

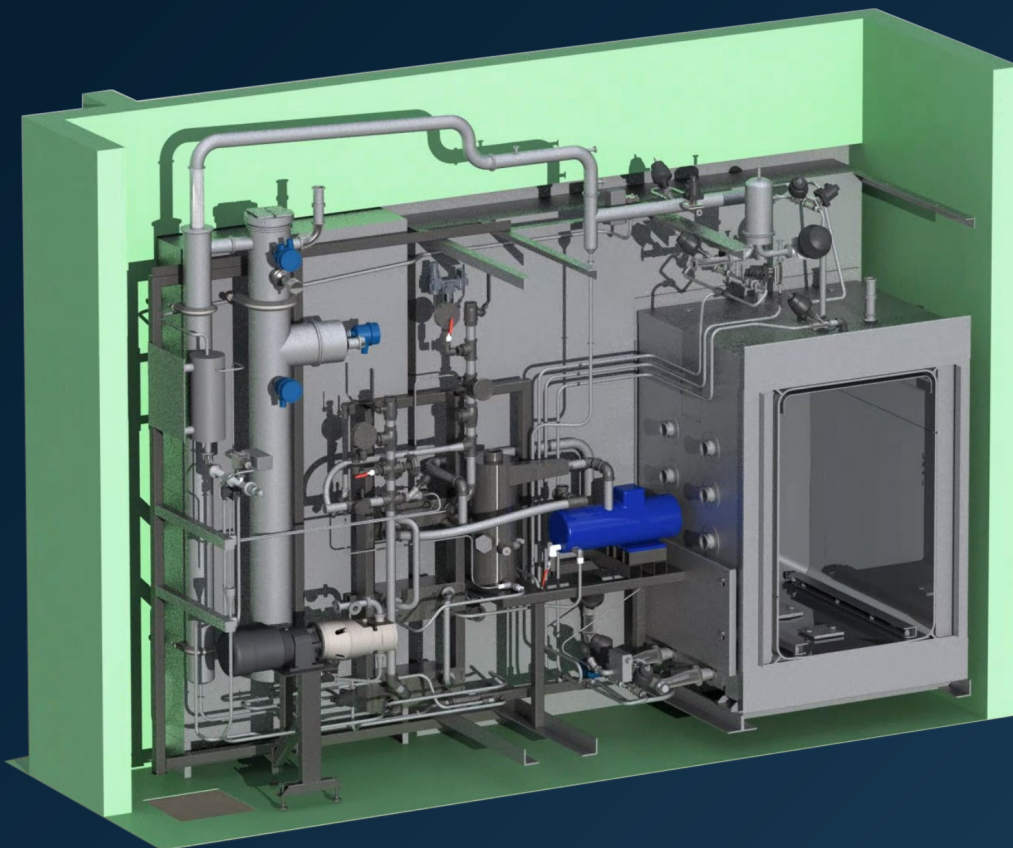


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# Beyond the Catalog

## Rethinking Sterilizer Design for Modern Pharmaceutical Production

A technical guide to custom-built, non-proprietary  
sterilization systems for pharmaceutical  
and biotech facilities



## Introduction

Sterilizers are essential to pharmaceutical research and production, ensuring product safety and regulatory compliance. As a result, reliability and readily available support are among the most important criteria for pharmaceutical facilities when evaluating equipment suppliers. Most autoclave manufacturers have structured their business around this dependency, offering catalog equipment in a limited range of fixed sizes and volumes, paired with long-term, proprietary service and spare parts contracts that keep end users solely reliant on them for support.

For pharmaceutical production facilities, this model often leads to the following constraints:

- Underutilized floor space resulting in reduced or less efficient loads
- Adapting workflows to the limitations of the equipment
- Dependency on the OEM for all spare parts and service

Custom-built, non-proprietary sterilization systems offer an alternative, allowing facilities to design equipment around their own process requirements without sacrificing performance, reliability, or access to support. This guide provides a technical overview of five key considerations in sterilizer design, construction, and long-term ownership for pharmaceutical and biotech facilities.



CHAPTER 1

# Designing the Sterilizer Around the Facility, Not the Other Way Around

Every sterilizer installation begins with two constants: the space available in the facility and the specific load that needs to be sterilized. Floor space, wall openings, drain locations, and utility connections are often determined before an equipment decision is made. The dimensions, volume, and container format of the load to be sterilized are also fixed.

With catalog sterilizers, the purchasing decision revolves around which model size and volume creates the least compromise. A chamber that is too large consumes more floor space than intended or that is available, either creating awkward gaps or forcing a costly reconfiguration of the room layout. A chamber that is too small requires facilities to run additional cycles to accommodate the same load, reducing throughput and increasing labor. Both outcomes introduce process inefficiency and extra operating costs.

Custom-built sterilizers approach the problem differently, allowing facilities to tailor the chamber dimensions, utility connections, and service access to both the space and the load. The result is a sterilizer that is configured to perfectly fit within the specified floor space or an existing pit for pit mounted units, with utilities and drain lines correctly positioned, eliminating potential installation issues and rework.

	Custom, Non-Proprietary Sterilizer	Catalog Sterilizer
Chamber Sizing	Chamber dimensions engineered to the exact volume and format of the load to be sterilized.	Fixed range of standard sizes. Facilities select the model that creates the least compromise for their load.
Facility Fit	Footprint and door configuration are designed to fit the available space or an existing pit precisely.	Standard footprint may not align with available floor space or pit dimensions, requiring room layout adjustments.
Utility & Drain Connections	Utilities and drain lines are positioned to align with existing infrastructure, eliminating installation rework.	Fixed connection points that may not align with existing utility and drain locations in the facility.
Clean/Pure Steam Source	Generator can be integrated directly into the sterilizer unit, eliminating standalone equipment, reducing overall footprint, and simplifying utility connections.	Generator typically specified as a separate standalone unit with fixed placement requirements, adding footprint and installation complexity.

## Steam Source and Integrated Generators

Like floor space and utility connections, the clean or pure steam source is another fixed facility constraint that the sterilizer design must accommodate.

Clean or pure steam is produced either by a steam-to-steam generator, which uses plant steam as a heat source to generate clean steam from purified water, or by an electric steam generator, which uses electric heating elements as the heat source.

In both cases, the generator can be specified as a standalone unit or integrated directly into the sterilizer. Each approach has practical advantages worth considering during facility planning. A standalone generator can serve as a centralized clean steam source for multiple pieces of equipment, making it the preferred choice for larger facilities running several sterilizers from a single supply. An integrated generator consolidates the steam source and the sterilizer into a single unit, simplifying installation, reducing the overall footprint, and eliminating the need for a separate piece of equipment and its associated utility connections.

When integrating the steam generator, custom-built sterilizers offer greater flexibility by allowing for custom placement and orientation to fit the available space. In installations where width and depth are constrained but vertical clearance is available, the generator can be mounted on top of the sterilizer chamber rather than beside it. Similarly, a vertically oriented generator vessel significantly reduces the mechanical space footprint compared to a horizontal design. A select few manufacturers can provide vertically oriented electric steam generators integrated directly into the sterilizer.

The right choice of steam generator type and configuration for your production will depend on your available utilities, the number of sterilizers in the facility, mechanical space, and whether a centralized or distributed steam supply better fits your facility design.

## What is Your Feedwater Quality?

The quality of water supplied to a pharmaceutical steam generator directly affects steam purity, generator longevity, and sterilizer performance. Pharmaceutical steam generators require purified feed water, typically reverse osmosis (RO) or deionized (DI) water, to ensure purity for injectable products and prevent scale buildup, mineral deposits, and corrosion inside the generator. Feed water quality should be specified, tested, and documented before commissioning and monitored routinely throughout the life of the equipment.

### Questions to Consider:

- What are the exact chamber dimensions and footprint required to fit your available floor space?
- Where are your existing utility connections and drain points located relative to the planned equipment position?
- What are the precise dimensions, volume, and container format of the load you will be sterilizing?
- Have you compared your load requirements against the published chamber dimensions of the catalog models you are evaluating?
- Have you determined your steam source, and have you evaluated whether an integrated or standalone generator best suits your facility layout?
- What compromises, if any, are you being asked to accept with the equipment currently under consideration?

CHAPTER 2

## Construction Quality Standards for Pharmaceutical Sterilizers

Sterilizer chamber construction directly affects long-term reliability, contamination control, and compliance with cGMP. Corrosion, standing water, and structural weakness under pressure can compromise sterility assurance and result in costly repairs or premature equipment replacement. Understanding key sterilizer construction quality standards helps facilities avoid making expensive mistakes.

	Best Practices	Potential Risk
Material & Weld Integrity	Uniform 316L stainless steel throughout chamber, jacket, and all contact surfaces with no dissimilar metals at any junction point	Mixed material grades or steel-to-stainless combinations that create galvanic corrosion risk under repeated heat and pressure cycling
Weld Quality	317L filler metal on 316L base material, ensuring corrosion resistance equal to or greater than the base metal at each weld point	Standard or unspecified filler metals that may create weak points at every weld joint
Surface Finish	Recommended internal chamber surface finish of 0.6 $\mu\text{m}$ (25 Ra) or better, verified and documented during manufacture	Surface finish unspecified or not documented, leaving cleanability and contamination risk unverified
Insulation	Fully insulated chamber and contact piping with covered and protected insulation	Uninsulated or exposed insulation that degrades over time and compromises temperature stability
Drainability	Pipework sloped to drain with no dead legs and sanitary fittings throughout	Pipework layout that allows standing water or moisture to collect between cycles

## Material Grade

316L stainless steel is the recognized material standard for pharmaceutical sterilizer chambers. Compared to lower grade stainless steels such as 304 or 316Ti, 316L offers superior corrosion resistance in the high-temperature, high-humidity conditions inherent to steam sterilization. Uniform 316L construction throughout the chamber, jacket, and all contact surfaces eliminates material inconsistencies that can lead to weak points and accelerate wear over time.

## Dissimilar Metals

The use of dissimilar metals in pressure vessel construction and welded joints creates conditions for accelerated corrosion and structural weakness under repeated heat and pressure cycling. Over the service life of a sterilizer, this can lead to pitting, cracking, and premature joint failure. Uniform material grade throughout the chamber, jacket, and all welded connections eliminates these risks.

## Weld Quality and Filler Selection

Weld quality is one of the most consequential and commonly overlooked variables in sterilizer construction. The filler metal used to seal chamber joints directly affects corrosion resistance at each weld point. Using a 317L filler on 316L base material ensures the weld joints maintain corrosion resistance equal to or greater than the surrounding chamber material, preventing welds from becoming the weak points in the chamber.



## Chamber Surface Finish

Internal surface finish directly affects cleanability and contamination risk. Ra is the standard unit of measure for surface roughness with higher Ra values representing coarser finishes that can create microscopic burrs in the surface where contaminants, biofilm, and residual moisture can accumulate and resist cleaning. The recommended surface finish for pharmaceutical sterilizer chambers is 25 Ra (0.6  $\mu\text{m}$ ) or better for cGMP applications.

Ra value alone does not always provide the full picture. In some cases, the finishing method matters as much as the number. A mechanically polished surface at a low Ra value can still retain microscopic grinding traces, leaving crevices where contaminants can accumulate. Electropolishing removes these crevices, producing a clean, uniform surface that is easier to clean. For demanding pharmaceutical applications, specifying both the Ra value and the finishing method ensures the surface performs as intended.

## Insulation

Proper insulation of the chamber and all contact piping helps maintain process temperature stability throughout the sterilization cycle, supporting repeatable results and reducing energy consumption. Insulation also eliminates condensation from external surfaces, which can compromise cleanroom environmental controls.

## Full Drainability and Sanitary Fittings

Standing water and trapped moisture within the chamber and piping create conditions that promote bacterial growth, undermining the sterility assurance the sterilizer is intended to provide. Proper pipework layout that is sloped to drain and does not contain dead legs prevents water from collecting, while orbital welded piping and sanitary fittings ensure connections are smooth, free of crevices, and cleanable in accordance with cGMP requirements. Sloped to drain piping and sanitary connections should always be verified in any cGMP sterilizer specification review.



## Standards and Certifications

Pharmaceutical sterilizer construction is subject to a range of applicable standards and certifications. cGMP regulations, enforced under FDA 21 CFR Part 211, establish the overarching requirements for equipment design, documentation, and validation in pharmaceutical production. The following codes and regulations are widely adopted across the pharmaceutical industry to support cGMP compliance.

ASME Boiler and Pressure Vessel Code governs the design, fabrication, and testing of pressure vessels, including sterilizer chambers. Similarly, ASME BPE governs the design and construction of piping systems, surface finishes, and material joining to ensure pharmaceutical-grade cleanliness throughout the sterilizer. UL certification covers the electrical safety of the sterilizer's control panel and associated electrical systems, ensuring the equipment meets nationally recognized safety standards for industrial electrical installations.

For pharmaceutical manufacturers supplying products to EU markets, EN 285 defines performance requirements, steam quality, and testing protocols for large steam sterilizers.

Compliance with each applicable standard should be confirmed and documented during the equipment specification and qualification process. Additionally, purchasing from an ISO 9001 certified manufacturer provides independent assurance that design controls, material traceability, and production consistency are subject to ongoing audit.

### Questions to Consider:

- What are the warranty terms on the chamber, and what does the warranty cover?
- Are material certifications for the chamber, jacket, and all contact surface components provided?
- Is the chamber and all contact piping fully insulated? If so, is the chamber insulation covered and protected?
- Are all chamber components, welds, and contact surfaces constructed from a uniform grade of stainless steel throughout, or are dissimilar metals used in any part of the construction?

## CHAPTER 3

# OEM Freedom and Non-Proprietary Parts

## The Cost of Single-Source Dependency

For many pharmaceutical facilities, purchasing an OEM-spec sterilizer is the beginning of a long-term financial commitment. Over a typical service life of 15 to 20 years, parts and service costs can equal or exceed the original equipment cost. These costs are compounded when sterilizers are assembled with all proprietary components and paired with mandatory annual service and spare parts contracts, locking facilities into fixed costs regardless of their actual service needs. Ultimately, facilities enter a procurement process with no competitive pricing, alternative sourcing, or recourse when lead times extend or prices increase. When a critical component is out of stock with the OEM, production waits.

Over a typical service life of 15 to 20 years, parts and service costs can **equal or exceed** the original equipment cost.

## Benefits of Non-Proprietary Equipment

Alternatively, sterilizers built around standard components provide facilities with the freedom to source parts and service from multiple qualified suppliers competing to earn their business based on price, availability, and service quality. Additional advantages include:

- Parts are available from multiple sources, eliminating single-source pricing and availability risk
- Lead times are competitive, reducing the risk that a parts delay causes a production stoppage
- Annual PM contracts and spare parts kits remain available from the equipment manufacturer, but are not mandatory
- Qualified in-house engineers or service providers can perform maintenance and repairs without restriction
- As components are improved and updated by manufacturers, the equipment benefits from those advancements without requiring reworks or retrofitting

## Questions to Consider

When evaluating sterilizer manufacturers, the following questions can help determine whether your post-purchase relationship with the manufacturer will be based on dependency or added value:

- Are replacement parts available from multiple suppliers, or only through you?
- Is a service and/or spare parts contract required to maintain the equipment warranty, and what are the terms?
- Can our in-house engineering team or a qualified technician service the equipment?
- What happens if a component is discontinued? Is a compatible replacement available without requiring rework or retrofitting?

## CHAPTER 4

# Open Architecture Controls: Integration, Data, and Compliance

The control system is the operational core of a pharmaceutical sterilizer. It governs every aspect of the sterilization cycle, records the data that supports regulatory compliance, and determines how well the equipment integrates with the broader facility infrastructure. The architecture of that control system, whether open or closed, has long-term implications that extend well beyond the equipment purchase.

	Open Architecture Control System	Proprietary Control System
PLC Platform	Industry-standard platforms such as Allen-Bradley or Siemens, familiar to most facility automation teams	Manufacturer-specific platform familiar only to OEM technicians
Software Access & Modifications	Control system programming accessible to qualified in-house engineers; changes can be implemented independently without OEM involvement	Control programming accessible only to OEM; all modifications and software changes require manufacturer involvement, creating lead times and associated costs
Facility Integration	Native integration with standard facility infrastructure without custom middleware	Custom interfaces required to connect with facility SCADA, BMS, and data systems
Cycle Data	Standard format data export compatible with electronic batch record systems and data historians	Data stored in proprietary formats requiring OEM software to access or export
GAMP 5	Validation documentation maintained by facility team; standard change control procedures apply	Validation documentation dependent on OEM support; limited facility control over lifecycle management

## Proprietary vs. Open Architecture

Many sterilizer manufacturers build their equipment around proprietary, closed control systems. The software is readable and modifiable only by the OEM, integration with facility-wide systems requires custom interfaces, and any programming changes or upgrades depend entirely on the manufacturer. For facilities with in-house automation expertise, this creates a frustrating and expensive dependency that mirrors the parts and service dynamic described in the previous chapter.

Open architecture control systems built on industry-standard PLCs remove these constraints entirely. Allen-Bradley CompactLogix and Siemens S7-1500 are among the most widely deployed industrial control platforms in the world. Virtually every pharmaceutical manufacturing facility has engineers with direct experience on one or both platforms. The software is transparent, readable, and modifiable by qualified in-house personnel.

## Facility Integration

Pharmaceutical facilities increasingly operate within integrated data environments connecting manufacturing equipment, building management systems, quality systems, and electronic batch record platforms. A sterilizer running a proprietary control system creates a data silo, requiring custom integration work and ongoing OEM involvement to maintain connectivity.

Open architecture PLCs using FactoryTalk or WinCC OA SCADA platforms integrate natively with facility-wide systems. Cycle data flows directly into existing data infrastructure without middleware workarounds or OEM-specific software licenses.

## Audit-Ready Cycle Data

Every sterilization cycle generates data that must be captured, stored, and retrievable for regulatory inspection. Time, temperature, pressure, and cycle parameters must be accurately recorded and protected against unauthorized modification.

Open architecture control systems generate complete cycle records in standard formats that integrate directly with electronic batch record systems and data historians. There are no proprietary data formats requiring OEM tools to read or export. The data belongs to the facility and is accessible on the facility's terms.

For facilities subject to FDA 21 CFR Part 11 and EU GMP Annex 11, which govern electronic records and electronic signatures in pharmaceutical manufacturing, open architecture controls simplify compliance significantly. Audit trails are generated natively, access controls are configurable by facility IT teams, and data integrity requirements are met without dependency on OEM software support.

## GAMP 5 and Service Considerations

GAMP 5, the Good Automated Manufacturing Practice guideline published by ISPE, is the industry framework for validating pharmaceutical control systems, including sterilizer PLCs. To achieve and maintain GAMP 5 compliance, PLC software must be fully documented, traceable, and maintainable by qualified personnel throughout its operational lifecycle. As process requirements evolve, facilities also need the ability to modify cycle parameters, add new recipes, and integrate new monitoring capabilities while maintaining GAMP 5 compliance and the system's validated state.

The architecture of the control system plays a critical role in how easily both can be achieved. Open architecture systems built on standard PLCs satisfy both, as validation documentation can be developed and maintained by in-house teams and software modifications can be performed independently following regulated change control procedures. Locked-down proprietary systems require OEM support for either, creating lead times, costs, and scheduling dependencies that may stall production.



## Questions to Consider

- What PLC platform does the control system use?
- Is the control system programming accessible to qualified facility engineers, or is access restricted to the OEM?
- Does the system integrate natively with our facility SCADA, BMS, and electronic batch record systems?
- How is cycle data exported, and in what format? Can it be accessed without proprietary software?

## CHAPTER 5

# Selecting the Right Sterilization Process for Your Application

The right sterilization process is determined by the load being sterilized and the container it is packaged in. Utilizing the right process ensures complete decontamination to support product safety, prevents damaging the product packaging or container, and optimizes production efficiency by matching cycle time requirements to throughput targets. There are four primary sterilization processes used in pharmaceutical and biotech production:

### Pre-Vacuum Steam Sterilization

The standard method for porous and dry goods, including wrapped materials, filters, linens, rubber stoppers, and filling line components. Alternating vacuum and steam pulses ensure thorough steam penetration throughout the load, followed by a rapid drying phase that leaves goods dry and ready for immediate use. Not suitable for sealed liquid containers, as the vacuum cycle creates pressure differentials that can compromise container integrity.

### Gravity Air Removal

Used for glassware, instruments, waste, and liquids in open or vented containers. Steam displaces air from the chamber by gravity, providing effective sterilization without the mechanical stress of vacuum cycling and protecting container integrity throughout the process.

### Steam-Air Mixture

Used for terminal sterilization of vials, ampoules, and syringes in sealed containers that are heat or pressure sensitive. Internal fans circulate the steam-air mixture for uniform temperature distribution while overpressure control protects sensitive containers from deformation or rupture. The load exits dry and ready for labeling, making steam-air mixture the preferred method where downstream labeling or packaging follows immediately after sterilization. Cycle times are typically longer than hot water cascade.

### Hot Water Cascade

Designed for rapid terminal sterilization of large volume liquids in sealed containers, including IV bags, large volume parenterals, and flexible plastic pouches. Purified water is heated via an external heat exchanger and distributed evenly over the load, with compressed air injected simultaneously to counterbalance rising pressure and protect container integrity. Due to the efficient heat transfer properties of water, the heating and cooling phases are significantly faster than the steam-air mixture process, making hot water cascade the preferred method for high-throughput production. Unlike steam-air mixture, the load exits the chamber wet, and downstream drying and handling workflows should be planned accordingly before product proceeds to labeling or packaging.

## Combination Systems

For contract manufacturers managing diverse products and load types, a combination sterilizer capable of performing all sterilization methods within a single unit provides a significant operational advantage. Rather than maintaining separate equipment for each sterilization method, a combination system applies the right process for any given product or container without additional capital investment. As client requirements evolve, the system adapts without modification.

Load Type	Recommended Process
Porous and dry goods – wrapped materials, filters, linens, rubber stoppers, filling line components.	Pre-Vacuum Steam Sterilization
Glassware, instruments, waste, liquids in open or vented containers.	Gravity-Air Removal Steam Sterilization
Vials, ampoules, syringes in sealed containers that are heat or pressure sensitive.	Steam-Air Mixture
IV bags, large volume parenterals, flexible plastic pouches.	Hot Water Cascade
Facilities processing multiple product types or container formats.	Combination System



## Questions to Consider

- What is the primary load type and container format you will be sterilizing?
- Are your containers sealed or open, and are they heat or pressure sensitive?
- What are your throughput targets, and do your chamber capacity and cycle time requirements support them?
- If you manage multiple product types or container formats, have you evaluated whether a combination system would eliminate the need for separate equipment?



Please [contact BMT USA](#) to speak with a sterilization engineer about your facility requirements.

[sales@bmtusa.com](mailto:sales@bmtusa.com) // [www.bmtusa.com](http://www.bmtusa.com)

BMT USA | Monroe, WA | [bmtusa.com](http://bmtusa.com)

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