

High purity systems overview



spirax
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spirax **/sarco** your perfect partner for high purity systems

The design of high purity steam and water systems is a complex and involved discipline. To ensure that your system is designed in accordance with current Good Manufacturing Practice (cGMP) you need a partner who understands your processes. Spirax Sarco will support you through every step of the project life cycle, as well as offering an extensive after sales service.

Since pioneering the first clean steam trap, high purity has been a focal element of our operations and is reflected today by our comprehensive product range.

Our global network of specialist engineers means we can provide you with total system solutions wherever your location. Proven system engineering experience guarantees compliance with current health and safety and regulatory requirements, ensuring your system is safe, reliable, productive and energy efficient. Ultimately this will result in a reduction in your operating costs and carbon footprint.



Consultation

- The world's leading authority on steam system engineering.
- Helping you to reduce costs and CO₂ emissions while improving efficiency.
- Members of ASME-BPE and ISPE, assures a global understanding of current and future industry requirements.

Design and project management

- Solutions incorporating:
 - cGMP regulations
 - ASME-BPE
 - ISPE Baseline Guides
- Global network of specialist design engineers.
- Design capabilities and flexibility to meet individual user requirements.
- Project management to support the whole life cycle of your project.



Manufacturing capabilities

- 11 Strategically placed manufacturing sites.
- Specialist facilities for high purity manufacturing.
- Dedicated full wet Factory Acceptance Test (FAT) facilities.
- Package fabrication & component manufacturing.

Worldwide support

- Customer focus with over 4 000 employees globally servicing over 100 000 customers.
- Global company with local service support.
- Steam quality testing.
- Service agreements.
- Training.
- Instant access to critical spares and replacements locally.

Water treatment and purified water

We offer complete solutions that will meet and exceed your water treatment requirements; whether provision of pre-treatment technologies to ensure consistent supply to downstream final processing steps or solutions for compendial purified water and highly purified water production.

We can help determine the equipment required to reach maximum efficiency levels whilst maintaining compliance, We can also fully support you with validation and engineering services.

Key features and benefits:

- Wide array of treatment technologies
- Purified water exceeding U.S, European and Japanese Pharmacopeia requirements
- cGMP design and regulatory compliance
- Good automated manufacturing practice (GAMP) qualified automation solutions
- Standard and bespoke packaged solutions



Preheating and degassing unit

A packaged system developed for feedwater treatment in steam generation for high purity applications. Our design pre-heats your feedwater to provide a constant water temperature; this maintains generator efficiency and removes unwanted pressure fluctuations, improving your steam quality.

The design also guarantees a reduction in the O₂ and CO₂ content of your system feedwater, ensuring conductivity compliance and low non-condensable gas content.

Key features and benefits:

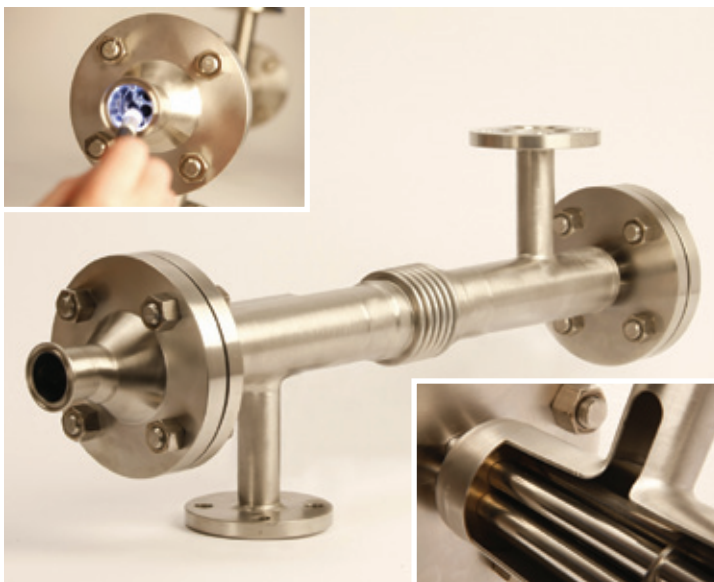
- Improved steam quality and purity
- Removal of feedwater pressure fluctuations
- Increased steam generator efficiency
- Sanitary modular design
- Storage tank with active level and temperature control
- External heat exchanger for ease of maintenance

Storage and distribution

In addition to purified water and water for injection (WFI) production, as part of an integrated system approach we are also able to provide complete storage and distribution systems, increasing system integrity and pharmacopeia compliance.

Key features and benefits:

- Single source and integrated system approach
- cGMP and ISPE Baseline principles
- Extensive system engineering experience



Sanitary heat exchangers

To ensure purified water and WFI system sterility, sanitary heat exchangers are required to heat and cool your media. Spirax Sarco has a dedicated range of double tube sheet, fully drainable sanitary heat exchangers available to ensure system optimisation.

Key features and benefits:

- Fully drainable
- Highest quality surface finish for all wetted parts
- Designed in accordance to ASME BPE, FDA, cGMP as well as PED and ASME
- Full manufacturing and material documentation

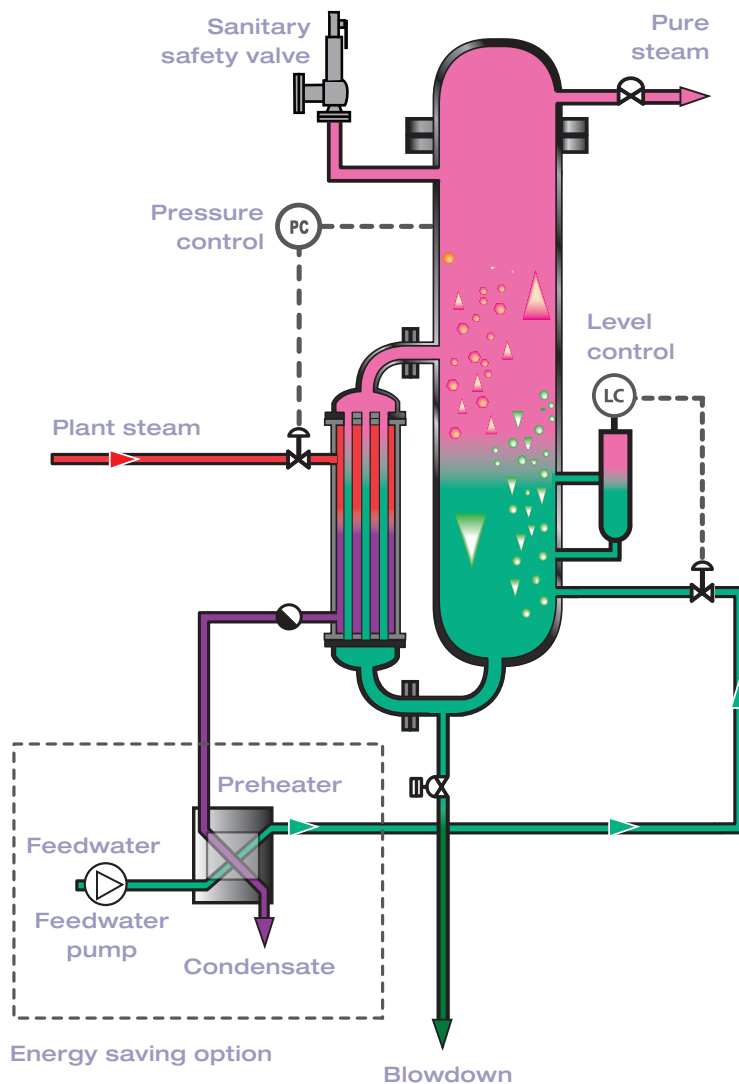
Pure steam generator

Spirax Sarco's range of pure steam generators (PSGs) is designed to the high requirements of the bio-pharmaceutical sector. They provide pure, dry, pyrogen free steam, which when condensed complies with international pharmacopoeia requirements for WFI. Steam quality will always satisfy the requirements of HTM 0101 (previously HTM 2010) and EN 285 as a minimum.

Our PSGs use Spirax Sarco components, guaranteeing quality and functionality throughout the supply chain, allowing access to critical spares locally across the globe, minimising downtime.

Where plant steam is not available, an electrically powered unit can be supplied, and where small quantities of WFI are required, an external sanitary condenser can be provided.

Operating principles



Key features and benefits:

- Capacity range from 50 kg/h
- External evaporator simplifies maintenance
- Unique optimised separation method
- Full PID level control for safe consistent performance
- In-house design and manufacture
- cGMP double tube sheet heat exchanger, ensuring high quality control and consistency
- cGMP design and regulatory compliance
- Preheater / degasser available for the reduction of non-condensable gases

WFI multi-effect still

Our range of Multi-Effect Stills (MES) is designed to produce international pharmacopoeia grade WFI.

Multi-Effect technology is a robust, proven and efficient method for the generation of such a critical product. In-house production means complete control of components, resulting in end-product reliability and reduced maintenance costs and carbon footprint.

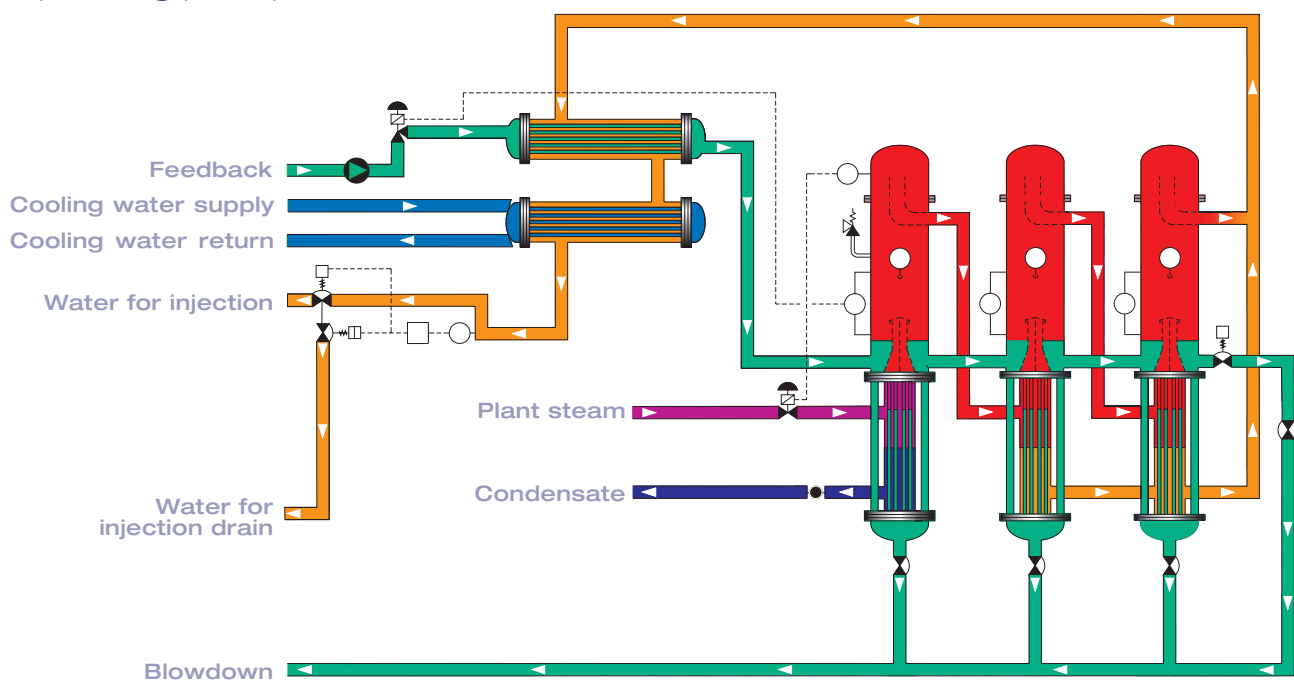
Options include the ability to supply pure steam from the first effect.



Key features and benefits:

- Capacity range from 100 l/h
- Optimised column selection for energy efficiency
- First effect PID level control guarantees consistent system efficiency
- In-house design and manufacture, including cGMP double tube sheet heat exchanger, ensuring high quality control and consistency
- The number of effects can be optimised to your requirements in order to increase energy efficiency and further enhance your life cycle costs

Operating principles



High purity distribution systems

Our entire high purity range of products are designed and manufactured to suit the demanding requirements of the high purity industry.

All components are designed to ASME-BPE and incorporate cGMP requirements. Product contact parts are universally 316L stainless steel with certified surface finishes applicable to process needs, with all elastomers conforming to FDA requirements. Each product range is available with various connections; from plain butt-weld ends suitable for orbital welding, to sanitary clamp ferrule connections.

All products are available with supporting documentation for material traceability, surface finish, elastomer FDA and USP Class VI compliance, and certificate of conformance.

SSC20 sample cooler



Designed for the quick and safe sampling of high purity media, a counter current flow is utilised to maximise cooler efficiency, resulting in a compact, space saving design.

Applications include clean steam, pure steam and hot WFI sampling.

Sanitary pressure gauge



The sanitary pressure gauge incorporates a diaphragm sealed pressure transducer suitable for high purity processes.

Applications include pure steam and high purity water distribution networks.

M70i and M80i sanitary ball valves



The M70i and M80i sanitary ball valves are designed in accordance with ASME BPE for sanitary requirements. Features include, full bore design and optional USP Class VI compliant cavity fillers.

Applications include pure steam isolation.

CS10 separator



The CS10 is a unique product that has been developed to enable clean and pure steam systems to comply with the dryness requirements of standards EN 285 and HTM 0101.

Applications include pure steam distribution networks and delivery lines to sterilizers.

Sanitary steam traps



A comprehensive range of thermodynamic and thermostatic steam traps developed for clean and pure steam applications. The range includes units that minimize condensate back-up for critical steam-in-place applications and high-flow capacities for dual CIP/SIP processes.

Applications include drainage of steam distribution lines, sterile steam barriers, SIP processes, fermenters and sterilisers.

STERI-TROL sanitary control valve



A pneumatically actuated, 2-port or 3-port angle pattern, sanitary control valve. Utilised for on/off or modulation control of high purity fluids.

Applications include pure steam and high purity water flow control for user points such as sterilisers, process equipment and CIP/SIP.

SRV66 sanitary pressure reducing valve



The SRV66 is a free draining direct acting pressure regulating valve suitable for fluid pressure control.

Applications include clean/pure steam, liquid and pure gas distribution, to bio-reactors, centrifuges, freeze dryers, sterilisers, process tanks and humidification.

SVL488 sanitary safety valve



The SVL488 is an all 316L stainless steel full lift safety valve, suitable for clean and pure steam, gas and liquid applications.

Ancillaries - check valve and sight glass



A range of sanitary check valves and sight glasses are provided as ancillary products to complement the high purity distribution range.

Can be used in steam, liquid or gas applications.

Compliance

Factory acceptance testing (FAT)

Every Spirax Sarco high purity system is subject to a full wet FAT at our dedicated testing facility. This ensures the system is fully compliant to your requirements before installation on site. This exhaustive testing covers many of the criteria required during the installation qualification (IQ) / operational qualification (OQ) validation exercise, helping to speed up validation execution.

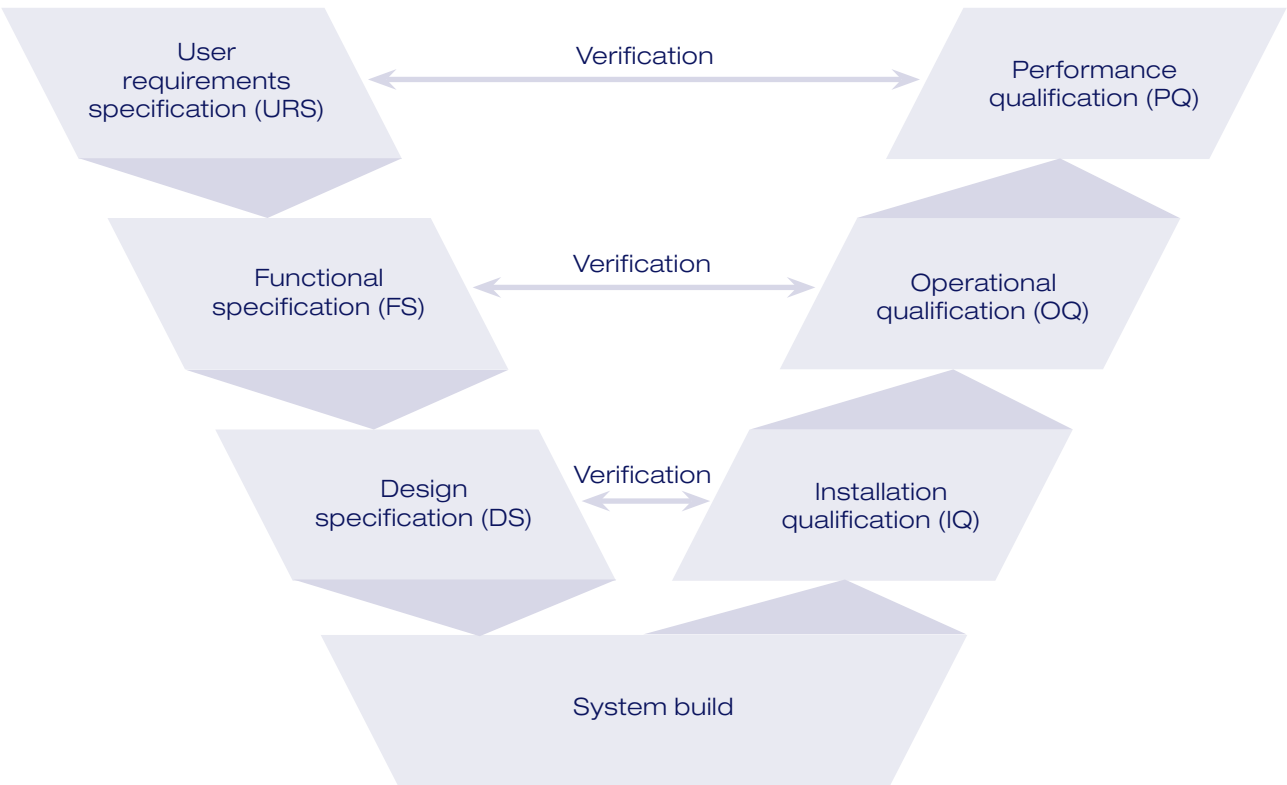
Qualification / Certification

We work within an ISO 9001:2000 audited system which encompasses good engineering practice (GEP) and good documentation practice (GDP) frameworks. Consequently, we are able to provide you with the necessary documentation to ensure validation compliance.

We develop system protocols for the project and equipment life cycle to achieve qualification milestones of design (DQ), installation (IQ) and operation (OQ). Enhanced with structured change-management procedures and supporting documentation, we verify full traceability and qualification from user requirement specification (URS) to performance qualification (PQ). Adopting the latest industry and cGMP practices we ensure that your system is qualified and certified to your regulator's highest expectations.

Our qualification and certification packages are supported by in-house activities which include:

cGMP orbital welding	316L SS fabrication	Electropolishing	Radiographic testing
Surface finish testing	Dye penetration	Pressure testing	Boroscope inspection





Dedicated service support

You have now improved the efficiency of your high purity system and will wish to maintain it at such a level. Therefore, outsourcing the maintenance and service to us is a cost-effective solution to make life simpler and safer for you.

Our global coverage means you have local engineers available to tailor your service agreement in-line with your budget and carry out routine and preventative maintenance. This will ensure that your processes are trouble-free and always provided with the correct steam, at the correct quality.

You will also have the reassurance that all products purchased from Spirax Sarco are made in-house using quality components, accompanied with the necessary warranty.

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Mexico
USA

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China
India
Japan
Korea
Malaysia
Singapore
Taiwan
Thailand

Australasia

Australia
New Zealand

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Syria



Some products, services or solutions may not be available in certain markets