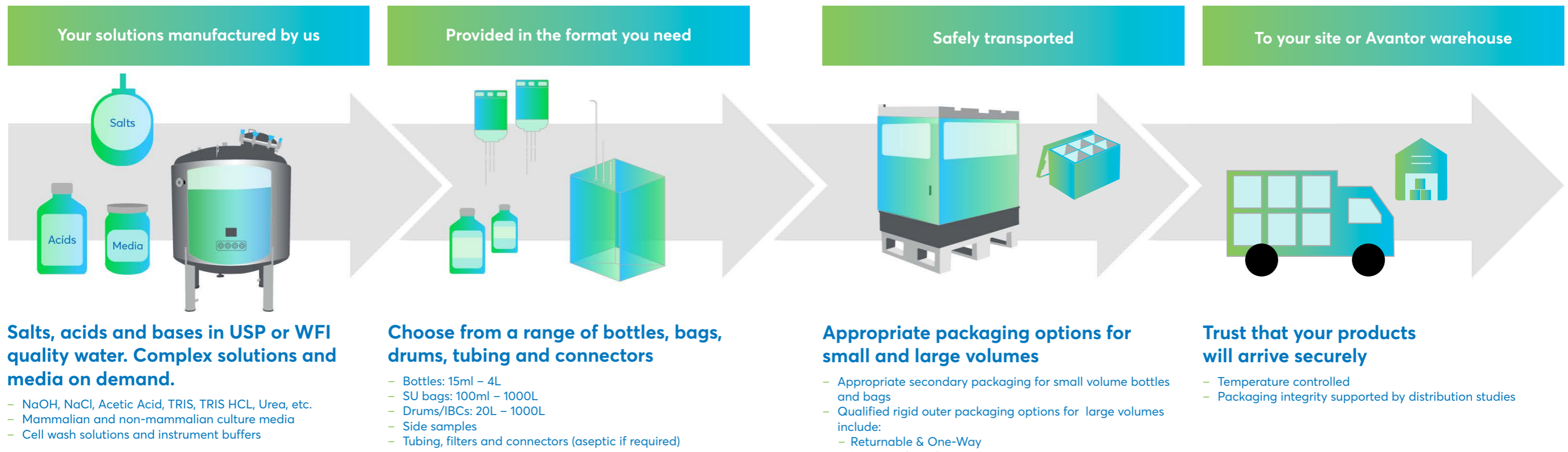
- Reduction of production process steps
- Reduced time for powder dissolution incl. declumping
- Reduced batch-time
- Labor savings/personnel can be assigned to other tasks
- Saving of storage in buffer bags or holding tanks
- Reduce facility footprint of the buffer management system
- Lower capital investment

Secured quality

- Multiple packaging options out of the same batch to streamline your workflows from R&D to commercialization
- Satellite samples to reduce cost and QC testing
- Quality support for rapid release and investigation
- Reduced regulatory risk
- Enhanced operator safety (e.g. reduced chemicals exposure, no spill cleanup)
- Decreased safety and ergonomic concerns during processing

Supply chain security

- Streamlined supply processes
- Remote access to raw material and finished good data
- Robust database to track chemical inventory
- Vertically integrated and redundant Avantor manufacturing capabilities



Salts, acids and bases in USP or WFI quality water. Complex solutions and media on demand.

- NaOH, NaCl, Acetic Acid, TRIS, TRIS HCL, Urea, etc.
- Mammalian and non-mammalian culture media
- Cell wash solutions and instrument buffers

Choose from a range of bottles, bags, drums, tubing and connectors

- Bottles: 15ml – 4L
- SU bags: 100ml – 1000L
- Drums/IBCs: 20L – 1000L
- Side samples
- Tubing, filters and connectors (aseptic if required)

Appropriate packaging options for small and large volumes

- Appropriate secondary packaging for small volume bottles and bags
- Qualified rigid outer packaging options for large volumes include:
 - Returnable & One-Way
 - Lease or Own Options

Trust that your products will arrive securely

- Temperature controlled
- Packaging integrity supported by distribution studies

Quality at Avantor

As a supplier to leading global biopharma manufacturers, quality is an essential element of every process, program, product and solution at Avantor. From the acquisition of raw materials through production and shipping, quality is the foundation for the value we deliver every day to our customers. We emphasize quality and supply chain security in both our own operations and those of our suppliers, with key elements including:

- **Supplier auditing and integrity:** We conduct risk-based audits to understand the capabilities of new suppliers and collaborate with suppliers to promptly address corrective and preventive actions (CAPAs), should they arise.
- **Collaborative planning, forecasting and replenishment (CPFR):** We provide service level reports on assurance of supply through our Critical Materials Care team
- **Documentation:** Product regulatory data sheets Quality or Analysis are available with SDS documents on our websites.

Avantor quality systems and standards

- cGMP/ICH Q7, IPEC, ISO 9001 and ISO 13485
- Full GMP process, cleaning, analytical validation
- **Testing:** Compendial, analytical method development and validation for custom specifications
- **Shell Life Determination:** Formal stability studies
- Avantor Management of Change (MOC) program
- Animal Origin Free facilities
- Preparation in ISO classed suites as appropriate

Avantor Management of Change program

The Avantor Management of Change (MOC) program puts key information into your hands for J.T.Baker® and Macron Fine Chemicals™ brand products so you can stay in control of changing situations and minimize risks associated with changes to manufacturing processes.

[Contact us](#) to discuss how Avantor can support your culture media and buffer management and how outsourcing your solutions preparation activities can help streamline your supply chain and increase productivity, while reducing facility footprint and risk of supply.

Learn more on how to achieve process optimization in our thought leadership articles :

[Alternative buffer management strategies to achieve downstream process improvements](#)

[Solving cost and supply challenges in biopharma downstream processing](#)

[Advancing gene therapy by solving challenges in scale-up & manufacturing](#)

[Raw data – a 4.0 approach to materials offers process development benefits](#)

[Integration of single-use technologies into fluid handling systems](#)

