GETINGE GROUP

# GEW cGMP washer/dryer
# Cleaning for production

# Complete **sterile processing** systems.

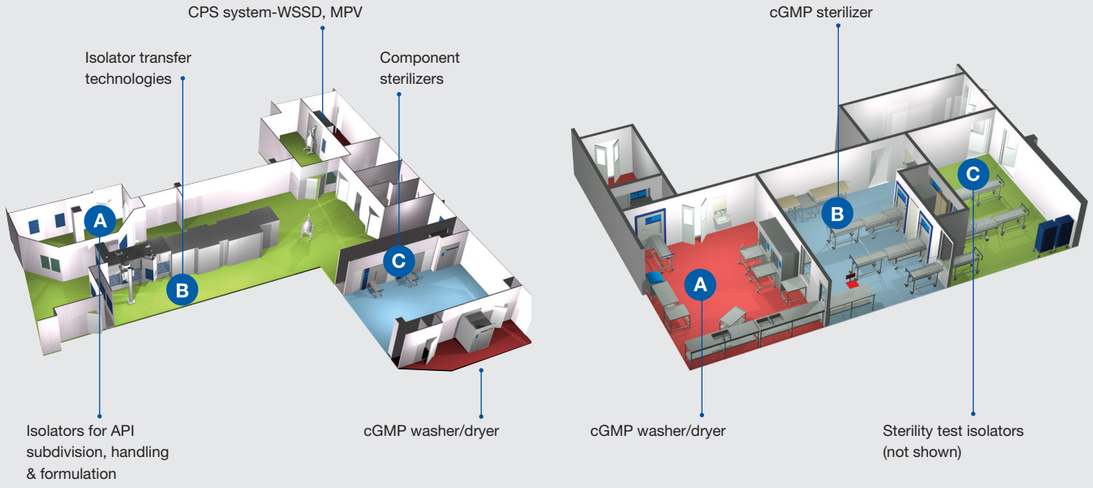
Getinge develops, manufactures and supplies completely integrated cleaning and sterilization systems for use within the BioPharmaceutical Industry. Two typical installation examples for applications in BioPharmaceutical production and quality assurance laboratories are shown below.

## Pharmaceutical Production

**A:** Formulation suite
**B:** Aseptic suite/filling area
**C:** Equipment/component preparation

## QA/QC Laboratory

**A:** Reception area
**B:** Preparation area
**C:** QA test area (clean area)




# Designed with the **application** in mind.

Getinge GEW washer/dryers have been designed “from the ground up” to meet the needs of the BioPharma Industry. Working in cooperation with users and engineers, our equipment has been developed to satisfy the unique demands and stringent regulations of the industry. The GEW Series of cGMP washer/dryers constitute the most comprehensive range on the market today.

## Versatility of GEW cGMP washers

The GEW Series washer/dryers are suitable for many common applications within BioPharma production, and are equipped with appropriate features and options for demanding processes within production and QA/QC laboratory environments. Full traceability (ASME BPE) and documentation packages are included.

**GEW P Series Washers** are configured to meet the most demanding requirements for pharmaceutical manufacturing. This series, together with purpose-designed inventory systems, provides critical cleaning of equipment, parts and components.

**GEW 888** For cleaning glassware and various parts in the biotech manufacturing and quality control areas. Automatic vertical sliding door for better ergonomics and space saving. Highly sanitary construction and two independent wash levels.

**Chamber capacity:** 500 L (132 gal)
**Internal dimensions:** 805 x 770 x 805 mm (31.8" x 30.4" x 31.8")

**GEW 9109** Multipurpose washer for cleaning glassware, filling lines and equipment parts in the BioPharmaceutical manufacturing area and quality assurance/quality control laboratory. Single or double door models. Horizontal sliding door and ultra-low water consumption.

**Chamber capacity:** 800 L (211.3 gal)
**Internal dimensions:** 900 x 1000 x 900 mm (35.5" x 39.4" x 35.5")

**GEW 101210 & GEW 131313** For cleaning of IBCs, carboys, equipment parts in the BioPharmaceutical manufacturing area and bulk chemical/API production. Single or double door models. Vertical hinged for space saving in cleanroom.

**Chamber capacity:** GEW 101210: 1250 L (330.2 gal)
GEW 131313: 2200 L (581.2 gal)
**Internal dimensions:** GEW 101210: 1005 x 1200 x 1005 mm (40" x 47" x 40")
GEW 131313: 1300 x 1300 x 1300 mm (51" x 51" x 51")

**GEW 131820** For cleaning of IBCs, vessels, carboys, machine parts in the BioPharmaceutical manufacturing area and bulk chemical/API production. Single or double door models. Sliding door for ergonomic operation.

**Chamber capacity:** 4700 L (1241.6 gal)
**Internal dimensions:** 1300 x 1800 x 2000 mm (51" x 71" x 79")

# **Experience** to rely on.


Getinge has a unique capability to provide you with complete sterile process systems. The earlier we are involved in the planning process for your new or replacement system, the more cost-effective solutions we can deliver.

Our knowledge and application expertise are drawn from over 100 years of dedication to cleaning and sterilization equipment within Healthcare and the Life Sciences.

**From Concept to Compliance.** We can support you with initial advice, system design, extensive ranges of washer/dryers and sterilizers, closure processing systems, barrier isolation technology, installation, validation, support and maintenance. Dealing with just one competent company saves you time, effort and money. Getinge can satisfy all your sterile processing needs – from concept to compliance.

**Optimal Lifecycle Economy.** Our systems are based on compatible modular units that can quickly be integrated and installed to form complete customized solutions based solely on your needs. The high quality and performance that have made Getinge the world leader in cleaning and sterilization systems ensure optimal lifecycle economy.

Because Getinge is a worldwide company, we have the resources to meet your service, maintenance and other support needs wherever you are. Our Getinge Academy offers thorough training to assure the proper and efficient handling of equipment for sterile processing. You are in safe hands with Getinge.



# Safeguarding **your investment.**

A production system represents a major capital investment in your future revenue stream. Getinge works hard to ensure that our GEW washer/dryers provide true value in design, performance, reliability and lifecycle economy.

**State-of-the-art Production.** Getinge continually invests in state-of-the-art factories, production equipment and process development for one reason – to ensure that we can continue to provide our clients with the best equipment available. We offer true value for money. This is reflected in our impressive client base as the world's leading BioPharmaceutical companies rely on Getinge.

**Satisfying your Needs.** GEW Series washer/dryers are the result of practical experience and are designed to handle the toughest applications. We know that most applications are unique, so we offer custom designed racks and load handling systems, as well as an extensive choice of standard accessories for common applications. Single door and double door models are available to suit your building layout and workflow.

**Ergonomic Design.** Our load handling systems are developed for user-friendliness. Hinged and sliding doors provide easy and safe access during loading and unloading, while a range of trolleys and other accessories enable easy transportation of racks and articles to and from the work area.

**Wide selection of Chamber Configurations.** The Getinge GEW Series consists of a range of chamber sizes that offer optimal handling of common loads. Five standard models, with a wide variety of options allows us to provide a custom configured washer/dryer to meet specific needs.

**Regulatory Issues.** Getinge actively participates in the groups and committees that establish and update industry practices, guidelines and regulatory requirements. All of our washer/dryers are manufactured in accordance with guidelines or standards relating to the intended application and the country of installation.

**Protecting the Environment.** The Getinge GEW washer/dryers combine unsurpassed chamber volume with a small environmental footprint. They operate on remarkably low water volumes and as a result, detergent dosage and energy consumption are minimized without compromising cleaning efficiency.

**GAMP 5 • EU & US cGMP • ASME BPE Standard • ISPE'S Baseline® Guides • ISO 9001 & 14001 • 21 CFR Part 11**

# A **comprehensive** range.

**GEW 888** The compact washer is the ideal solution for small premises dealing with space constraints. Its vertical sliding down door enhances ergonomics and compactness. From 50 liter Nalgene bottles to vials and small glassware items, this washer has been designed to provide you with flexibility and increased throughput thanks to its two independent wash levels.

The GEW 888 can be fitted with a cross contamination barrier (CCB) (option) and service access can be provided from the front or side depending on the wash room configuration. Reduced water consumption, only 40 liters per fill, makes for an outstandingly low environmental impact.

**GEW 9109** The GEW 9109 is an ideal washer for multipurpose applications. Its 810 liter chamber allows for washing on two levels with ultra-low water consumption. In addition to low cycle costs and high productivity, the automatic sliding doors allow for good ergonomics.

A CCB (option) physically helps separate the loading from the unloading side, a needed feature in today's BioPharmaceutical manufacturing area. As with all Getinge cGMP washers, it is provided with a full traceability and validation package.

**GEW 101210 & GEW 131313** The medium sized GEW 101210 and GEW 131313 washers are designed primarily for the manufacturing area. The base model of each includes many standard features necessary for GMP compliance. A wide range of optional features are also available to make models adaptable to a variety of applications.

The chambers are equipped with one or two vertical hinged glass doors for single ended use or pass-through operation. The hinged door optimizes space and minimizes footprint. The loading height is 710 mm (28"). A variety of standard racks and an ergonomic transport trolley are available for common applications. Custom racks can also be designed and provided.


**GEW 131820** The GEW 131820 is the largest washer in the series. It is designed for pit mounting in a 320 mm (12.6") deep pit, allowing direct floor loading of large, heavy or bulky items. Where pit mounting is not possible, the machine may be floor mounted with a loading height of just 320 mm (12.6").
This unit is intended for BioPharmaceutical manufacturing operations, including cleaning of bulk chemical containers, vessels and machine parts. Racks are designed according to the application, based on our extensive experience.



# Features and support to satisfy **your processing needs and global plans.**

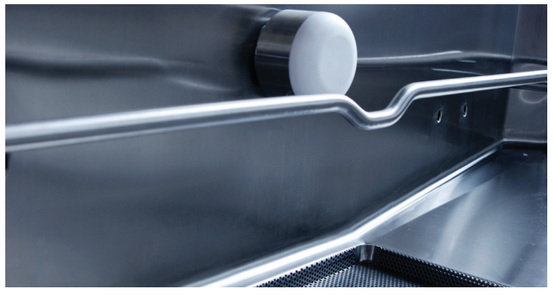
**The Getinge GEW Series Pedigree.** The GEW cGMP washer/dryers have been developed using the knowledge and experience gained over many years. These industry leading washers are manufactured in Getinge's Center of Excellence for Life Science washers: the Getinge Lancer factory in Toulouse, France. This factory has been a part of the Getinge Group since the inception of parametrically controlled cleaning for the BioPharmaceutical industry in the early 1990's.

Formerly known as the Getinge-Lancer "PCM" range, the features of these washer/dryers have been fine-tuned using a process of technological development coupled with the experience of working with a very wide variety of applications on behalf of our clients from the pharmaceutical, biotechnology and the cosmetics industries.

Today, the Getinge-Lancer factory is equipped with the latest technology and fabrication equipment for design and assembly of these washer/dryers. The equipment is distributed and supported through the Getinge organization, which comprises more than 32 Getinge sales companies serving all major markets, and more than 70 authorized distributors. We can provide truly global service to support you wherever you choose to manufacture.

**Key Features**

- Hinged and sliding glass door(s)
  -Designed to optimize installation footprint
  -Heat and noise insulated glass allows for visual monitoring of cleaning process
- Single or double door models
- Cross Contamination Barrier (CCB) to prevent clean area from contamination and excessive air transfer
- Fully drainable, sanitary design
  -Maximized use of orbital welding
  -Chamber and piping slopes >2%
- ASME BPE compliant design
- HEPA filtered dual path drying system
  -Independent channels for chamber and load
- Lowest utility and water consumption on the market
  -Most powerful recirculation pumps versus competitors for cleaning efficacy
- Selection of automation systems
  -Rockwell – Allen Bradley (Compact Logix as standard)
  -Siemens – (Simatic S7 platform)
- GAMP 5 compliant documentation and programming
- Highest level of parametrically controlled cleaning to meet the demands of the BioPharmaceutical industry



# Intelligent **function and design.**


**1.** Efficient drying

Two separate drying systems (one for the chamber and one for the process path and racks) provide once-through HEPA filtered air for maximum drying efficiency. Ceramic heating elements (steam heating is an option) allow variable drying temperature control for different materials. All components are upstream of the final HEPA filters. Air is exhausted to a vent connection on the washer.

**2.** Filter monitoring

DOP ports and differential pressure transmitters are standard features, providing essential routine monitoring capability of the HEPA filters. Magnhelics® differential pressure gauges are available for visual verification of filter loading.

Siemens interface

**3.** Fully automated

The Getinge GEW washer/dryer is equipped with a GAMP 5 compliant, 21 CFR Part 11 capable, state-of-the-art modular PLC system. Getinge offers a selection of Allen Bradley or Siemens platforms, all with equal functionality and documentation.

**4.** Robust and sanitary construction

Sanitary main recirculation pump with vertical outlet. Sloped (min 2%) design, and smooth (Ra < 0.6 mm/25 mm), crevice-free construction of chamber, piping and racks eliminates water retention and sites for biofilm or corrosion. 316L stainless steel is used throughout, with EPDM, PTFE or other FDA (21 CFR part 177) and USP class VI approved gaskets. Globally available components, e.g. GEMU process valves, are standard. Orbital welding is used wherever possible and extensive documentation is provided.

**5.** Washing configurations

Integral chamber spray system with wash rack interface provides multi-level washing that optimizes load configuration and minimizes processing time. Water is heated using a sanitary steam-water heat exchanger in the sump of the chamber (electrical heating is optional) for efficient and effective heating.

**6.** Installation

All models are provided with brush finish stainless steel fascia panels for recessed installation, with additional side panels to form a cabinet as an option. Single or dual cross contamination barriers to maintain clean area classification and facilitate room air balancing. (Available on larger models.)

**7.** Chemical addition

The washer can be fitted with up to five peristaltic dosing pumps (according to application) for cleaning and neutralization agents to aid the mechanical cleaning process. Sanitary dosing valves are uniquely welded directly to the chamber wall to ensure proper rinsing. Pump pressure is monitored and a conductivity sensor is available to confirm proper additive dosing.

**8.** Final rinse with WFI

The sump is filled with water for injection (WFI) and recirculated throughout the hydraulic circuit to provide a single fluid path design ensuring complete rinsing of the entire system. The process continues for a time interval (determined by conductivity and/or total organic carbon (TOC) during process development studies).

Conductivity and/or online TOC monitors are available to confirm that all cleaning agents and soil have been removed. This process minimizes WFI consumption and provides a validatable, repeatable result.

**9.** Single pass final rinse

To meet specific process requirements, Getinge offers a Single Pass Final Rinse (SPFR) system which can be programmed as a part of the total validated cycle. During SPFR, components are not exposed to recirculated water. The SPFR cycle can be user-programmed and repeated in accordance with process requirements. Rinse water conductivity is monitored by the control system. If the conductivity goes out of range, a fault code is activated.

**10.** Door configurations

Each model is available in single door or double door configuration. Doors are equipped with interlocks to prevent opening during washer operation and simultaneous opening of the dual door units.

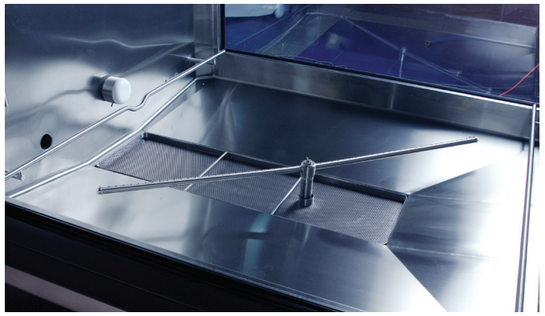
| Model | Configuration<br>doors | Overall Dimensions<br>W x H x D |
|---|---|---|
| GEW 888-1<br>GEW 888-2 | single<br>double | 2000 x 2170 x 1076 mm (78.7" x 85.4" x 42.4")<br>2000 x 2170 x 1170 mm (78.7" x 85.4" x 46.1") |
| GEW 9109-1<br>GEW 9109-2 | single<br>double | 2350 x 2233 x 1185 mm (92.5" x 87.9" x 46.6")<br>2350 x 2233 x 1320 mm (92.5" x 87.9" x 52") |
| GEW 101210-1<br>GEW 101210-2 | single<br>double | 2189 x 2485 x 1345 (1185*) mm (86.2" x 97.8" x 53" (46.6"*))<br>2189 x 2485 x 1345 (1185*) mm (86.2" x 97.8" x 53" (46.6"*)) |
| GEW 131313-1<br>GEW 131313-2 | single<br>double | 2439 x 2603 x 1947 (1482*) mm (96" x 102.5" x 76.6" (58.3"*))<br>2439 x 2603 x 1947 (1482*) mm (96" x 102.5" x 76.6" (58.3"*)) |
| GEW 131820-1<br>GEW 131820-2 | single<br>double | 3250 x 2850 x 2300 mm (128" x 112" x 90")<br>3250 x 2850 x 2600 mm (128" x 112" x 102") |

** With trolley brackets removed.*

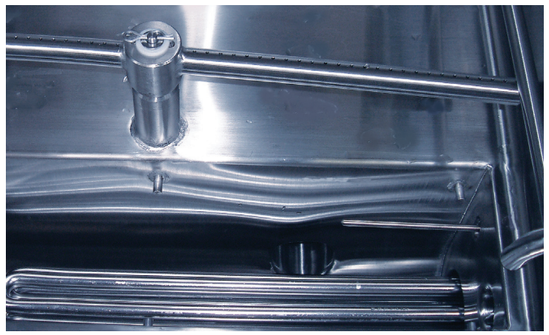
| Model | Configuration<br>doors | Overall Dimensions with SPFR Option<br>W x H x D |
|---|---|---|
| GEW 888-1<br>GEW 888-2 | single<br>double | 2364 x 2686 x 1125 mm (93.1" x 105.7" x 44.3")<br>2364 x 2686 x 1170 mm (93.1" x 105.7" x 46.1") |
| GEW 9109-1<br>GEW 9109-2 | single<br>double | 2593 x 2495 x 1260 mm (102.1" x 98.2" x 49.6")<br>2593 x 2495 x 1320 mm (102.1" x 98.2" x 52") |
| GEW 101210-1<br>GEW 101210-2 | single<br>double | 2350 x 2485 x 1345 (1185*) mm (92.5" x 97.8" x 53" (46.6"*))<br>2350 x 2485 x 1345 (1185*) mm (92.5" x 97.8" x 53" (46.6"*)) |
| GEW 131313-1<br>GEW 131313-2 | single<br>double | 2678 x 2603 x 1947 (1482*) mm (105.4" x 102.5" x 76.6" (58.3"*))<br>2678 x 2603 x 1947 (1482*) mm (105.4" x 102.5" x 76.6" (58.3"*)) |
| GEW 131820-1<br>GEW 131820-2 | single<br>double | –<br>– |

** With trolley brackets removed.*

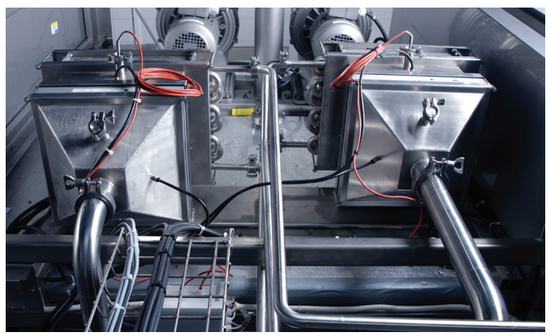
Sanitary spray systems in the chamber in combination with injection outlets on racks ensure complete and uniform coverage of both internal and external surfaces of processed items. Optional detection sensors for spray arms ensure proper rotation and confirm correct operation.



Chambers are made of 316L stainless steel and fully welded (no crevices). All welds are polished and passivated. All models feature rounded corners (>12 mm radius) with minimum slopes (min 2%) to ensure complete drainage. Chamber fixtures are sanitary and all non-stainless steel materials are FDA approved and USP Class VI.



A sanitary steam heating coil in the sump rapidly heats circulating water and controls the temperature with accuracy. If steam is not available, electrical heaters may be provided at the same location.



Exclusive twin channel drying system. Each channel includes a high capacity blower powered by a brushless motor, a heating system (electrically heated ceramic element as standard, steam heating as option) and a HEPA filter (in that sequence). One channel is used to dry the chamber and external surfaces of the load while the other ensures fast drying of the hydraulic circuit, rack and internal surfaces of the load.


Getinge washer-dryers equipped with SPFR use a two-way, two-valve system to control rinse water delivered to the chamber during the phase. When the recirculation valve is closed, rinse water enters the chamber and pours over the load. The water does not recirculate through the system. This ensures that only the single pass final rinse water is in contact with washed components.



# GEW P series **features and options.**

● / ○ Standard / Optional Features

### Chamber

| | |
|---|---|
| 316L stainless steel construction/FDA (USP class VI) approved elastomeric seals / Ra < 0.6 µm (< 24 µin) surface finish or better. Radius-corner chamber (>12 mm (½") and fully drainable hydraulic circuit | ● |
| Chamber welds ground flushed | ● |
| Chamber welds polished | ● |
| Chamber light for load viewing/verification of water distribution | ○ |

### Door

| | |
|---|---|
| Glass door for load viewing, double pane insulated safety glass for verification of water distribution | ● |

### Process Piping and Valves

| | |
|---|---|
| Fully drainable hydraulic circuit | ● |
| Orbitally welded, chamber piping slope > 2% | ● |
| Forged sanitary diaphragm valves | ● |
| ASME BPE 2009 compliant | ● |

### Pump

| | |
|---|---|
| Sanitary recirculation pump | ● |
| Recirculation pump pressure monitoring with vertical pump outlet | ● |

### Water Inlets

| | |
|---|---|
| Quantity of water inlets<br>**If the SPFR option is chosen, one additional water inlet will be required.* | 1 |
| Additional water inlets (up to 3 total) | ○ |
| Water distribution loop piloting | ○ |

### Chemical Dosing Systems

| | |
|---|---|
| Quantity of dosing pump | 1 |
| Additional dosing pump (up to 5 total) | ○ |
| Chemical pump pressure monitoring | ● |
| Conductivity monitoring-final rinse phase | ● |
| Conductivity monitoring-final rinse phase and wash phase | ○ |

### Automation System

| | |
|---|---|
| Allen Bradley/Siemens PLC | ○ |
| Thermal printer | ● |
| A4 printer (for Siemens) | ○ |

### Installation

| | |
|---|---|
| Side (GEW 888, GEW 9109, GEW 101210, GEW 131313 and GEW 131820) access for easy maintenance | ● |
| Single (GEW 888 and GEW 9109) or dual cross contamination barrier (GEW 101210, GEW 131313 and GEW 131820) | ○ |
| Flush brush finish stainless steel front panels/easy cleaning/washdown capable | ● |

### Documentation

| | |
|---|---|
| GAMP 5 compliant validation support for documentation package and comprehensive manuals | ● |
| Weld numbering, weld mapping and weld boroscopic report | ● |
| Full material traceability (3.1 certificates) | ● |

### Testing and Qualification

| | |
|---|---|
| Prequalification in factory | ○ |

### Accessories

| | |
|---|---|
| Range of customized and standard modular racks (basic rack, jet rack) | ○ |
| Custom made racks - e.g. glassware, filling line, hoses, IBCs, carboys | ○ |
| Transfer trolleys for racks | ○ |

### Rinse

| | |
|---|---|
| Single Pass Final Rinse System | ○ |

# Inventory systems:
# **efficiency, ergonomy, efficacy.**

Smooth, uninterrupted production requires that the right tools and equipment are available and ready for use when you need them. Equally important is the ability to move heavy or awkward articles where they are needed, safely and efficiently.

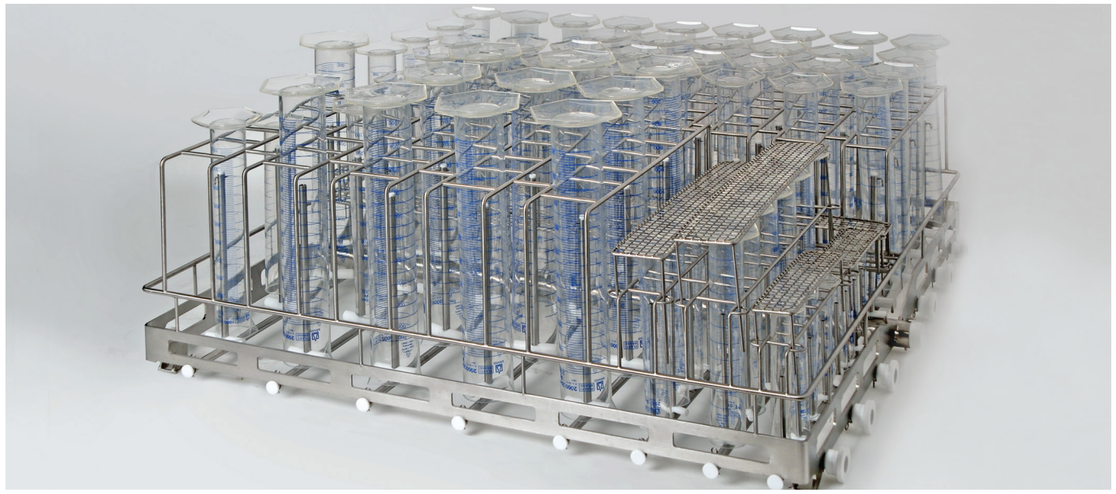
Getinge's inventory management and handling accessories are specifically designed to meet these needs. Working in cooperation with our customers, and manufacturers of production equipment when necessary, we optimize washer/dryer accessories to assure a safe, ergonomic system that keeps you up and running.

Equally important to production efficiency is cleanliness: elimination of the possibility of cross contamination with residues or dirt from previous use. Getinge uses CAD systems with 3D modeling to ensure that every corner and cavity of the article being processed is thoroughly washed. After washing, the same injection porting is used to convey hot sterile filtered air inside for drying.

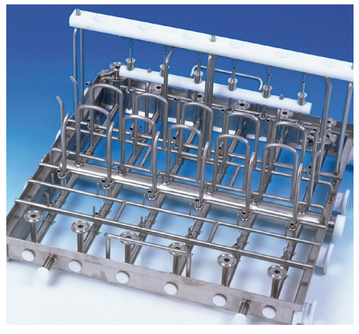
The following pictures show examples of the many customized systems Getinge has supplied. A wide variety of standard racks are available for the more common applications.

Valve bodies, mounted on a customized manifold fitted to an otherwise standard rack, ensure 100% coverage of all product contact parts, as well as the exterior surfaces.

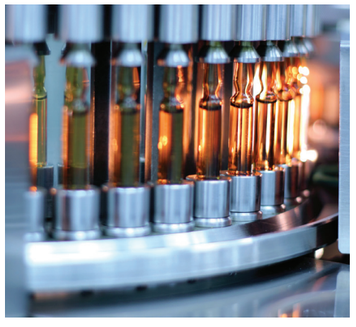




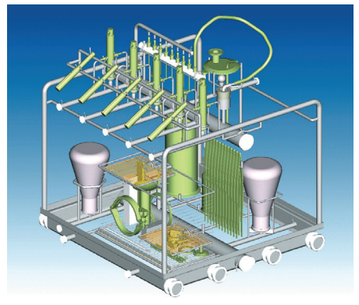
Glassware racks can be provided with a variety of holders and nozzles to ensure optimal cleaning without risk of damage.



Injection rack; designed and fabricated using a wealth of experience.



Machine parts are frequently sent to Getinge for modelling/rack design.



3D CAD modeling is used to design tailor-made racks for different applications, usually in cooperation with the user or equipment supplier.

Injection nozzles, designed for effective cleaning and drying, may be disassembled for cleaning and maintenance.

Loading trolleys can be provided to efficiently move materials to and from washer/dryers.

Special rack/basket for cleaning and drying silicon and metal tubing together with their tri-clamp fittings.

# Inspection, testing and documentation.


Every GEW washer/dryer undergoes rigorous factory acceptance testing in a dedicated test bay with facilities to support our clients during the inspection and testing of their equipment.

## As a general principle, Getinge follows ISPE's Baseline® and GAMP 5 Guides in respect to project execution and documentation to support our clients' qualification of sterile process equipment.

Quality is inherent to every Getinge product. From the design specification, through component selection, fabrication, assembly and factory testing, every aspect of the manufacturing process is examined and documented to ensure and prove that the product is designed, built and tested according to the customer specifications and performance requirements. Our objective is to demonstrate and document that we adhere to a cohesive quality control program in accordance with Good Engineering Practice.

**Comprehensive Validation Support Documentation.**
During the manufacturing process, in-process checking is performed to ensure compliance with specifications; documentation is maintained as confirmation.
After manufacturing, every unit undergoes comprehensive and rigorous Factory Acceptance Testing (FAT), again accompanied by detailed documentation. A complete package comprising these, together with installation, user and technical manuals, is provided with the equipment. These documents are intended to support your subsequent qualification procedures, thus saving considerable time, effort and expense on site.

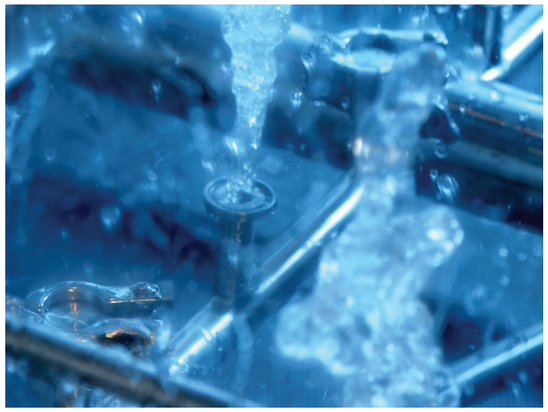
We can also provide a "Pre-Qualification" of the system upon request, carrying out the same test procedures as defined in the IQ/OQ protocols, which will later be performed on site as part of the validation exercise. This exhaustive procedure identifies any minor issues with equipment and documentation and ensures a trouble free startup and site acceptance testing later on.

Deliverable documentation packages include:
- Submittals (design documentation)
- Construction
- Automation
- Testing and qualification
- Installation manual
- User manual
- Technical manual



# Control systems.

## Reproducibility and reliability of process control is crucial in life science applications.



To achieve this and minimize human error, Getinge supplies PLC based automation systems designed for the challenging environments typically found in life science applications.

Getinge offers a choice of hardware platforms, each with the same fundamental equipment functionality and programming methodology.
- Rockwell – Allen Bradley (Logix platform)
- Siemens – Simatic (S7 Based platform)

All systems accurately handle tasks such as parameter setting, recipe handling, sequence control, and data processing, presentation and storage.
TOC monitoring option is also available on every Getinge GMP washer. With this option, you will be able to self-run controls on level of endotoxines and microbes at the end of your cycle – a key element to track the efficiency of your cleaning process. The TOC option saves time and money by providing direct results of your cleaning process, no need to wait for external results – reactivity improved.

**Versatile Features.** The features included in our automation systems are:
User friendly interface
- Extensive documentation
- Remaining cycle-time indicator
- Automatic sensor calibration
- Comprehensive alarms/alerts
- Process and alarm logging
- Multi-level password protection

**Regulatory Compliance.** Getinge's automation systems are developed according to stringent GAMP 5 (Good Automated Manufacturing Practice) guidelines of the Pharmaceutical industry, and are FDA 21 CFR part 11 capable. Every system is supported with comprehensive documentation.


The Allen-Bradley control system incorporates an intuitive touchscreen interface that provides reports, control options and real-time system monitoring.

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GETINGE GROUP

Getinge Group is a leading global provider of innovative solutions for operating rooms, intensive-care units, hospital wards, sterilization departments, elderly care and for life science companies and institutions. With a genuine passion for life we build quality and safety into every system. Our unique value proposition mirrors the continuum of care, enhancing efficiency throughout the clinical pathway. Based on our first-hand experience and close partnerships, we are able to exceed expectations from customers – improving the every-day life for people, today and tomorrow.

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