

# BIOPHARM TANKS



**MUELLER**  
BIOPHARM SYSTEMS

# Get to Know Mueller® BioPharm Systems

Since our inception in 1940, Paul Mueller Company has evolved from a small scale fabricator into a global process solution provider with one million square feet of manufacturing space. Mueller® offers a full range of tanks from shop-fabricated alloy vessels up through 20 feet in diameter to field-fabricated vessels up through 2,000,000 gallons; furthermore, we offer integrated systems, modular fabrication, field construction, plant maintenance and repair, and complete turnkey project execution. Our facility is uniquely qualified to handle large and complex fluid handling systems from project concept through installation. Mueller products are used in over 100 countries in a wide variety of applications. Paul Mueller Company delivers outstanding equipment and unique solutions to the process industries with our technical expertise, innovative engineering, and manufacturing resources.

We know that building a quality product starts from the ground up. Our unprecedented purpose is to make your system as valuable and efficient as it can be, and to guarantee that you receive the highest possible quality in our processes and products. With our skilled craftsmen, quality materials, and one of the best technologically advanced manufacturing facilities in the country we are able to build exceptional products at a reasonable price.

Mueller products are made by our highly skilled craftsmen, whose average experience exceeds 15 years. Our process is well defined and consistently developed. Each Mueller team member fully understands the importance that their individual roles play in producing a quality product. On any given day, their talent and pride of workmanship can be observed in any our production areas. Our central United States production facility lowers your transportation costs and speeds delivery of product to your location.

Mueller Transportation, Inc. lets us provide you with competitive delivery rates on standard products, as well as dedicated handling for large or critical delivery items. We offer a perfect package by working directly with you to resolve any transportation issues.

Mueller Field Operations, Inc. offers our customers more versatility and flexibility. Our field construction capabilities allow us to install Mueller advanced products at a low cost.

Factory technicians and field service available. Mueller offers rapid response to your service needs with trained factory personnel knowledgeable in all aspects of Paul Mueller Company equipment.



## The Mueller Reputation

Every piece of Mueller BioPharm processing equipment is precision engineered for quality form and fit, close tolerances, and high quality finishes. You can depend on Mueller to deliver a product that will perform required functions and offer reliable product protection.





## Our Philosophy is Simple:

We are committed to meeting and exceeding our customers' expectations of value by providing high quality equipment, excellent service, and complete process solutions.

## Mueller BioPharm Tanks

For decades, Mueller has been recognized as a trusted supplier of tanks and vessels to the pharmaceutical and biotech industry, and our cumulative experience in this field is unrivaled. From smaller portable tanks and “smart” tanks to larger processing vessels, we have the capabilities and engineering, manufacturing, and documentation resources to deliver your custom BioPharm tanks as required.

We provide you with a vast array of services, including a diverse engineering organization with specialists in the areas of heat transfer, agitation, and CIP, in addition to the most technologically advanced manufacturing capabilities.

Our extensive tank and vessel manufacturing capabilities, one million square foot facility, and hundreds of production workers and craftsmen allow us to provide the entire scope of these products in-house. Mueller manufactures 100% of the heads, shells, manways, and heat transfer surface within our facility. This, in conjunction with our electropolishing capability, lets us control the entire scope of supply for your tank or vessel. This means that you can expect tight control of quality and schedule throughout the manufacturing process, consistent documentation, and on-time delivery via Mueller Transportation, Inc.

In addition, we offer installation, full Factory Acceptance Testing (FAT), and extensive standard documentation packages, or we can supply a custom package to meet your project's specific needs. From projects requiring a single portable vessel to multiple quantity large vessel orders, let Mueller BioPharm Systems contribute to the success of your next project!

# BioPharm Tanks

## Portable Tanks

Mueller offers you a full range of portable vessels. Our engineering and manufacturing staff has decades of experience in the design and manufacture of portable tanks with heat transfer, agitation, top-head manways, and virtually any requirement that might exist.



## “Smart” Tanks

A recent trend in the Biopharm industry, a “smart” tank is a vessel which has most or all of its required control hardware and capability integrated onto the vessel itself or an attached skid.

Our vessel capability, coupled with our highly skilled controls group, can meet all of your requirements for such a project. From initial consultation to software programming and FAT, we can meet your most complex project requirements.





## Processing Tanks

Paul Mueller Company has the capability to fabricate the largest and most complex processing tanks the biopharm industry requires. We are experienced working with material from thin gauge up to one inch thick with any combination of fittings, manways, heat transfer, and mixing equipment. These capabilities mean there is almost no limit to the level of complexity and size of vessel we can manufacture.

We manufacture a wide range of heat transfer products, which means we can provide precise temperature control to meet your requirements, along with a variety of agitation devices for critical aseptic applications. Our capabilities also allow us to offer all surface finishes utilized in the biopharm industry.



## Bioreactors and Fermenters

Paul Mueller Company custom bioreactor and fermentation systems are fully instrumented and integrated skid mounted systems built and designed to your custom specifications.

The complete systems are offered in sizes ranging from 20 liters to 25,000 liters to meet your unique needs.

The equipment can be fully tested in our shop at elevation closely meeting the actual utility parameters at the installation site. We can even ship these systems using our own fleet of trucks.

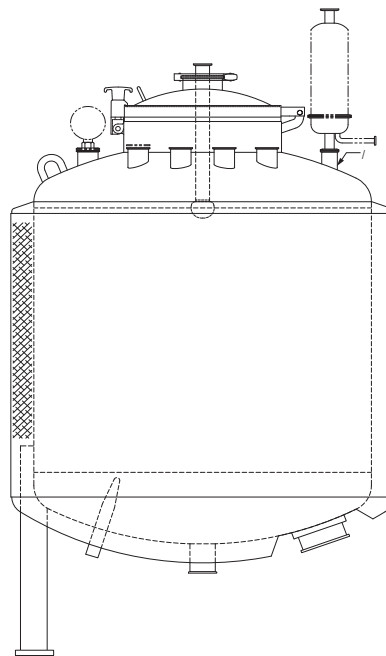
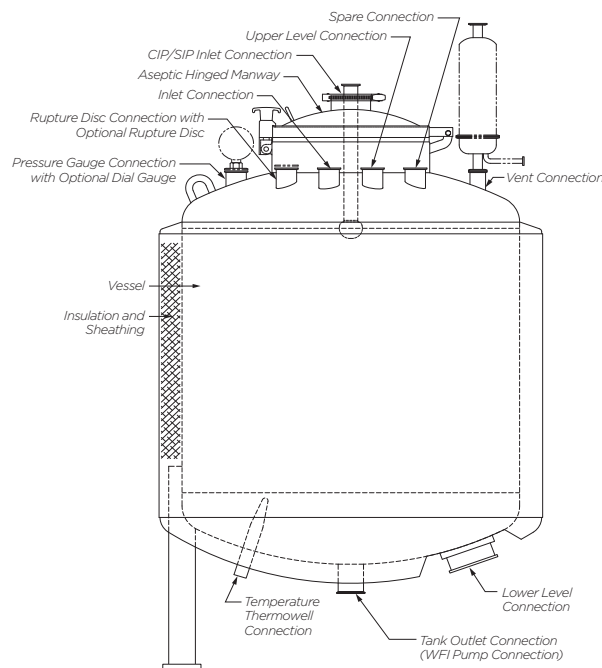


# Affordable High-Purity Water Storage

## Water-for-Injection Tanks

Mueller WFI tanks are engineered specifically for the special needs of the pharmaceutical and biotech industry. They consist of a Type 316L stainless steel vessel and utilize sanitary clamp style connections, an aseptic manway, and a spray ball for interior sanitization. Chloride-free insulation surrounds the tank's sides and bottom, which is covered with Type 304 stainless steel outer sheathing. The vessel and all components are fabricated to the requirements of ASME Section VIII, Division 1. Standard tank sizes range from 250 to 15,000 gallons (945 to 56,780 liters) to satisfy a broad spectrum of capacity requirements. Custom fabrication is also available.

### Specifications



### Features and Benefits

- Seismic design means strength enough to withstand earthquakes up to and including Zone 4 conditions.
- With Paul Mueller Company's 75 years of experience in stainless steel fabrication and finishing, quality and reliability in design and construction are assured.
- Mueller manufactures a broad range of standard WFI tank sizes to meet your specific storage needs. In addition, we offer custom sizes and dimensions for special requirements.
- Insulated sides and bottom of vessel helps maintain WFI temperature.
- Mueller WFI tanks are Integrated with our PyroPure® stills and pure steam generators and tested as a system prior to shipment, which speeds installation by pre-assembly and shop fit-up.
- CIP coverage and FAT testing is available. Each tank comes with a complete documentation package that speeds validation of your system.

## Components

**Vessel.** The ASME Code stamped WFI vessel has a rating of 40 psig and full vacuum at 300°F. Interior surfaces are mechanically polished to 25 Ra maximum and then electropolished (BPE SF6) to maintain optimum sanitary conditions. Exterior surfaces are 2B or mill finish with welds buffed. Mechanically polished material and/or flush ground weld finishes are available options.

**Aseptic Manway.** The 18" hinged opening meets cGMPs standards for validation ease. It has an EPDM O-ring seal and is made of Type 316L stainless steel to match the vessel. It may be centered on top of the vessel or located off center, depending upon installation requirements. Silicone and Viton O-rings are available options.

**Connections.** Standard sanitary clamp-type connections include an outlet connection, inlet connection, CIP/SIP connection, vent connection, rupture disc connection, pressure gauge connection, upper and lower level connection, temperature thermowell connection, and a spare connection.

**Insulation.** A 2" chloride-free insulation surrounds the sides and bottom of each WFI vessel. A 12-gauge, Type 304 stainless steel sheathing is welded around the insulation to seal it from moisture.

**Sanitary Spray Ball.** When connected to a CIP or SIP system, the spray ball will rinse the vessel interior and top head with hot water to keep the tank environment sanitary. The spray ball and its components are removable for cleaning and inspection. The ball is constructed of electropolished Type 316L stainless steel. CIP coverage testing is available.

## Optional Equipment

**Heat Transfer Surface.** Dimpled heat transfer surface can be included on the bottom of the vessel to keep WFI at a constant temperature using plant steam. The surface is ASME rated at 125 psig at 360°F and is constructed of 14- gauge Type 316L stainless steel. Additional heat transfer surface on the sidewall is also available.

**Rupture Disc.** Protects the vessel from excessive pressure buildup when combined with a sanitary port.

**Pharmaceutical Vent Filter.** Allows air in while protecting stored water from airborne contaminants with a 0.2 micron hydrophobic, steam sterilizable filter element. Both the filter and the element comply with requirements for LVP cGMPs.

**Temperature Indicator.** Provides a digital readout of WFI temperatures via an RTD probe.

**Pressure/Vacuum Gauge.** Stainless steel casing encloses a sanitary diaphragm pressure sensor. Gauge attaches to the vessel.

**Sanitary Level Controller.** Monitors tank level and can be set to activate a level alarm while starting/stopping the connected still.

**Vortex Breaker.** Prevents problems caused by high draw-off rates.



# Material and Weld Finishes

## Material Finishes

Mueller products can be fabricated with any of the following material finish options. These designations apply to stainless steel sheet, plate, pipe, and bar.

### Types and Descriptions

**Hot Rolled (HR).** Rough, dull surface appearance. Most scale removed by pickling. Applies to all steel plate thicknesses above ¼". Also available in 7 gauge and ¼". Specify where surface finish is a low priority.

**2B Mill Finish (2B).** A smooth, bright, moderately reflective finish suitable for "as is" specifications or as a preliminary finish for further polishing. Available only in 10 gauge or thinner sheet material.

**No. 3 Finish.** A semi-polished surface achieved by finishing with the equivalent of an 80 grit abrasive. This finish has a pronounced grit line. Typically used with a No. 3 weld finish.



Hot-Rolled (HR)



2B Mill Finish (2B)



No. 3 Finish



No. 4 Finish



No. 6 Finish



No. 7 Finish



Industrial Electropolish (IND-EP)



Electropolish (EP)

**No. 4 Finish.** An aesthetic industrial finish with visible grain that prevents mirror-like reflectivity. Used where clean industrial surfaces are required. Typically used with a No. 4 weld finish (150 grit).

**No. 6 Finish.** This polished finish is achieved with the equivalent of 240 grit abrasive. Finer grit lines and higher reflectivity than No. 4 finish. Improved product release, cleanability, and appearance. Typically used with a No. 6 weld finish.

**No. 7 Finish.** Highly reflective surface obtained with the equivalent of 320 grit abrasive. Minimal grit lines. Used where product contact surfaces are critical. Typically used with a No. 7 weld finish.

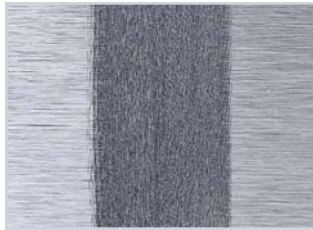
**Industrial Electropolish (IND-EP).** Reflective surface achieved by passing direct current through material that is suspended in electrolyte. Used where improved product release or cleanability is necessary.

**Electropolish (EP).** A highly reflective surface that provides the level of product release and cleanability required by the medical, chemical, pharmaceutical, and electronic industries. Process removes impurities and surface materials, but may not remove nonmetallic inclusions that may be present in parent material. Used to improve release on any of our product material finishes. Degree of improved performance depends on weld and material finishes specified prior to EP.



# Weld Finishes

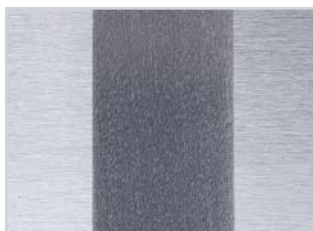
While it is possible to grind and polish every weld on a piece of equipment, in many cases it is not necessary or practical. The following describes the various weld finishes that are available from Mueller and, where applicable, the appropriate use of the finish.



Course Grind (No. 2) Industrial



Medium Grind (No. 3)



Fine Grind (No. 4)



Extra-Fine Grind (No. 6)



Ultra-Fine Grind (No. 7)

## Types and Descriptions

**As-Is (AI).** Characterized by fine spatter and smoke and weld discoloration. Tack welds, start-stop areas, and severe spatter are ground as required for nondestructive examination of the weld and weld area.

**Sandblast (SB).** Uniform, dull gray appearance to match cold- or hot-rolled material finish. Large spatter, slag, and burrs are first removed by grinding. Welds are then sandblasted to remove weld discoloration on material surfaces, leaving a clean, banded appearance.

**Glass-Bead Blast (GB).** Follows sandblasting to produce a satin, gray appearance closely matching a 2B finish.

**Buff (BF).** A process in which the weld is brightened. There is minimal removal of weld material. This finish is not flush and will contain crevices, ripples, silicone islands, and irregularities in the remaining weld material. Dark lines on either side of the weld and within the weld ripple may also remain. Generally used on exterior and interior plate surfaces where finish is not critical. Weld ripple size and appearance depends on the welding process used. Typically used with HR, CR, and 2B mill material finishes.

**Coarse Grind (No. 2) Industrial.** Welds are ground smooth but not flush. The upper surface of the weld bead is removed. Visual pits are not removed. This is not a 100% flush weld finish. Ra\* is not applicable. Characterized by coarse grit lines which may run in any direction. Discoloration remains on both sides of weld. Used as a preparatory finish where a flush and uniform surface are required.

**Medium Grind (No. 3).** Weld is ground flush and all discoloration is removed. A near sanitary finish generally used where a flush and uniform surface is required. Moderate grit lines remain. Target Ra is 75.

**Fine Grind (No. 4) 150 Grit.** Results in an aesthetic industrial finish surface normally used with a No. 4 material finish for applications where clean industrial contact surfaces are required. Grain and grit lines are visible. Target Ra is 32.

**Extra-Fine Grind (No. 6) 240 Grit.** Finer grit lines and higher reflectivity than fine grind. Improves product release and cleanability. Target Ra is 25.

**Ultra-Fine Grind (No. 7) 320 Grit.** A highly reflective, sanitary surface with minimal grit lines. Normally used to provide excellent product release and cleanability. Use where sanitary product contact surfaces are most critical. Target Ra is 15.

*\*Ra: Roughness average is the most universally recognized parameter of roughness. Its arithmetical average definition is measured normal to the centerline (AA or CLA).*

# Heat Transfer Solutions

## Heat Transfer Surface

Paul Mueller Company offers a variety of heat transfer surfaces to meet your particular requirements. Mueller heat transfer surface is ideally suited for applications involving high pressure and temperature extremes. It can be routinely fabricated in an almost unlimited number of shapes, sizes, and materials to fit any vessel design. Styles are available for use with almost any type of refrigerant or heating media. We work closely with you on each project to select the right surface for your equipment.



### Double-Embossed

Most commonly utilized in immersion applications, double-embossed Mueller Temp-Plate heat transfer surface helps maximize heating and cooling by using both sides of the heat transfer plate.



### Half-Pipe Coil

Our half-pipe coil heat transfer surface can handle large volumes of flow and is suited for high pressure applications and low pressure drop requirements.



### Dimpled

Dimpled Mueller Temp-Plate surface is machine punched and swaged prior to welding to increase the flow area in the passages.



### Single-Embossed

Single-embossed Mueller Temp-Plate heat transfer surface is economical to use for interior tank walls, tank heads, and when a flat side is required.

## Temp-Plate® Heat Transfer Surface

Mueller Temp-Plate heat transfer surface provides precise, consistent control capability with minimum pressure drop. Its design provides extremely efficient heat transfer performance that is more economical than other competitive types of heat transfer surface. Temp-Plate has spot-welded and inflated channels that induce the fluid turbulence necessary to attain high heat transfer coefficients. Lower flow rates are essential to achieve the high velocities of heating and cooling media.



## Half-Pipe Coil Heat Transfer Surface

Mueller half-pipe coil heat transfer surface handles large volumes of flow and is suited for high pressure applications and low pressure drop requirements. It is ideal for cyclic heat transfer conditions where heating and cooling cycles occur several times a day, as it is very resistant to stress corrosion cracking. Available in a variety of materials, half-pipe coil may be used for heating or cooling using steam, hot oil, water, glycol, ammonia, and refrigerants. ASME Code stamping is available.



## Dimpled Heat Transfer Surface

Mueller's dimpled Temp-Plate heat transfer surface is ideally suited for applications that involve high pressure and temperature extremes. It is routinely fabricated in an almost unlimited number of shapes, sizes, and materials to fit any vessel design. Styles are available for use with almost any type of heating or refrigerant media.





# Documentation and Validation

## Documentation

### Material Traceability

The documentation for your system begins before the first drawing is generated or the first welding arc is struck. Material traceability is established with the purchase and receipt inspection of materials and is systematically maintained throughout the manufacturing and assembly processes.

### Process Traceability

Many different processes take place during the fabrication of BioPharm equipment. Several methods are used to document that the equipment has been designed, fabricated, assembled, and tested appropriately. These include:

- Borescope inspection and video capabilities.
- Factory testing procedures.
- Inspection records.
- Software design specification (as required).
- Master inspection traveler.
- Weld records.



### Submittals

After receipt of your order, Mueller will send you drawings for final approval. These documents define the mechanical scope of supply and allow procurement and fabrication of the key components to proceed so the schedule is minimized while ensuring that the proper equipment will be supplied. Subsequent submittals are provided for software and functional testing details as required. We encourage you to comment and provide feedback on these documents to ensure compliance with your project requirements.

### Turnover Packages — Per BPE Requirements

The resulting turnover package provides a well organized and comprehensive validation reference that parallels customer protocols. In addition to the standard three-ring binders, packages are also provided in CD/DVD formats.

### IQ/OQ Capabilities

Mueller offers installation qualification (IQ) and operational qualification (OQ) documents to support our products. Execution of these protocols can be performed by Paul Mueller Company service technicians at the time of start-up and commissioning.

## Factory Acceptance Testing

Mueller factory acceptance testing starts prior to your arrival on site with your review and approval of the test documents. We also pre-test the equipment prior to your arrival. Any project specific requirements outlined in the functional specification and design specification documents will be checked and tested as needed.

## Validation

As a world leader in water and processing systems for the finished pharmaceutical, bulk, API, biotechnology, medical device, and medical diagnostic industries, we have extensive industry experience preparing comprehensive turnover documentation and validation packages. The many projects that Mueller has completed have withstood scrutiny by the numerous customers, independent validation companies, as well as the Food and Drug Administration (FDA).



As the pharmaceutical industry has evolved, so has our approach to validation. We are qualified to provide documentation and validation compliance due to our extensive experience within the industry, our attention to regulatory changes, and our capability to adapt to each of our customers' specific needs. The optional completed installation qualification (IQ) and operational qualification (OQ) documentation and validation packages provide documented evidence that our systems are built and commissioned in accordance with user requirements specifications (URS), functional requirements specifications (FRS) and detail design specifications (DDS), as well as FDA and cGMP standards.

Paul Mueller Company maintains a staff of professionals with considerable experience within the pharmaceutical industries and broad educational backgrounds in quality, engineering, chemistry, and technical services. Since our validation and quality systems are integrated within the company structure, there are substantial benefits realized from shared databases as well as our detailed understanding of the equipment.

## Industry Experience

Mueller has successfully provided documentation and validation assistance for large and small pharmaceutical and biotech projects including:

- Multiple-effect stills and pure steam generators.
- Seed train and production bioreactors, including controls and related process equipment.
- Process equipment for numerous buffer hold and preparation facilities consisting of as many as 40 vessels, as well as the associated controls, electrical equipment, structure, utility piping, and process piping.
- Vessels used in pharmaceutical and biotech service.



# Complete Service from Start to Finish

## Mueller Field Operations, Inc.

Mueller Field Operations, Inc., a wholly owned subsidiary of Paul Mueller Company, offers complete construction services with particular emphasis on expanded scope projects utilizing our construction management, engineering, procurement, and field integration capabilities. We provide specialized labor for on-site field erected tanks/vessels, equipment installation, vessel retrofit, vessel repair, and process piping that allows us to go beyond the capabilities of our manufacturing facility.

Mueller Field Operations, Inc. has extensive experience in providing on-site solutions in sanitary design for the food, juice, dairy, beer, wine, and pharmaceutical industries. Industrial applications, such as ASME and API code stamped equipment, are also available through our services.

In-house manufacturing of components in our state-of-the-art facility ensures that all parts such as tank heads, cylinders, manways, fittings, agitators, and heat transfer surface are fabricated correctly and coordinated to support our construction schedule in the field.

From project start to finish, we instill stringent quality control processes for design, component manufacturing, equipment transport, field installation, commissioning, final performance testing, to project completion. We also offer complete maintenance and start-up services to ensure our customer's needs are upheld.

Mueller Field Operations, Inc. is supported by Paul Mueller Company's nearly one million square foot manufacturing facilities, centrally located in Springfield, Missouri, and Osceola, Iowa. Manufactured components are delivered to the job site by Mueller's own fleet of trucks.

...We're with you from the ground up.





# Mueller Product Support Team

## Our Mission

The mission of the Mueller product support team is to meet and exceed our customers' expectations of value by setting the industry standard for exceptional service. In support of this mission, we maintain a technical staff of specialized technicians highly trained on our products, vendor software, controls, and the various trade disciplines. Our equipment is serving customers worldwide. Our factory-trained technicians are available to meet the needs of our customers and can normally be on-site within 72 hours of notification.

Paul Mueller Company makes some of the most reliable equipment in service today. However, no matter how well built a product is, continuous use without periodic inspection and maintenance may result in mechanical failure and costly downtime. When you buy Mueller equipment, you are not just buying machinery—you are investing in a partnership. We work together to assure that your equipment continues to perform at its best for years to come.



## Our Services

### Technical Support Via Phone, Fax, or Email

There is never a charge for technical support from the factory via telephone, fax, or email. Your experienced operators and our factory technicians are able to resolve most issues over the phone, which saves you time and money. Please call 888-281-5800, send a facsimile to 417-575-9662, or email us at [biopharm@paulmueller.com](mailto:biopharm@paulmueller.com).

### Replacement Parts

Each documentation package includes a list of recommended replacement parts that will minimize downtime in the event of a failure. Mueller stocks the most critical replacement parts for your equipment. Our parts specialists literally provide replacement parts to you as quickly as possible when your machine is down.

**“It has been our privilege to place the skills and techniques of Paul Mueller Company at the service of many of the nation’s leading companies. It would be a further privilege to serve your company.”**

**MUELLER**

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