Washing systems
Serving the global pharma industry
Solutions for the pharmaceuticals and biotechnology companies

Located in modern factories near Venice in Italy, Steelco Group is a major global supplier of infection control and contamination prevention for the healthcare, laboratory and pharmaceutical sectors. Steelco’s success is demonstrated by its strong growth, becoming the partner of choice for many of the world’s leading pharmaceutical companies who appreciate the company’s:

**Extensive product range**
With over 3000 installations worldwide, Steelco offers a wide portfolio including:
- Innovative washing equipment, customizing loading racks to customer needs.
- Diversified, steam and ETO sterilization range.
- Innovative fully automated closure processing equipment.
- Drying and depyrogenation ovens
- Automation systems to maximize productivity and safety.

**Flexible solutions**
- Ability to meet the most challenging processing needs.
- Only using best proven readily available control systems and components.

**Experience and knowledge**
- Strong track record of establishing long term global partnerships.
- Integrated in-house operations from incoming raw materials to installation, validation and technical support.
- Fully certified quality systems with knowledge of pharmaceutical manufacturing standards.

**Global footprint**
- Global HQ in Italy with regional customer support centres in America and Asia.
- Network of factory trained agencies in over 100 countries worldwide.

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Center of sterilizers production

Center of washing systems production

Steelco Headquarters
Quality engineering process

Steelco Group’s engineering experience encompasses knowledge and understanding to be able to satisfy the most stringent requests from clients.

Technical consulting, design, engineering, project management, as well as commissioning and qualification services of our equipment is offered, with customers appreciating the cost effective high performance solutions offered to resolve complex washing and sterilization challenges.

Our respected engineering experience in the medical, laboratory, pharmaceutical and biotech fields allows us to develop a proven approach that prioritizes the pharma manufacturing process and safety bearing in mind life cycle costs of the equipment.

Our methodical approach is to first develop an in-depth understanding of the project and the product goals in order to offer the best equipment and solution for the application.

Customers are always welcome to visit Steelco factories to see design and manufacturing methods and audit our processes.

Quality system certification

In addition to having a certified Quality System as per ISO 9001 (and ISO 13485 for Medical Division), our products are subject to rigorous quality control systems and inspection. This coupled with continuously training our technically specialized personnel ensures you receive best in class product solutions and support.

We constantly strive to improve on our high standards to enable us to deliver optimal solutions for our partners in the pharma industry.
3D project layouts

Steelco Group offers complete ‘turnkey” solutions for washing and sterilization processes in the pharmaceutical sector, with the ability to undertake all stages of a project from concept to delivering solutions that exceed customer expectations.

Steelco’s extensive experience assists customers to increase process productivity and quality with improved ergonomics whilst limiting costs.

Steelco Group: Leading the Way with a Risk Based Approach to Data Integrity
Extensive customer support services

Steelco Group offers a comprehensive range of services to ensure the success of projects at each important step including:

• Process and workflow design
• Process equipment design and manufacture
• Automation and SCADA
• Installation and commissioning
• Training packages, from basic to in-depth
• Validation and documentation:
  • cGMP compliance consultancy and assessment
• Training and assistance if requested by pharmaceutical companies as well as regulatory inspectors on GMP related topics
• Spare parts supply and first line service training
• Fully comprehensive and preventative maintenance contracts
• Periodic validation and re-qualification as required.

For all previously installed equipment Steelco can offer a range of customizable service packages. Customer service excellence is Steelco Group’s commitment to our clients and a cornerstone of our success with emergency service support if needed available, 24 hours, 7 days a week.

Academy

Subject matter expertise is shared by our trainers at the Steelco academy near Venice, Italy or at locations convenient to customers, with training on a wide range of topics that are focused on:

• Standards and work practices
• Equipment and its use
• Technical service training

Design warranty

Thanks to the design and quality of equipment, as well as the reliability of the components used, Steelco can offer extended warranties.

Performance and guarantee on Steelco equipment is according to the technical characteristics stated in the offer.

Only the best available “Non-Proprietary” components such as valves are sourced. Components are selected for their reliability and availability to reduce running costs and down time.

Steelco can use customer preferred parts provided that these meet performance and reliability requirements.
Control system

*User friendly control systems developed according to the latest GAMP and design for 21 CFR Part 11 available, sourced from the best available suppliers avoiding customized electronics.*

Steelco Group can provide software source codes, allowing its customers to become owners of the control system of the machine (“open source architecture”).

System platforms available include Siemens and Allen-Bradley which are easily integrated with those already installed by pharmaceutical companies. The software is structured and commented in English to allow a better understanding of functionality. **Multi Language tool** for development software is also available.

Software is developed in compliance with current coding rules and programming and according to standard ISA 88, ISA 95, IEC 61131-3 standard & GAMP 5.

The structure is designed for straightforward validation by the end user. **Tools to simplify validation** are also available (validation wizard).

**Remote diagnostic capabilities** are available for all our controller solutions.

### International standards:

<table>
<thead>
<tr>
<th>Standard</th>
<th>Description</th>
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<tr>
<td>ISA 88</td>
<td>Standard addressing batch process control</td>
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<tr>
<td>ISA 95</td>
<td>Enterprise-Control System Integration</td>
</tr>
<tr>
<td>IEC 61131</td>
<td>Programmable controllers</td>
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</tbody>
</table>
## Integrated architecture

**Steelco can install new equipment into an existing automation system through the adoption of a simple (HMI) or more sophisticated (SCADA) man-machine interface.**

Complete customization of access levels is available (local or domain users).

In compliance with the individual internal policies of each customer, Steelco Group offers remote service access by using virtual private networks to ensure the confidentiality and safety of all transferred data.

Safe remote access using UMTS/LTE/GPRS networks solutions are also available.

All Steelco machines share the same interface system: despite different functions of models with a logical evolution based graphic interface to ensure easier training and use by operators.

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### Level 4
**BUSINESS LOGISTIC SYSTEMS (ERP)**
- Plant Production Scheduling, Operational Management, etc.

**BUSINESS PLANNING & LOGISTICS**
- Establishing the basic plant schedule - production, material use, delivery, and shipping. Determining inventory levels.
  - **Time Frame:** Months, weeks, days

### Level 3
**MANUFACTURING OPERATIONS SYSTEMS**
- MES, BATCH, LIMS, AM, etc.

**MANUFACTURING OPERATIONS MANAGEMENT**
- Work flow / recipe control to produce the desired products, maintaining records and optimizing the production process.
  - **Time Frame:** Days, Shifts, hours, minutes, seconds

### Level 2
**CONTROL SYSTEMS**
- PLC, DCS, PAC

**MANUFACTURING CONTROL**
- Monitoring, supervisory control and automated control of the production process.
  - **Time Frame:** Minutes, seconds

### Level 1
**INTELLIGENT DEVICES**
- FLOW, VISION, PRESSURE, etc.

**MANUFACTURING CONTROL**
- Sensing the production process, manipulating the production process.
  - **Time Frame:** Minutes, seconds, milliseconds

### Level 0
**The actual production process.**
- **Time Frame:** Minutes, seconds, milliseconds

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*Our machines are level 1 and 2 of the standard ISA 95, with the ability to connect and supply all the next levels.*
Validation documents

User safety, product quality and data integrity are Steelco Group core values.

Equipment is developed and validated according to the latest GAMP and cGMP standards. Steelco “know-how” allows the client's to benefit from optimal solutions for their individual requirements, in order to perform effectively and reproducibility cleaning, sterilization and validation of pharma production components.

A risk based approach to comply with regulatory requirements is fundamental in the development of our validation documentation. An extensive package is available to minimize on-site validation time.

Steelco Group documents include but are not limited to the following:

- Hardware Design Specification
- Functional Design Specification
- Software Design Specification
- P&ID (Piping and Instrumentation Diagram)
- Component List
- General Arrangement Drawing
- Electrical Drawings
- Quality and Project Plan
- Traceability Matrix

Steelco Group is available to customize documentation packages according to customer standard requirements and to produce specific documents upon request.

Pre-validation of Steelco Group equipment ensures minimal project risk, less time and cost to qualify the units on site.
Acceptance Tests & on site activities

Factory Acceptance Test and Site Acceptance Tests.

Steelco Group is available anytime to support customers during all acceptance on site including process development and mapping.

All on site activities undertaken to pre-agreed written to pre-agreed protocols according to GDP and HSE requirements.

Steelco keeps records of the technical file of each machine to enable full access in case of third party inspection to verify compliance with directives and regulations currently in force.

Expertise in Design Quality and Hazop is available to customers.

Installation qualification (IQ), operational qualification (OQ), and performance qualification (PQ) are provided in standard version or customized according to the final scope of supply.

Our equipment manufacturing centres are equipped with water production systems that can simulate water quality found at customer sites.

Spray coverage test: riboflavin contamination of critc areas before cleaning phase.

V-Model for specification, installation, start up and qualifications

- User Requirements Specification
- Design Specification
- Functional Specification
- System Build
- Installation Qualification
- Operational Qualification
- Performance Qualification

"Tested and validated solutions"
Compliance and guidelines

The design and the production of our washing and drying systems is based on standards and guidelines recognized both worldwide as well as in the final installation country:

**Guidelines:**
- European cGMPs
- US FDA CRF
- 21CFR part 11
- cGLP
- UNI-INAIL (similar to OSHA standards)
- ASME
- ANNEX 15
- ICH Q9: Quality risk Management
  (European guideline)
- ISPE baseline

**Standards**
- Directive 2006/42/EC
- Directive 2014/30/EU
- IEC 61010
- EN ISO 12100
- EN 61326-1
- EN 13849-1
- EN ISO 14159
- ASTM A380
- ASTM A967
- UL Standards

Think globally
Tailoring your future

Steelco Group subsidiaries and agents provide technical expertise and support in over 100 countries worldwide
cGMP
WASHING SYSTEMS

Unparalleled high performance range
Steelco DS Series
Pharma Grade Washers

Exceed industry standards

Pharmaceutical grade machines are available as single door or pass-through double door versions to provide an effective barrier system between different zones. All machines feature large glass sliding doors to reduce size and assure easily and safety access.

Steelco standard pharma machines range from 0.23 to 2.4 m³ volumes capacity for standard washing requirements with customers additionally having the option of specifying customized chamber dimensions to meet their individual needs.

Using their extensive experience and sophisticated computer modelling Steelco’s engineering department optimizes cart design in order to reduce process time and water consumption whilst maximizing process effectiveness.

Field of application

Counting some the largest Pharma companies as its customers, Steelco has an in-depth understanding of the particular critical cleaning, disinfection and drying requirements of equipment and components used in pharmaceutical production including:

- Glassware
- Filling line components and tools
- Tubing, TC fittings
- Valve and pump bodies, filter housings
- Punches and Dies
- Reactor vessels and diverse equipment
- Bulk containers, tanks and carboys

Technical data, utilities consumption and drawings available upon request.

Complete layout versatility

Washing/Drying machines available as single door or pass-through double version, with automatic motorized opening in vertical (either up or downward) or horizontal sliding doors. Also available in hinged door version.
Safety and ergonomy is our priority. Possibility of interfacing unloading door with various models isolators.

Interfacing with isolator

- Highest cleaning performance
- Protection of processed items
- Low power and consumption
- Drying efficiency system
- Repeatable and validatable process
- Globally available components and technical support

DS 2500 PH
DS 2000 PH
DS 1500 PH
DS 1000 PH
DS 800 PH
Steelco DS PH range

Technical features

The washing chamber and the hydraulic system are designed and constructed with extreme care and finished to Ra<0.5μm/19.7μin smoothness, of crevice-free construction, with orbital welding for piping in order to eliminate water retention and stagnation points where bioburden could form.

AISI 316L stainless steel is used internally throughout with EPDM, PTFE or other FDA approved gaskets (21CFR part 177).

All models feature angled surfaces and rounded corners to ensure complete drainage.

Special applications

Steelco can provide customised solutions with special drying programs or HPV (hydrogen peroxide vapor) decontamination according to customer needs.

Pull out electrical panel configured to different global electrical standards

Water treatment supply
**Combination of clamps and welded construction**
Extensive documentation is provided on the orbital welding.

**Washing chamber and sump**
All the connections to the washing chamber respect the L/D <3 formula to ensure the cleaning integrity of all surfaces.

**Smooth and completely drainable surfaces.**

**Detergent valves**
Detergent inlet valves with zero dead legs.

**Exhaust valve**
With partial closure to reduce energy loss. With hermetic closure in case of washing toxic substances.

**Washing pump**
Stainless steel high quality washing pump with drain valve.

**Drain valves**
Double drain system with single or double total closure with no residual water left.

**Drying and filtering**
The heating elements enable variable drying temperature control. The HEPA filter is placed in line at the end of the drying path before entering the chamber and rack.

**Chemical dosing system**

**Alcove for sampling system**

**Total Organic Carbon**
TOC analysis provides cleaning validation and detects organic contaminants in process water.
Pharma carts and trolleys
*Standard and customized solutions*

Steelco’s engineers experience and sophisticated 3D CAD programs ensures that every point, corner and cavity of an item to be processed is deeply and accurately washed. This avoids the possibility of cross-contamination and eliminates all soil and contaminant residues from the previous use.

The same injection porting is used to also convey hot sterile filtered air inside each cavity for drying.

- Optimized load configuration
- Process effectiveness
- Reduction of cycle time
Steelco has developed a global reputation for being able to respond to the most challenging customer requests.

Steelco designs, develops, manufactures and tests all its own wash cart racks in-house, ensuring that the quality of this critical process is carefully monitored.
Steelco ML PH Series
Pharma Grade Parts and Glassware Washers

This machine offers pre-washing, washing, rinsing, drying and cooling phases with optimal performance in a compact size and footprint solution.

Hinged type chamber doors with single or double door and double locking device made in accordance with requirements for clean environments.

Use of FDA approved components (valves, filters, piping, tri-clamp fittings, pumps, etc.). Drying by HEPA filtered hot air at max. 130°C.

Field of application
Machines are designed for pharmaceutical products such as glassware, pipettes, machine parts, tanks, glass bottles, pill stamps, carboys, tubes, needles, etc.

Construction features

- Low running and life cycle costs.
- Use of 316L stainless steel with roughness less than 0.5 μm (20 micro inches) on all components in process contact (machine body, machine doors, spray nozzles bars, process piping, instruments, valves, racks, internal carts, baskets, etc.).
- Orbital welding on all piping with tri-clamp fittings.
- Respecting 3-D dead legs with the application of Zero-Static (0-Dead legs) components.
- All internal corners of the chamber have radiuses as per cGMP requirement.
CABINET WASHING SYSTEMS

For the perfect cleaning of large items
Steelco LC PH Series
Cabinet washing system

Chamber volume
from 4.250 litres / 150 cu.ft
                        to 10.500 litres / 371 cu.ft
in several different dimensions
with configurable options

With a full range of washing carts dedicated to:

- Glassware
- Filling line components and tools
- Tubing, TC fittings
- Valve and pump bodies, filter housings
- Punches and Dies
- Reactor vessels and diverse equipment
- Bulk containers, tanks and carboys
Advantages features

The Steelco LC PH range is a versatile system to wash containers, large components, ultracentrifuges, bulk chemicals: developed for all applications where it is necessary to treat large volume of items or large diameter components.

The machine base, manufactured with easy removable continuous modules, allows the operator to walk with safety on it. The lateral rotating washing tubes achieve perfect washing results.

High performance efficiency with steam heater versions available.

- ✔ Highest cleaning performance
- ✔ Easy cart connections
- ✔ Double drying unit with capacity of 1000 m³/hour
- ✔ Lateral rotating washing pipes with nozzles to assure a adequate cleaning of all parts of loaded items.
- ✔ Repeatable and validatable

From concept to execution

“Large object washed to pharmaceutical standard”
Steelco LC PH Series
Washers technical features

The washing chamber and water circuits are designed and constructed with extreme care, finishing with a minimum smoothness of Ra<0.5µm/19.7µ/in, with crevice-free construction of chamber, piping and racks in order to eliminate water retention and stagnation points where biofilm or corrosion could form.

Washing chamber manufactured in AISI 316L stainless steel and external body in AISI 304 stainless steel. AISI 316L stainless steel is used throughout the machine with EPDM, PTFE or other FDA approved gaskets (21CFR part 177).

All models features sloped base and rounded corners to ensure complete drainage. Extensive documentation is provided for the orbital welding.

Heaters
The heater is made to a special design to ensures self cleaning and avoid water stagnation points.

Filters
Air filtering system with HEPA, ULPA filters available option; DOP test connections and filter status check with pressure system.

Easy maintenance

Fully accessible operating area
The machine is developed taking into consideration access of technicians to the maintenance and service area. Easy access to all components, conforming to safety regulations.

Upper level can be walked on and is designed for easy maintenance access.
Construction features

Free draining surface
Extremely accurate project design for the elimination of water stagnation points, surface slopes and complete washing of the whole chamber interior.

Detail thoroughness
Each small cavity is reached. The complete washing of inlet connections for chemical products is assured with special dedicated nozzles.

Self cleaning chamber
Self cleaning chamber with nozzles positioned at critical points and sloped surfaces to ensure that no residual water is left.

Cleaning nozzles
Washing nozzles easy to disassemble for periodic maintenance.

Cleaning and inspection
Strong and easily removable grid: enables easy access for cleaning and inspection as well as a rigid stable surface to walk on.

Globally available components
Globally available components, e.g. Gemu, Bürkert, Itt process valves, are standard. Melted or forged, welded on pipe or fixed by clamps (other fittings on request).

Control system for chemical dosing with protection of components
“Large object washed to pharmaceutical standard”
Pharma carts and trolleys

*Standard and customized solutions*

Steelco’s experienced engineers using sophisticated design software ensure that each point, corner and cavity of the item to be processed is deeply and accurately washed.

This eliminates the possibility of cross-contamination and the deposition of residues from previous cycles.

The same injection ports can be used also to direct hot sterile filtered air inside each cavity for drying.

*Easy cart connection*

Examples of customized accessories for cart connection. Machines can be equipped with special cart connections for water injection. Manual or automatic versions are available.
Flexible cart configuration

Changing the dedicated insert/support the same wash cart can be used for different loads.

Specific solutions for the most challenging requests
Steelco LB Series
Bin Washer Solution

The Steelco LB Series is a system specifically designed for the cleaning and drying of containers and drums in pharmaceutical validated processes.

Custom made for individual customer needs, these units feature the possibility to rotate both the container being cleaned and/or the spray nozzle arm 360° inside the object ensuring exceptional cleaning of all surfaces of the container.

Field of application
Bins, drums, tanks, IBV, IBC

Mixed loads
The chamber can be configured for mixed loads.

Chamber volume
from 5,000 litres / 177 cu.ft
to 10,000 litres / 353 cu.ft
in several different dimensions
with configurable options

- Highest cleaning performance
- 360° continuous bin rotating during operation
- Continuous moving top spray arms
- Drying unit with 1000 m³/hour capacity
Steelco DS PL Series
Industrial challenging application washers

Steelco designs dedicated equipment for industrial demand, including petrochemicals, cosmetic and nutraceutical fields. Effectiveness, safety and high productivity equipment range.

Steelco Sterilizers Series
for life science and pharmaceutical production

Steelco offers an extensive range of steam sterilizing autoclaves for any size facility.
Steelco DS PL range
Industrial challenging application washers

Steam sterilizers VS L series
for pharma and research laboratories

Washers, disinfectors and automated systems
for animal cages, feeding bottles and fish tanks

Laboratory glassware
washing systems

Sterilization solutions
Serving the pharma industry worldwide

Headquarters and
Center of washing systems production

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