

Avantor hydration platform



Optimizing your buffer preparation management in downstream applications

Buffers play a significant role in biopharmaceutical manufacturing. Typically representing a major component by volume used in biopharma downstream processing steps, buffer preparation constitutes a significant proportion of a facility's footprint, labor requirements and equipment cost.

There are multiple ways buffers can be supplied; an established way to manufacture buffers in-house is with the use of USP or WFI grade water to hydrate powders in stainless steel or single-use tanks.

While this method is established and ideal for large volumes, these operations need significant infrastructure. This includes warehouse space for holding raw materials prior to use and a weighing and dispensing area for raw materials.

The footprint for stainless-steel tanks themselves within the facility must also be considered, especially considering exothermic hydration reaction.

Looking at the cost and complexity of in-house buffer preparation, the adoption of hydrated, premade liquid, buffers and buffer concentrates is a cost-, time- and resource-saving alternative in downstream processing.

Depending on the size of the biopharma manufacturer's operations and facility, different buffer management strategies can be applied as a stand-alone solution or in combination in order to achieve workflow improvements.

Examples include:

- Buffer concentrates to be used in conjunction with inline dilution
- Buffer stock concentrates to be used in conjunction with buffer stock blending
- Ready-to-use cGMP buffer solution

Avantor can work with you to find the most appropriate hydrated buffer solution to clear bottlenecks from your downstream processes.

Avantor enables outsourcing of your single- and multi-component buffer preparation. This allows you to free up valuable space in your facility, while also offering cost, time and labor savings.



Reduce total cost of ownership by outsourcing buffer preparation, choosing the Avantor hydration platform

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



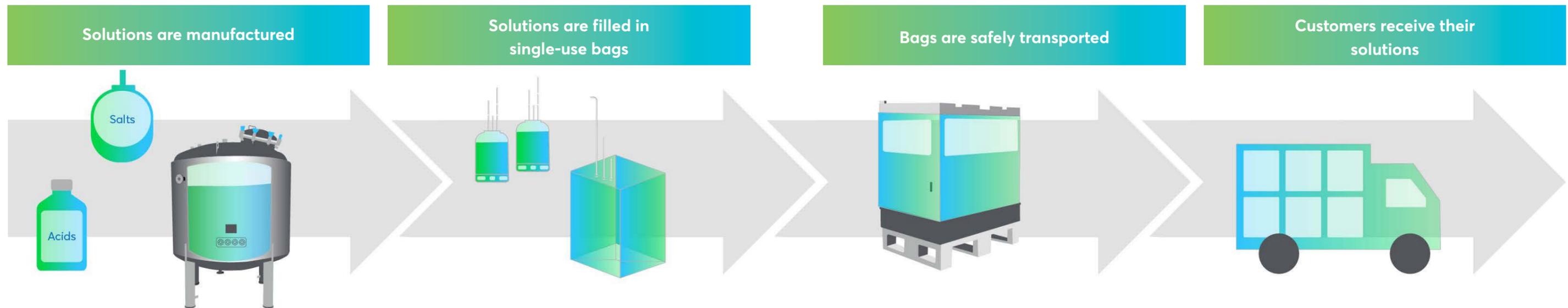
Secured quality

- Tested to extensive analytical specifications
- Reduced non-conformities
- Satellite samples for reduced 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



Products include salts, acids, bases in USP or WFI quality water

- NaOH, NaCl, Acetic Acid, TRIS, TRIS HCl, urea
- 1x, single or multi component

Choose from a range of bags, drums and tubing

- SU bags: 50L, 100L, 200L, 1000L
- Drums/IBCs: 19L, 25L, 200L, 1000L
- Side samples
- Tubing, filters and connectors

Qualified rigid outer packaging options

- 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
- **Validation:** Full GMP process, cleaning, analytical validation
- **Testing:** Compendial, analytical method development and validation for custom specifications
- **Shelf Life Determination:** Formal stability studies
- Avantor Management of Change program (MOC*)

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 buffer management and how outsourcing your buffer preparation activities can help streamline your supply chain and increase productivity while reducing facility footprint and risk of supply.

Learn more in our [white paper](#) on "Alternative buffer management strategies to achieve downstream process improvements".