WHITE PAPER

GEW 888 neo

Compact cGMP Biopharmaceutical Washer

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Abstract

The Getinge GEW 888 neo is designed to meet the needs of cGMP washing and drying in cleanrooms where space is minimal in accordance with numerous industry standards. The small-footprint cGMP washer provides high throughput, low operational costs, and an ergonomic design. Ease of qualification and numerous improvements, including the innovative Getinge Single Pass Final Rinse (SPFR), make the GEW 888 neo the ideal compact washer for biopharmaceutical producers, QC laboratories, pilot plants, and other cGMP applications.

Validated Component Cleaning for Small Spaces

Cleanrooms and clean zones are classified by the number of allowable particles per cubic foot of air according to one of two main current Good Manufacturing Process (cGMP) regulatory systems, the *EU GMP Guidance Annex 1: Manufacturing of Sterile Medicinal Products* or the US Food and Drug Administration's (FDA's) *Guidance for Industry: Sterile Drug Products* Produced by Aseptic Processing Current Good Manufacturing Practice. These systems are used worldwide to regulate aseptic and terminal sterilization processes in the manufacture, control and release of pharmaceutical products.

Repeatability and Reduction of Contamination

As facility managers know, cleanrooms do not eliminate contamination, they only control it to an acceptable level. Cleaning components used for the production of powder, tablet or capsule drugs poses challenges of releasing API (active pharmaceutical ingredient) particulates into the air, removing all particles from all areas of components and eliminating water-insoluble powders from surfaces.[1]

For liquid pharmaceuticals and injectables, however, the largest challenge is to ensure consistent, thorough cleaning of all surfaces. This not only prevents cross-contamination between different drug batches it also prevents the growth of microbial contamination that can be missed in unvalidated automated washing cycles or through manual component washing. For sterile, aseptic, or low-bio-burden liquid medicinal products, any opportunistic microorganisms present will be able to thrive in supportive media. Product quality is impacted if an aseptically processed product is contaminated through improperly cleaned components. Thus, these facilities are designed with "dirty corridors" to keep potentially harmful organisms out of the cleanroom. Additionally, droplets of liquid don't tend to become airborne, unlike powder particles.

To help prevent microbial contamination risks, cGMP cleanroom guidelines recommend automated, validated cleaning using a pass-through system that separates equipment washing with a clean and dirty side. When it comes to component cleaning, consistent, repeatable results of a pre-validated solution are essential. Automated cGMP washers help to reduce or eliminate human error common in manual washing by better balancing each factor of the washing process. These factors, known collectively as the Sinner's Circle, include time, temperature, chemical and mechanical functions.[2]

Yet regardless of the cGMP system followed, many manufacturers are still faced with the need to ensure reliable, repeatable results while maximizing throughput and reducing operational costs. One of the best ways to achieve these goals is to use an automated, cGMP washer for cleaning production equipment, components, and glassware used in biopharmaceutical production. Cleanroom space is at a premium. Therefore, it can be difficult to find a cGMP washer that provides the requisite quality and is compact enough for cleanroom use.

The Getinge Solution

Global Leader in Pharmaceutical Equipment Solutions

Getinge is a highly recognized global provider of products and systems that contribute to productivity improvement, repeatability and cost-efficiency in biopharmaceutical and pharmaceutical production solutions, biotechnology research and healthcare. The company's proficiency in design, production and validated installation of system solutions has evolved over generations of advances in science and medicine.

Experts in cGMP Washers

Getinge GEW Series cGMP Washers have been specifically designed for cleaning of components and production equipment used in biopharmaceutical drug manufacturing. All Getinge units are crafted with components of superior quality that support contamination control, promote a sanitary process, and ensure safe and dependable results that are essential to safeguarding product, personnel and the environment in a biopharmaceutical facility. From the polished stainless-steel surfaces to the user-friendly machine interfaces, each part is intricately designed into a highly efficient system that is indispensable to quality assurance.

High Throughput, Reliable Cleaning

The legacy Getinge cGMP GEW 888 washer is known worldwide for reliability and repeatability. While the legacy model relied on a compact chamber volume, the overall footprint was still large.

To meet industry needs, the GEW 888 has been redesigned to deliver high-performance component cleaning in a compact footprint. This new model, the cGMP GEW 888 neo is a validated component washing solution that merges innovative updates with a history of reliability.

It is thoughtfully engineered to meet the demanding needs and regulatory standards of biopharmaceutical, biotech, and allied industries in the pharmaceutical manufacturing of sterile, or low bio-burden and liquid medicinal products.

Meeting Industry and Regulatory Demands

As experts in cGMP washers, we understand the strict regulatory requirements and standards faced by the pharmaceutical industry and the importance of quality assurance protocols. The Getinge cGMP GEW 888 neo washer is thoughtfully designed for the pharmaceutical industry to comply with applicable standards and ensure validated cleaning results.

Security and software capabilities in the Getinge cGMP GEW 888 neo have been enhanced to satisfy the latest industry demands. The cGMP washer can be equipped with either a high-quality Allen Bradley or Siemens programmable logic controller (PLC) to comply with FDA 21 CFR Part 11 or EU Annex 11, depending on customer need.

The cGMP GEW 888 neo also meets GAMP 5 (Good Automated Manufacturing Practice) requirements and complies with ASME BPE (American Society of Mechanical Engineers: Bioprocessing Equipment) standards for the design and manufacturing of equipment used in the production of biopharmaceuticals. The cGMP GEW 888 neo is designed with dead legs of ≤2D to achieve high performance cleaning, lower rest volume of water, lower risk of cross-contamination between phases, and to meet pharmaceutical industry standards.

All system components are manufactured from high-quality materials to maintain the same stringent quality standards and low surface roughness as the water circulation pathway in the Getinge cGMP GEW 888. All internal system piping is compliant with ASME BPE standards and ISPE (International Society for Pharmaceutical Engineering) guidelines. This piping is AISI 316L stainless steel with a smooth interior (Ra ≤0,5µm).

Standard Compliance

- Current Good Manufacturing Practices for Finished Pharmaceuticals (cGMP): CFR Title 21, Part 211, Subpart D - Equipment
- FDA 21 CRF Part 11
- EU Annex 11
- GAMP 5
- ASME BPE
- ISPE

Improved Ergonomics and Efficiency

The washer model is equipped with several features to enhance ergonomics and safe handling by the operator. The automatic vertical sliding door prevents additional height above the washer. The walk-in-trolley is space saving and more importantly ensures a safe way to load and or unload the loading rack in and out of the washer.

The cGMP GEW 888 neo is compatible with the space-saving Getinge walk-in trolley, which enhances washer loading and unloading ergonomics while optimizing the loading efficiency and the distribution of goods.

Improved Throughput and Performance

Performance
High-performance, high throughput cleaning in a compact footprint with validated repeatability.

Validation
Designed for easy validation, qualification / documentation in pharmaceutical and biopharmaceutical applications.

Quality
Crafted with superior quality components inside and out.

Ease of Operation
User-friendly touchscreen interface enables easy operation of programmable, validated cycle.

Control System
Based on leading, compliant systems used in worldwide markets.

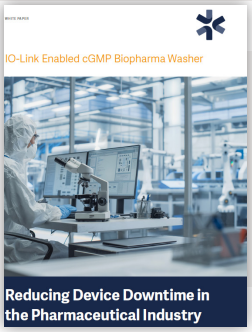
Security
Enhanced security and software to meet the latest industry demands.

Safe loading and unloading
Safe operator handling with the walk-in trolley.

Sustainability
Reduced water and energy consumption helps improve sustainability while reducing operating costs.

Improved Throughput and Cleaning Performance

- Industry-Standard PLC - Siemens or Allen Bradley PLC available depending on customer control system regulatory requirements (FDA 21 CFR Part 11 or EU Annex 11).
- Vertical, automatic sliding door saves space while improving ergonomics and safe handling. The door-closing locking system ensures operator safety.
- Updated Docking System - Introduces water underneath the wash rack and ensures a tighter seal. Enables higher pressure to balance water circulation and improve cleaning performance while resulting in lower water consumption.
- State-of-the-Art Technology - IO-link* interface allows digitally connection to other equipment in the IoT.
- Maintenance - Intelligent sensors enable higher functionality, easier integration, and pave the way for optional preventive maintenance features.
- Modern cGMP Design - Gaps and crevices on the washer exterior are minimized to fit cGMP guidelines and provide a sleak, modern design.
- High-performance drying system provides complete drying of the load following the wash process. An optional heat exchanger provides accelerated drying time while also improving sustainability. The heat exchanger reduces HVAC load by lowering exhausted humidity and heat while reducing energy consumption.



*** White Paper: Reducing Device Downtime in the Pharmaceutical Industry**
By leveraging advanced IO-Link technology the GEW 888 neo integrates seamlessly into new and existing IIoT automation systems. The use of IO-Link enables remote monitoring and control, enhanced diagnostics, faster compliance, improved uptime, and significantly reduces installation and commissioning times.
Read more: https://www.getinge.com/int/products/gew-cgmp-888-neo/

IO-Link inside

Innovative Single Pass Final Rinse (SPFR)

The innovative optional SPFR available in the Getinge GEW 888 revolutionizes the single pass final rinse stage without impacting exterior dimensions. The innovative solution requires lower water consumption for reduced operational costs and improved sustainability – all in a compact footprint.

Whether used as the final rinse phase (single pass final rinse) or as a prewash (single pass first rinse), the Getinge SPFR Solution helps eliminate contamination by ensuring soiled rinse water is not recycled. Water only passes items in the chamber once before being drained, preventing contact with recirculated water. When used as a pre-rinse, the single pass system removes bioburden before the SPFR phase. Depending on validation requirements, the single pass can be set to repeat numerous times while still gaining the benefits of lower water consumption compared to standard SPFR systems.

Getinge SPFR Key Features:

- Sustainable and cost-effective; water consumption is ~7 L (1.5 gal) of PW/WFI per rinse.*
- Clean process air ensures complete coverage of all surfaces in the wash chamber for thorough, reliable rinsing.
- Conductivity is monitored to ensure removal of soil or process chemicals has been successful.
- Sterile compressed air with incorporated safety release system.
- Permits additional single pass phases with minimal time between next single pass.

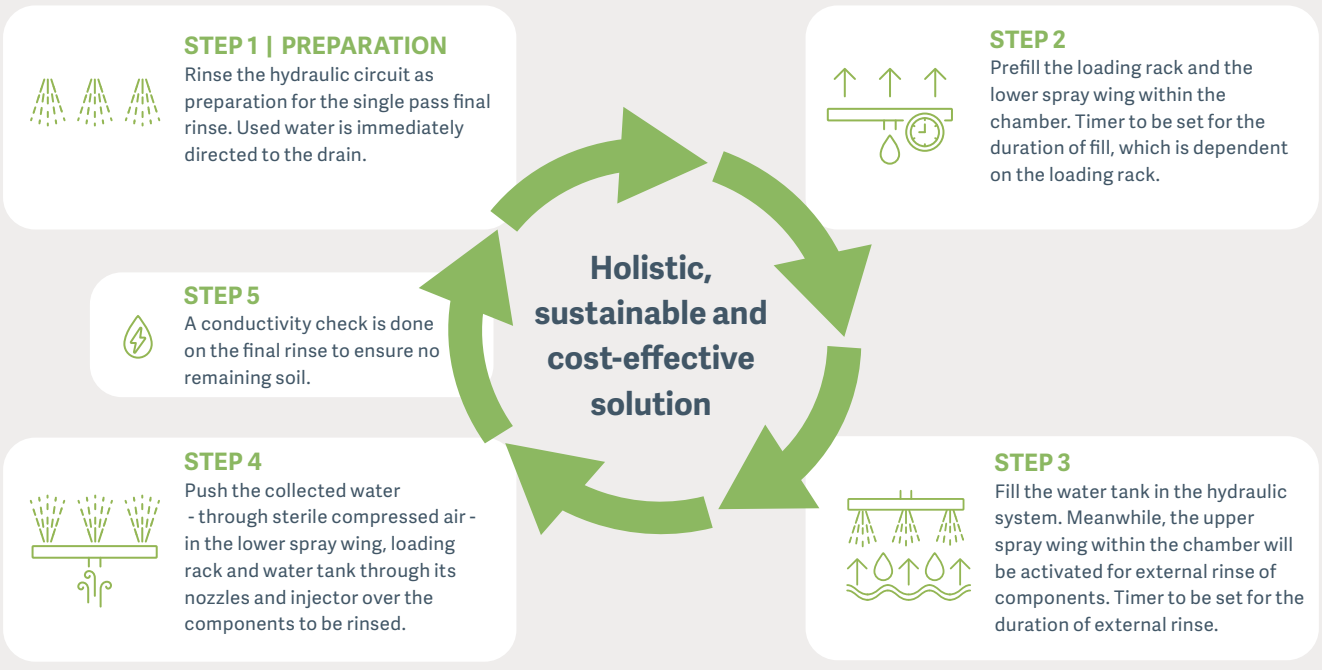
In the rinse phase, pharmaceutical product residue is rinsed from components in the washer chamber in a single pass. Cycle water is then carried directly to the drain, along with the removed residue. While SPFR options typically require a high volume of water, the Getinge SPFR Solution has revolutionized the SPFR system in the GEW 888 neo to reduce water and energy consumption.

The newly redesigned SPFR used for the GEW 888 neo eliminates the need for a large, separate water tank. Because the Getinge SPFR system does not increase the GEW 888 neo size when added, valuable cleanroom space is conserved for other needs. The Getinge SPFR Solution needs only a small tank and relies on a hydraulic system and sanitary SPFR valves to disburse water through the top and bottom spray arms located in the washer chamber, optimizing the chamber size to footprint ratio. This significantly reduces the washer footprint to a total of only 1.3 square meters (13.99 sq.ft.), freeing up valuable space and enabling an industry-leading cGMP washer footprint.

Getinge's SPFR system is designed to meet specific process requirements and can be programmed into the validated cycle. Not only can it be set up by the user to be repeated according to process requirements. Additionally, SPFR units monitor the conductivity of the rinse water and will stop the cycle if the conductivity levels exceed the range.

*Water consumption is dependent on selected load rack as well as on timer set for the external single pass rinse.

Sequence steps of new Single Pass Final Rinse



Note: In case of a repeat final rinse, step 1 will only be done the first time and step 5 will only be done the last time. In between the sequence jumps from step 4 to step 2.

Operational Costs & Sustainability

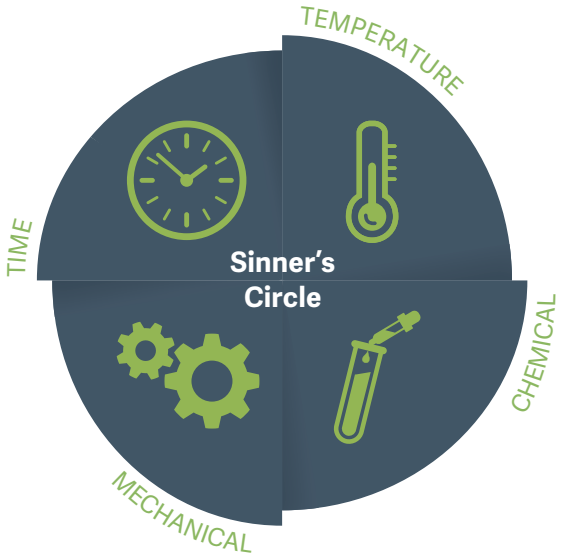
The innovative, compact design of the GEW 888 neo helps decrease the need for costly additional cleanroom space and reduces water and energy consumption, lowering operating costs and helping facilities meet sustainability goals. A balanced auto circulation system with an optimized water pump helps further reduce utility consumption.

The GEW 888 new offers superior washing capacity with high throughput and reliable, repeatable cleaning results. The washer secures your investment by providing low operational cost, including reduced water consumption for sustainable performance.

Sustainability Snapshot

- Well-balanced water circulation system reduces energy needs.
- Water pressure sensor accurately monitors the chamber water volume to reduce utility consumption.
- Drying system with HEPA and electrical heating element includes a heat exchanger that reduces energy consumption by utilizing accumulated energy within the chamber.
- Reducing heat and humidity exhausted into facilities following drying helps lower HVAC demands, further reducing energy consumption and utility costs.

Regardless of the procedures in place, manual washing inevitably introduces human error, which can create uncertainty in the quality outcome of a manual cleaning process. The manual washing process is also fundamentally slow, inevitably leading to increased



operational costs through low throughput. As with other automated systems used by pharmaceutical companies, automated washing solutions include numerous benefits. A validated, automated component washing solution provides precise control of factors in the Sinner's Circle, improving quality control through consistent, repeatable results. Automated washing also ensures the highest possible throughput.

A programmable washer permits users to initiate a completely automated washing function that precisely controls and matches water consumption to fit the needs of different cycle phases that are configurable to fit different soils.

Increased Production Throughput

The validated outcome increases throughput while improving cleaning quality, consistency and personal safety and regulating the use of consumables

Getinge Solution Key Benefits

- All system components are manufactured from high-quality materials to maintain the same stringent quality standards and low surface roughness as the water circulation pathway in the Getinge cGMP GEW 888.
- All internal system piping is compliant with ASME BPE and ISPE standards. This piping is AISI 316L stainless steel with a smooth interior (Ra ≤0,5µm).
- Meets biopharmaceutical industry requirements for a single pass final rinse (SPFR) option as part of validated processes.
- Two-way pneumatic valves allow the rinse water recirculation loop to open or close according to application requirements and programming.
- Water pressure regulation system optimized the cleaning process to ensure high-quality, efficient, repeatable cleaning results.
- The washer control system closely monitors rinse water conductivity. If the conductivity drifts out of range, a fault code is activated and the system suspends the cycle.
- The complete water circulation has dead legs less than 2D to meet ASME BPE. This reduces cross contamination by prevent any rest water still in the water circulation system from coming into contact with the process between water phases.

Chamber Features

All parts in contact with the process produced in stainless steel AISI 316L, surface roughness ≤0,5µm.

Inlets for consumables with stop valves.

Main water circulation pump located below chamber has improved laminar flow and maintains high performance for high temperature phases.

Water pressure sensor accurately monitors chamber water volume, reducing utility consumption.

Water inlet can be located on right- or left-hand side. In addition, top connection is also available to fit all installation requirements. Water vales are of type, sanitary diaphragm valves.

All surfaces, hydraulic pipes slope 2%, comply with ASME BPE.

Optional electro-polished chamber.

Heavy-duty loading rack runners within the chamber can handle a weight up to 100 kg (220 lbs).

Main water circulation pump is equipped with a frequency drive.

Conclusion

The Getinge cGMP GEW 888 neo washer is an innovative solution that combines compact design with high throughput, making it an ideal fit for cleanrooms where space is at a premium.

The Getinge cGMP GEW 888 neo fulfills the industry need for a compact, reliable, efficient washer designed to ensure repeatable results. This redesigned model merges innovative updates with the reliability of its predecessor, creating a validated component washing solution that maintains compliance with regulatory standards and ensures repeatable cleaning suitable for demanding pharmaceutical manufacturing applications.

The GEW 888 neo has been designed with enhanced security and software capabilities that align with the latest industry demands. Automated cGMP washers help to reduce or eliminate human error common in manual washing by better balancing each factor of the washing process. The GEW 888 neo introduces several features that help decrease operational costs and enhance sustainability, including the innovative Getinge SPFR, a balanced water circulation system, and updated docking system with tighter seal.

The washer secures your investment by providing low operational costs, including reduced water consumption, for more sustainable performance.

Complete Range of cGMP GEW Washer/Dryers

GEW 888 neo
480 L (17 cu.ft.)

GEW 9109
810 L (29 cu.ft.)

GEW 101210
1212 L (43 cu.ft.)

GEW 131313
2146 L (76 cu.ft.)

GEW 131820
4680 L (165 cu.ft.)

Pharmaceutical Production Solutions

Getinge is an industry leader in product solutions for pharmaceutical production sterility testing, API handling and aseptic filling. Our isolation technology and isolator manipulation devices are trusted worldwide to provide a safe and controlled environment for your most critical steps.

Learn more: getinge.com/int/products-and-solutions/pharmaceutical-production/

References

1. Learn more about the Air Exhaust Unit in our application brief "Containment of APIs released through component washing, " https://www.getinge.com/int/insights/articles/pharmaceutical-production/containment-of-apis-released-through-component-washing/.
2. Learn more about balancing the Sinner's Circle and how automated washing can optimize cleaning in our white paper "Manual vs. automated labware washing, " https://info.getinge.com/manual-vs-automated-labware-cleaning.

GETINGE

With a firm belief that every person and community should have access to the best possible care, Getinge provides hospitals and life science institutions with products and solutions aiming to improve clinical results and optimize workflows. The offering includes products and solutions for intensive care, cardiovascular procedures, operating rooms, sterile reprocessing and life science. Getinge employs over 10,000 people worldwide and the products are sold in more than 135 countries.

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