

GETINGE

GETINGE GEW WASHER/DRYERS
SECURING CRITICAL CLEANING IN
THE MANUFACTURING ENVIRONMENT

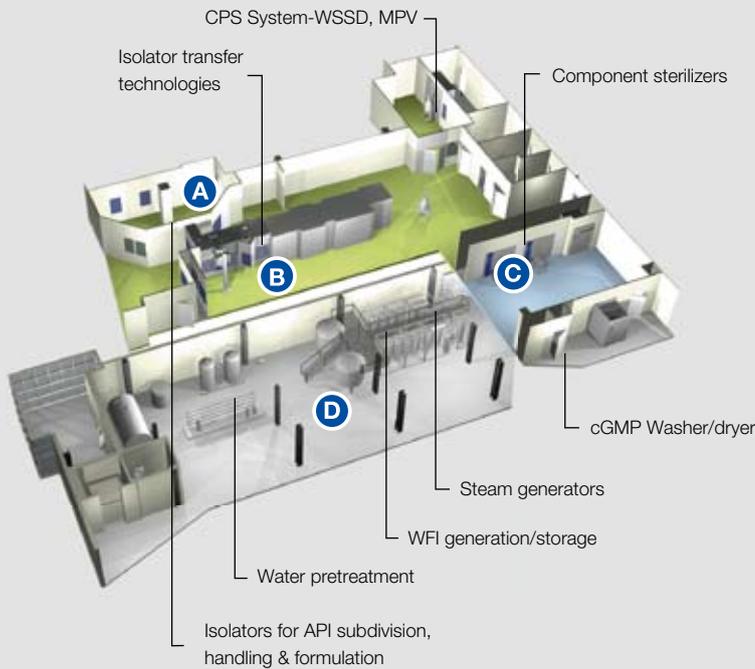


COMPLETE STERILE PROCESSING SYSTEMS

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

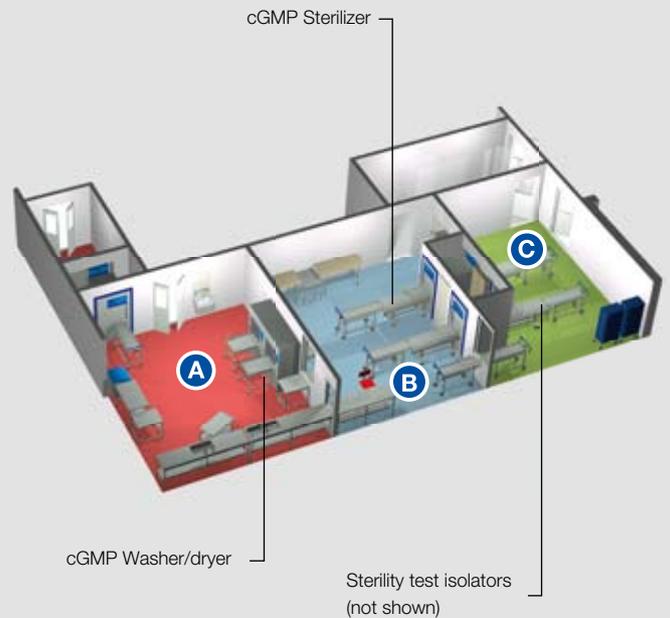
PHARMACEUTICAL PRODUCTION

- A:** Formulation suite
- B:** Aseptic suite/ Filling area
- C:** Equipment/component preparation
- D:** Utility area



QA/QC LABORATORY

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



PURPOSE DESIGNED FOR THE APPLICATION

Getinge GEW washer/dryers have been designed “from the ground up” to meet the needs of the Bio-Pharmaceutical 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 constitutes the most comprehensive range on the market today.

The versatility of GEW cGMP washer/dryers

The GEW Series washer/dryers are suitable for many common applications within Bio-Pharmaceutical production, and are equipped with appropriate features, options and processes for demanding applications within production and the QA-QC Laboratory environments.

GEW 666

For cleaning of glassware, equipment parts in the Bio-Pharmaceutical manufacturing area and Quality assurance / Quality control laboratory. Single or double door models. Vertical, sliding door for ergonomic operation.

Chamber capacity: 0.3 m³ (10 ft³).
Internal dimensions:
660 x 660 x 660mm (26 x 26 x 26")



GEW 131313

For cleaning of IBC's, carboys, equipment parts in the Bio-Pharmaceutical manufacturing area and bulk chemical / API production. Single or double door models.

Vertical, hinged for ergonomic operation.
Chamber capacity: 2.2 m³ (78 ft³).
Internal dimensions:
1300 x 1300 x 1300mm (51 x 51 x 51")



GEW 131820

For cleaning of IBC's, vessels, carboys, machine parts in the Bio-Pharmaceutical manufacturing area and bulk chemical / API production. Single or double door models. Sliding door for ergonomic operation. Chamber capacity: 4.7 m³ (165 ft³). Internal dimensions: 1300 x 1800 x 2000mm (51 x 71 x 79")



Four configurations are available for specified applications, with a range of configurable options:

PHARMACEUTICAL: GEW P Series

Configured to meet the demanding requirements for pharmaceutical manufacturing. This model, together with purpose-designed inventory systems, is designed for critical cleaning of equipment, parts and components.

BIOTECH: GEW B Series

Biotech industry requirements differ from pharmaceutical applications in terms of types of cleaning requirements and technical specifications. The GEW B is based on the same platform as the GEW P but is configured to meet the process (and budgetary) needs of Biotech users.

LABORATORY: GEW L Series

In the laboratory sector, the focus is on efficient cleaning of glassware and utensils. For QA work, this must be repeatable and validatable to an extremely high level while considering budgetary requirements.

COSMETICS: GEW C Series

Applications in the cosmetics industry increasingly requiring cGMP cleaning for their process equipment. A robust machine with flexible chemical control is required to remove these hard to clean soils.



EXPERIENCE TO RELY ON

Getinge is uniquely capable of offering you complete sterile process systems. The earlier we are involved in the planning process for your new or replacement system, the more cost-effective the solution we can offer you.

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

From concept to compliance

We can support you with initial advice, system design, steam generation and water distillation equipment, 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 virtually 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. And our Getinge Academy offers thorough training to assure the proper and efficient handling of equipment for sterile processing.

You're in safe hands with Getinge.



SAFEGUARDING YOUR INVESTMENT

A production system represents a major capital investment. That's why Getinge works hard to ensure that our GEW washer/dryers provide true value in terms of design, performance 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 believe we offer true value for money. This is reflected in our impressive client base – the world's leading Bio-pharmaceutical companies rely on Getinge.

Satisfying your needs

GEW Series washer/dryers, the products of many years of practical experience, are designed to handle the toughest applications. We recognize that most applications are unique, so we offer made-to-order racks and 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 transport of racks and articles to and from the work area.

Wide selection of chamber configurations

The Getinge GEW Series comprises a range of chamber sizes that offer optimal handling of common loads. Three standard models meet the requirements of most applications.

Regulatory issues

Getinge closely follows industry trends, practices, guidelines and regulatory requirements. We also actively participate in groups and committees that work to refine these requirements.

GAMP • cGMP • ASME BPE • MHRA
ISPE BASELINE GUIDES • ISO9000 21CFR
PART 11 • FDA • EMEA

All of our washer/dryers are manufactured in accordance with the guidelines or standards relating to the intended applications and the country of installation.

Protecting the environment

All processes are optimized to minimize the use of energy and chemicals.

A COMPREHENSIVE RANGE

GEW 666

The range begins with the GEW 666, which is intended for use in the QA laboratory and for small scale production operations including pilot plants and hospital pharmacies. The base specification includes a comprehensive variety of core features designed to provide repeatable, validatable cleaning, reliability and longevity. A range of optional features facilitates customization according to the client's specific application needs. These fully automatic, compact washer/dryers are available with a single vertical sliding door or two sliding doors for pass-through operation.

The loading height is 800 mm (32"). A selection of standard loading racks is available for common applications. Alternatively Getinge provides a parts modelling service to design customised racks. The racks are transported to and from the washer/dryer on a trolley.



GEW 666

GEW 131313

The medium sized GEW 131313 is designed primarily for the manufacturing area and has a high specification base platform with a wide variety of optional features to make it adaptable to a variety of applications.

The chamber is equipped with one or two vertical hinged doors for single ended use or pass through operation. The use of a hinged door on this model optimizes space and minimizes the footprint of the basic unit.

The loading height is 710 mm (28") for ergonomic operation and a variety of standard racks, together with a convenient transport trolley are available for common applications. Custom racks may also be designed and provided.



GEW 131313

GEW 131820

The largest washer in the series, the GEW 131820 is designed for pit mounting in a 300 mm (12") 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 just 300 mm (12") loading height.

This unit is intended for Bio-Pharmaceutical manufacturing operations, including cleaning of bulk chemical containers, vessels and machine parts. Racks are designed according to the application, based on our extensive experience.



GEW 131820

FEATURES THAT SATISFY YOUR PROCESSING NEEDS; SUPPORT THAT SATISFIES YOUR 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 Lancer factory in Toulouse, France, which has been a part of the Getinge Group since the inception of parametrically controlled cleaning for the Bio-Pharmaceutical industry in the early 1990's.

Formerly known as the Lancer "PCM" range, the features of these washer/dryers have been honed by a process of technological development coupled with the experience of working with a very wide variety of applications on behalf of our clients in the pharmaceutical, biotechnology, and cosmetics industries, globally.

Today, the 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 25 Getinge sales companies serving all major markets, and more than 70 authorized distributors. We can provide a 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 insulating glass allows visual monitoring of cleaning process
- Single or double door models
- Cross contamination barrier to prevent clean area contamination and excessive air loss
- Completely drainable, sanitary design
 - Maximized use of orbital welding
 - L/D Ratio of <4
 - Chamber and piping slopes >2%
- Powerful sanitary main pump
- BPE compliant design and components (P version)
- HEPA filtered dual path drying system
 - Independent channels for chamber and load
- Low power and utilities consumption
- Selection of automation systems
 - Rockwell – Allen Bradley (Compact Logix as standard)
 - Siemens – (Simatic S7 platform)
 - Getinge PACS 3500 platform
- GAMP compliant documentation and programming
- Highest level of parametrically controlled cleaning to meet the demands of the industry



INTELLIGENT FUNCTION AND DESIGN

1. Efficient drying

Two separate drying systems: one for the chamber and one for the process path and racks. 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.

2. Filter monitoring

DOP ports and differential pressure transmitters are standard features, providing essential routine monitoring capability. Magnehelic® differential pressure gauges are available (option) for visual verification of filter loading.

3. Fully automated

The Getinge GEW Washer/Dryer is equipped with a GAMP compliant, 21CFR Part 11 capable, state-of-the-art modular PLC system. Getinge offers a choice of our own PACS 3500 system or a selection of Allen Bradley or Siemens platforms, all with equal functionality and documentation.

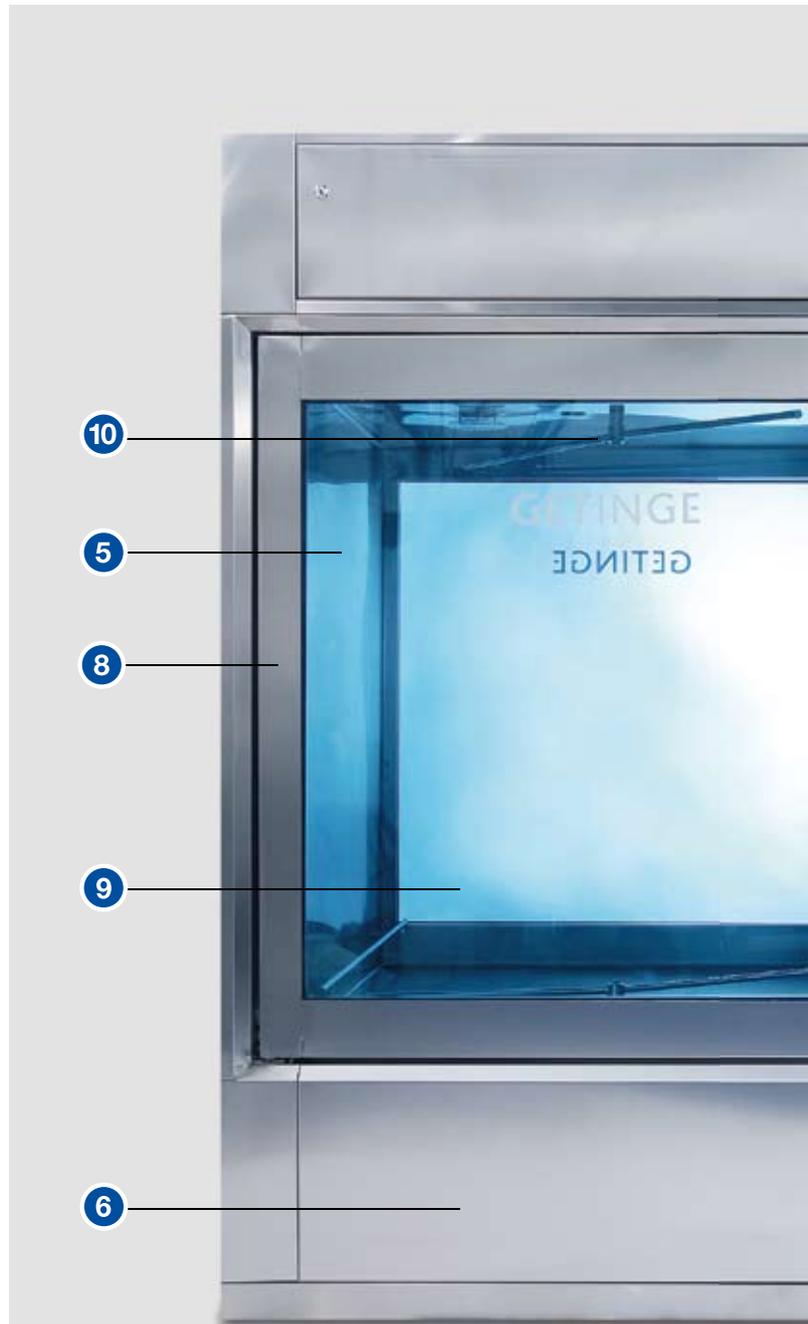
4. Robust and sanitary construction

Sanitary main circulation pump with vertical outlet. Sloping (min 2%) design and smooth ($Ra < 0.6\mu\text{m}/25\mu$), crevice-free construction of chamber, piping and racks eliminates water retention and sites for biofilm or corrosion. Dead-legs are limited to a maximum of 4 x pipe diameter ($L/D < 4$). Type 316L stainless steel is used throughout, with EPDM, PTFE or other FDA-approved gaskets (21CFR part 177). Globally available components, e.g. GEMU process valves, are standard. Orbital welding is used wherever possible and extensive documentation is provided.

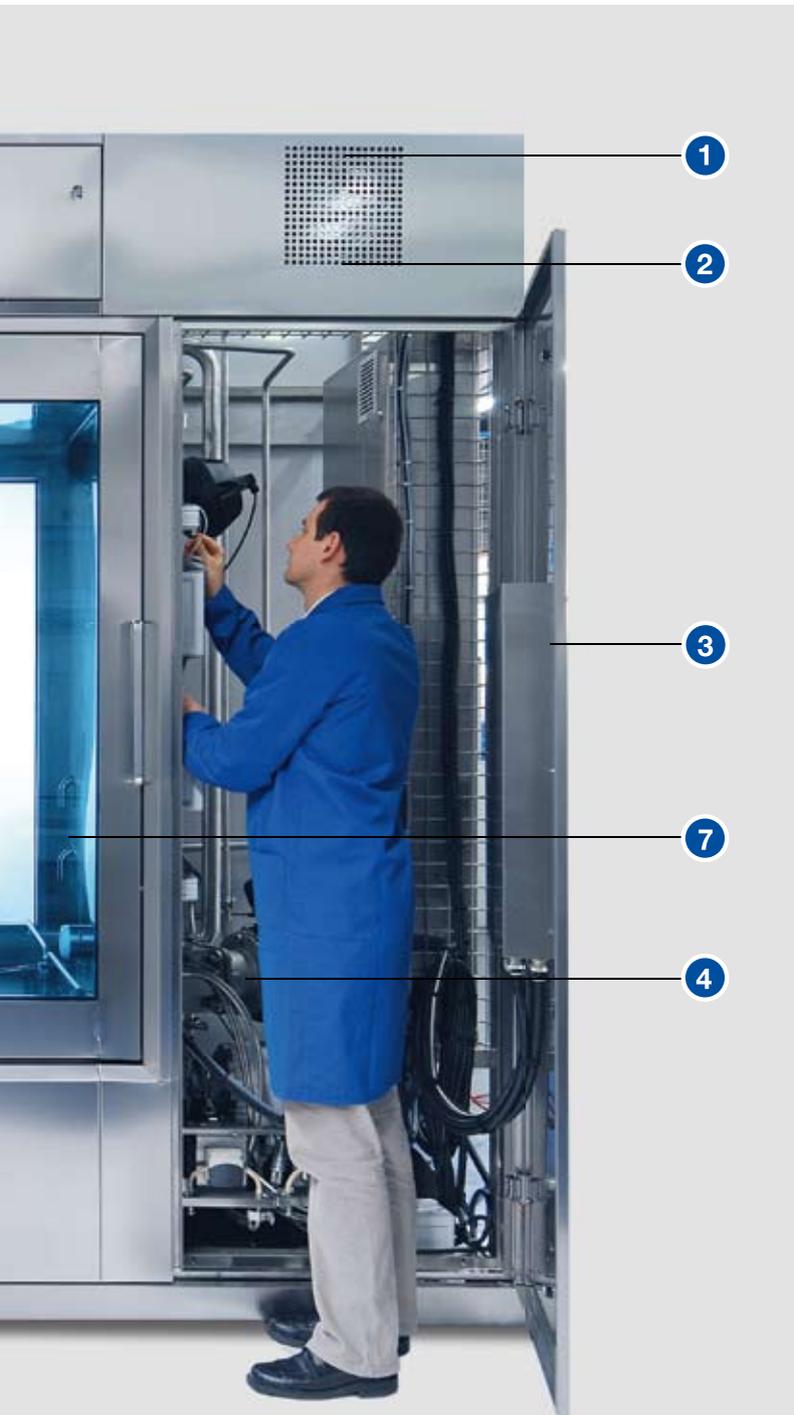
5. Washing configurations

Multi-level washing optimizes load configuration and minimizes processing time.

Water is heated using a steam-water heat exchanger in the sump of the chamber (electrical heating optional).



SINGLE DOOR MODELS	CHAMBER SIZE (Nominal internal) W x H x D		OVERALL SIZE
			W x H x D
GEW 666-1	mm	660 x 660 x 660	1800 x 1993 x 965
	inch	26 x 26 x 26	71 x 78 x 38
GEW 131313-1	mm	1300 x 1300 x 1300	2470 x 2560 x 1485
	inch	51 x 51 x 51	97 x 101 x 58
GEW 131820-1	mm	1300 x 1800 x 2000	3250 x 2850 x 2300
	inch	51 x 71 x 79	128 x 112 x 90



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 is fitted with 1 to 5 peristaltic dosing pumps (according to application) for cleaning and neutralization agents to aid the mechanical cleaning process. Additional pumps are available. 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 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 TOC during process development studies). Optional conductivity and/or 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.

A drain cooler system is available to limit the drain outlet temperature, typically to typically to 60°C (140°F).

9. Custom designed inventory systems

Racks and frames are designed to solve specific cleaning and drying challenges, based on extensive experience gained over many years and hundreds of projects. 3D CAD modelling software is used to assure that cleaning is effective internally and externally.

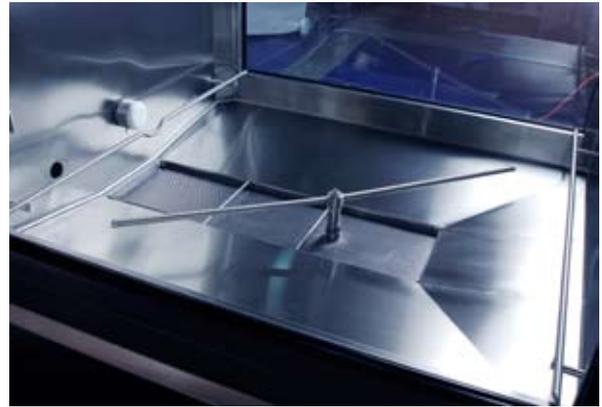
10. Door configurations

Each model is available in single door or double door configuration. Doors on the pass-through models interlock to prevent simultaneous opening (and doors remain locked while the chamber is above a preset temperature).

DOUBLE DOOR MODELS	CHAMBER SIZE (Nominal internal) W x H x D		OVERALL SIZE W x H x D
	mm	inch	mm
GEW 666-2	660 x 660 x 660	26 x 26 x 26	1800 x 1993 x 965
			71 x 78 x 38
GEW 131313-2	1300 x 1300 x 1300	51 x 51 x 51	2470 x 2560 x 1485
			97 x 101 x 58
GEW 131820-2	1300 x 1800 x 2000	51 x 71 x 79	3250 x 2850 x 2600
			128 x 112 x 102



Sanitary spray systems (rotating spray arms and/or balls) in the chamber, in combination with injection points on racks ensure complete, uniform coverage of both internal and external surfaces of the items to be cleaned. Optional rotation sensors on spray arms confirm correct operation.



Chambers are 316L stainless steel and fully welded (no crevices). All welds are polished and passivated. All models feature rounded corners (>12mm radius) and a sloping base (min 2%) to ensure complete drainage. Chamber fixtures are sanitary and all non-stainless steel materials are FDA approved (e.g. PTFE).



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



CAD is used extensively in the design phase. Our customization and 3D modeling service, for example, is normally used to help design inventory systems for specialized components to be processed.



Exclusive twin channel drying system. Each channel comprises a high capacity blower powered by a brushless fan, 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 load exterior whilst the other assures rapid drying of the hydraulic circuit, rack and load interior.



Doors slide or are hinged to provide convenient and ergonomic loading while optimising space usage (overall footprint) and ergonomics. All doors comprise of two sheets of toughened tempered glass, with an air gap providing heat and noise insulation. The glass door allows visual monitoring of the cleaning action – e.g. spray arm rotation, facilitating qualification. Optional chamber illumination.

PHARMACEUTICAL • BIOTECH • LAB • COSMETIC	P	B	L	C
CHAMBER				
316L stainless steel construction / FDA approved elastomeric seals / 0.6 micron (24 Ra) surface finish or better	●	●	●	●
Radius-corner chamber (>12mm (1/2")) and fully draining hydraulic circuit	●	●	●	●
Chamber welds ground flush	●	—	—	—
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, deadleg ratio L/D<4, chamber and piping slope >2%	●	●	●	●
BPE 2002 Compliance	●	○	—	—
Forged sanitary diaphragm valves	●	●	—	—
Hygienic Angle Seat valves	—	—	●	●
PUMP				
Sanitary recirculation pump	●	●	●	●
Recirculation pump pressure monitoring	●	●	○	○
WATER INLETS				
Quantity of water inlets	1	1	2	2
Additional water inlets (up to 3 total)	○	○	○	○
Water distribution loop piloting	○	○	○	○
CHEMICAL DOSING SYSTEM				
Quantity of dosing pumps	1	2	2	4
Additional dosing pumps (up to 5)	○	○	○	○
Chemical pump pressure monitoring	●	●	○	○
Conductivity monitoring – Final rinse phase	●	●	○	○
Conductivity monitoring – Final rinse and wash phases	○	○	○	○
AUTOMATION SYSTEM				
Getinge PACS	○	●	●	●
Allen Bradley /Siemens PLC	●	○	○	○
Printer	●	●	●	●
INSTALLATION				
Full frontal (GEW 666) or side (GEW 131313 and 131820) access for easy maintenance	●	●	●	●
Single or dual cross-contamination barrier seal (GEW 131313 and 131820)	○	○	○	○
Flush brush finish stainless steel front panels / easy cleaning / washdown capable	●	●	●	●
DOCUMENTATION (selected items from a comprehensive list of document options)				
GAMP compliant validation support documentation package and comprehensive manuals	●	●	●	●
Weld numbering, weld map, and weld boroscope report	●	○	○	○
Full material traceability (31B Certificates)	●	○	○	○
TESTING AND QUALIFICATION				
Prequalification in factory	○	○	○	○
ACCESSORIES				
Range of standard racks (basic rack, jet rack)	○	○	○	○
Custom made racks – e.g. glassware, filling line, hoses, IBC's, carboys	○	○	○	○
Transfer trolleys for racks	○	○	○	○

● = Standard ○ = Option — = Not available

INVENTORY SYSTEMS: EFFICIENCY, ERGONOMY AND 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 to where they're 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, where necessary, manufacturers of production equipment – 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 pictures on this page 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.



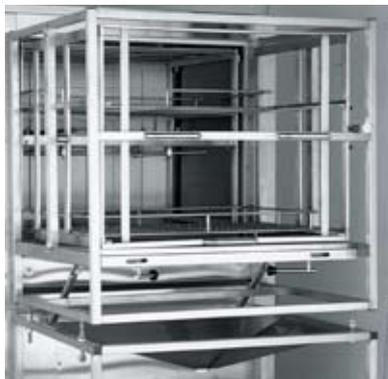
Machine parts are frequently sent to Getinge for modelling/rack design.



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 themselves be disassembled for cleaning and maintenance.



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



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

INSPECTION, TESTING AND DOCUMENTATION

As a general principle, Getinge follow ISPE's GAMP guidelines in respect of project execution and provision of documentation to support our clients' qualification of sterile process equipment.



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

Quality is an intrinsic feature of 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, and 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 equip-

ment. 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 start-up and site acceptance testing later on.

Deliverable documentation packages include:

- Submittals (design documentation)
- Construction
- Automation
- Testing & 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, and programmed using a wealth of experience gained since Getinge introduced the first PACS computer controlled sterilizers in the mid 1980's.

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)
- Getinge – PACS 3500

All systems accurately handle tasks such as parameter setting, recipe handling, sequence control, and data processing, presentation and storage.

Versatile features

The features included in our automation systems are:

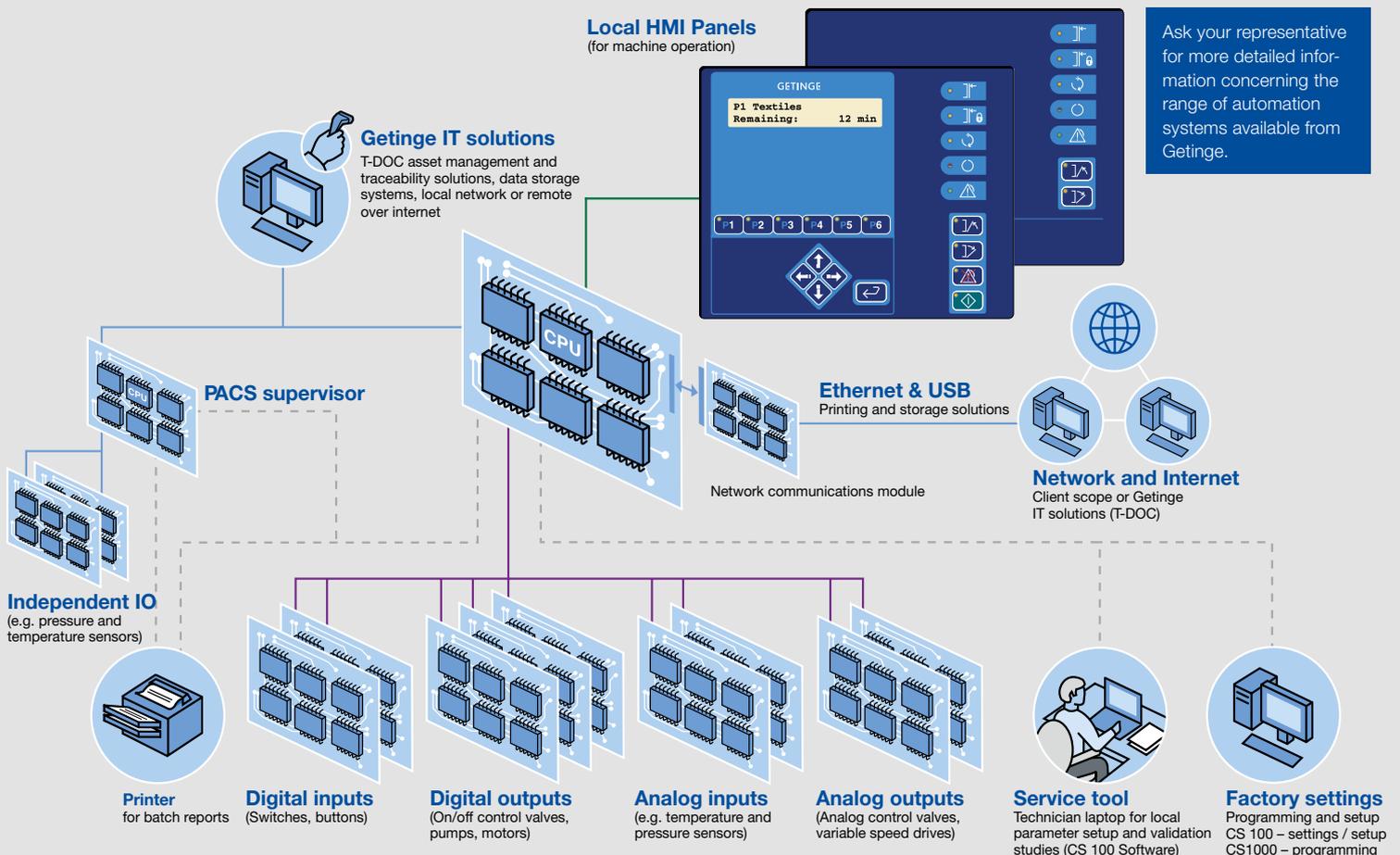
- User friendly interface
- Extensive documentation
- Remaining cycle-time indicator
- Automatic sensor calibration
- Comprehensive alarms/alerts
- Process and alarm logging
- Multi-level password protection



Alternate Local HMI Panel

Regulatory compliance

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



Ask your representative for more detailed information concerning the range of automation systems available from Getinge.

Note: Illustration shows all possible connections, though not all can be made simultaneously.



Getinge provides complete solutions for effective and efficient cleaning, disinfection and sterilization in the healthcare and life science sectors. Our know-how comprises everything from architectural planning, production and handling equipment, to systems for full traceability of sterile goods. Our commitment covers expert advice, training and long-term technical support.

GETINGE

Getinge Infection Control
 PO Box 69, SE-310 44 Getinge, Sweden
 Phone: +46 35 15 55 00
 Fax: +46 35 18 14 50
 info@getinge.com www.getinge.com

GETINGE

GETINGE GROUP is a leading global provider of equipment and systems that contribute to quality enhancement and cost efficiency within healthcare and life sciences. Equipment, service and technologies are supplied under the brands **ArjoHuntleigh** for patient handling and hygiene, disinfection, DVT prevention, medical beds, therapeutic surfaces and diagnostics, **GETINGE** for infection control and prevention within healthcare and life science and **MAQUET** for surgical work places, cardiopulmonary and critical care.