



# Pharmaceutical Steam System Capabilities

Sustainability in Pharmaceutical Manufacturing

*First for Steam Solutions*

EXPERTISE | SOLUTIONS | SUSTAINABILITY

**spirax**  
**sarco**

# Comprehensive steam system solutions for sustainable pharmaceutical manufacturing

## At Spirax Sarco we take steam system engineering best practice very seriously indeed

Everything we do is focused on one purpose - to ensure steam of the correct quality and quantity is generated, distributed, and arrives at point of use. We relentlessly apply engineering best practice to deploy safe, compliant, and sustainable plant and process steam systems.

We understand, from vitamins to vaccines, the global pharmaceutical industry works relentlessly in the pursuit of one simple but often complex goal - to improve the quality of life.

It is widely recognised that steam is a highly efficient thermal energy transfer fluid. It is therefore critical that the thermal energy transfer attributes of steam (Steam Quality to EN 285 standard) are correctly managed from generation, through distribution, to each point of use. Furthermore, it should be noted that a mechanically correct and appropriately maintained plant and process steam system underpins sustainable operations. These critically important factors enable a reduction in energy consumption and carbon intensity through the optimisation of the boiler's duty cycle, allowing sustainability goals to be met, maximising process productivity, whilst ensuring health and safety measures are kept paramount.

As a world leading authority, through the application of steam system engineering best practice, we support sterile and non-sterile pharmaceutical manufacturing to comply with

stringent industry legislation, health and safety, and current Good Manufacturing, Engineering, and Documentation Practices (cGMP, cGEP, and cGDP).

Our innovative solutions ensure the correct quality and quantity of steam arrives at the point of use. The optimal thermal energy transfer attributes of steam (Steam Quality to EN 285 standard) directly impact sustainable production, through increased productivity, minimal downtime, and ultimately reducing operational cost and carbon emissions. We always treat the plant and process steam system as one – they impact each other.

Our capabilities extend across the complete plant and process steam system, including dedicated packaged solutions, such as heat exchangers and process steam generators (producing chemical free steam for non-sterile manufacturing facilities).

Supported by our global network of specialist engineers we are able to tailor our knowledge to benefit your specific operation. We can assist you from system concept and design, to operational energy management, striving to ensure we support your ongoing sustainable manufacturing challenges.

Ultimately, Spirax Sarco take time to deeply understand your steam system requirements, and the exacting standards that the pharmaceutical industry demands.

## Your trusted sustainable steam and thermal energy partner:

- Comprehensive steam system advice applied to your plant and process operations
- Single source of supply for steam and thermal energy solutions from generation to point of use
- Compelling service and audit capabilities, from routine maintenance to detailed assessments
- Engineered packages for seamless integration and rapid field installation
- Reassurance of full compliance and supporting validation documentation
- Global presence, with local service and support
- Complete steam and thermal energy partners, from concept to operational management



## An integrated steam system requires an integrated solution approach

Spirax Sarco's unique capabilities encompass your complete plant and process steam system requirements, acting as a single source of supply, where sales and service solutions are seamlessly integrated to ensure maximum value to your operation.

### Focusing on your plant steam system

Spirax Sarco takes a holistic view of your complete plant steam system, as we know all too well the thermal energy transfer attributes of your plant steam system have a direct impact on your process steam system. It is therefore essential that good engineering practices are deployed to ensure your plant steam is dry, contains minimal non-condensable gases, and minimal superheat, as these factors negatively impact efficient thermal energy transfer.

Spirax Sarco offer a comprehensive range of generation, distribution, and point of use control solutions to ensure steam of the correct quality and quantity arrives at point of use first time, every time. Spirax Sarco continually strive to deploy complete steam system optimisation solutions to support your safe, compliant, and sustainable operations.

- Steam quality management and steam system optimisation
- Steam system auditing and service capabilities
- Steam boiler optimisation and control
- Instant hot water and temperature control
- HVAC and humidification steam related solutions
- Steam distribution, control, and condensate return solutions

### Complete thermal energy packages solutions

Spirax Sarco offer standard and bespoke engineered packages – from process heating to energy saving solutions. All Spirax Sarco packages are sized, pre-assembled, inspected, and factory tested for optimum performance and seamless integration, allowing rapid installation with minimum disruption to your manufacturing operations.

### Focusing on you process steam system

Building on our complete steam system approach, Spirax Sarco's process steam capabilities have grown in strength and depth, forming a critically important part of our business since we pioneered the first true sanitary steam trap in the 1980s. Spirax Sarco's class leading ISO 7 cleanroom manufacturing capabilities ensure that we take every possible step to mitigate contamination risk, from generation, through distribution, to deliver steam of the correct quality and quantity at point of use, first time, every time.

- Process steam quality management and steam system optimisation
- Steam system auditing and service capabilities
- Clean-in-Place (CIP), Sterilise-in-Place (SIP), and direct steam injection solutions
- Sterilisation of pharmaceutical products, process vessels, and equipment
- HVAC and humidification process steam related solutions
- Process steam distribution and point of use control solutions
- Chemical free process steam (from a CSG) for non-sterile manufacturing

## Fully compliant documentation is critical to process quality

At Spirax Sarco we work within a fully accredited ISO 9001 and ISO 14001 system, to ensure quality throughout our operations

Our ISO 9001 and ISO 14001 accredited manufacturing operations are strategically located around the world as we continue to meet the complex demands of the pharmaceutical industry. Our ISO 7 cleanroom manufacturing capabilities ensure we take every possible step to mitigate sources of contamination risk through our broad portfolio of process steam distribution and control offerings.

Our fully compliant documentation and supporting validation certification is harmonised to the stringent control standards of the global pharmaceutical industry, ensuring full compliance with current Good Manufacturing (cGMP), Engineering (cGEP), and Documentation (cGDP) Practices. Spirax Sarco's process solutions are fully compliant with current and future legislation through relentless attention to detail and continuous improvement.

### Spirax Sarco sanitary process steam distribution and control offerings

- All Spirax Sarco sanitary process steam distribution and control offerings are fully USP, FDA, and ASME-BPE compliant, complete with supporting EN 10204 3.1 validation documentation
- Spirax Sarco process steam offerings deliver world class performance with ease of use, whilst mitigating contamination risk, supported by clear maintenance schedules
- Spirax Sarco's ISO 7 cleanroom manufacturing capabilities ensure cGMP, cGEP, and cGDP compliance



Our products and packages, where appropriate, are supported with full documentation covering:

- Supporting EN 10204 3.1 validation documentation
- Welding inspection
- Technical datasheets and drawings
- Factory Acceptance Test (FAT) protocols
- Pressure and integrity testing
- Design, Installation, and Operation Qualification protocols
- Full material certification
- Standard Operations Procedures (SOPs)
- FDA, USP, and ASME-BPE compliance
- Installation, service and maintenance manuals
- Surface finish certification
- Welding dossiers

“Spirax Sarco’s solution cut our implementation costs and gave us the compact, high efficiency solution we needed.”

Gilead Alberta spokesperson, Canada

## Steam quality management ensures mitigation of contamination risk, and efficient thermal energy transfer across the complete steam system

Keeping your steam system at optimum efficiency not only reduces your total cost of ownership, but also increases production efficiency, whilst meeting stringent standards and regulation. Our global network of more than 1200 specialist steam system engineers enable us to support you, wherever your location.

### Benefit from our steam system engineering knowledge and expertise

We apply steam system engineering best practice to meet your plant and process steam system challenges worldwide. Our local engineering teams are ready to support you to enable your steam systems and associated equipment to run efficiently and effectively, whilst providing you with the assurance necessary to support local assessment and legislation.

### Spirax Sarco will focus on your complete steam system, allowing you to focus on your operations

Spirax Sarco's comprehensive steam system audits focus on Steam Quality Management encompassing safety, mitigation of contamination risk, and sustainability improvements through rigorous management of steam's thermal energy transfer attributes. Furthermore, Spirax Sarco's City & Guilds accredited Steam Quality Testing Training course ensures globally recognised EN 285 testing standards are universally applied.

Our qualified, knowledgeable, and experienced engineers will work alongside your team to sustain and improve your plant and process steam system. We will ensure robust steam system practices are deployed to enable safe, compliant, and sustainable operations, providing you with the reassurance that steam of correct quality and quantity arrives at point of use, first time, every time.

Moreover, our preventative maintenance programmes support your critical to quality systems which are subject to continuous performance evaluation.

### Spirax Sarco take every possible step to mitigate sources of contamination risk

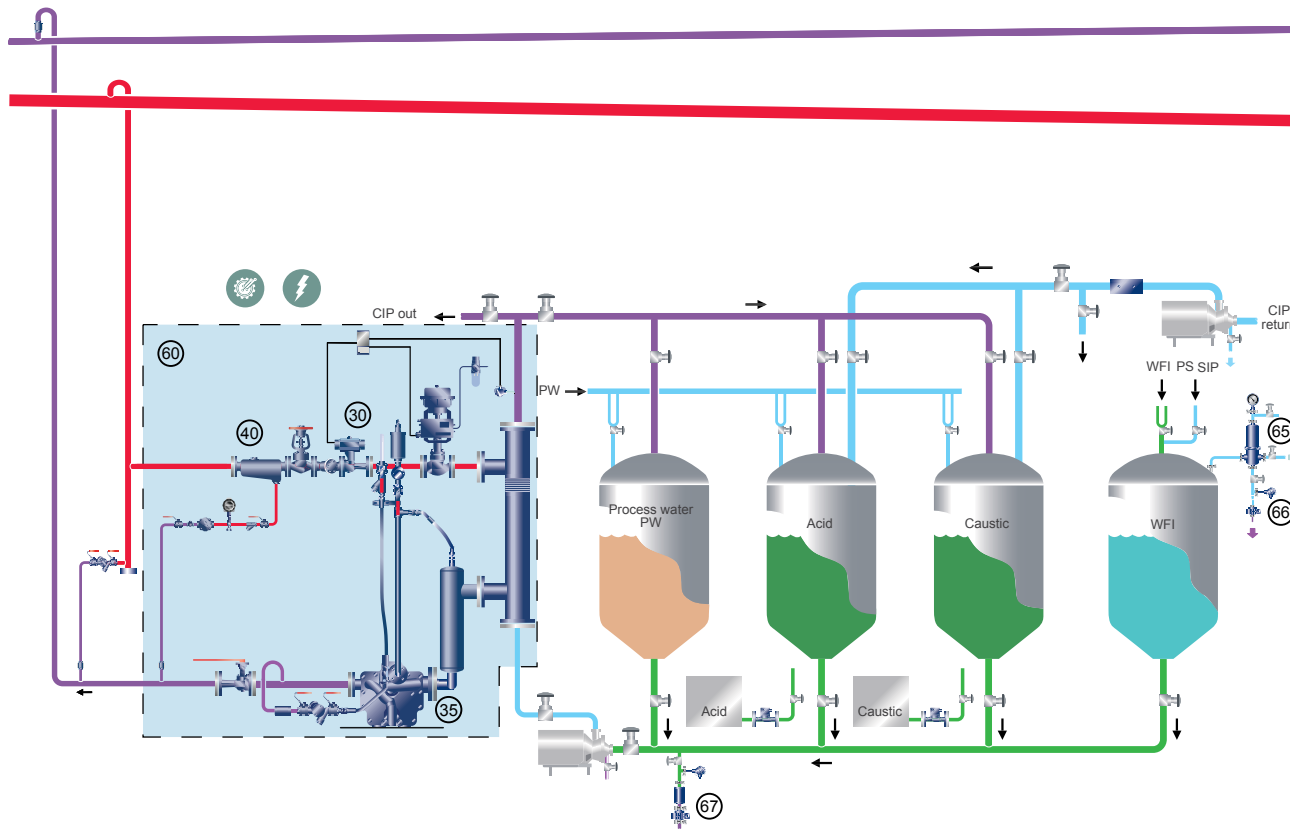
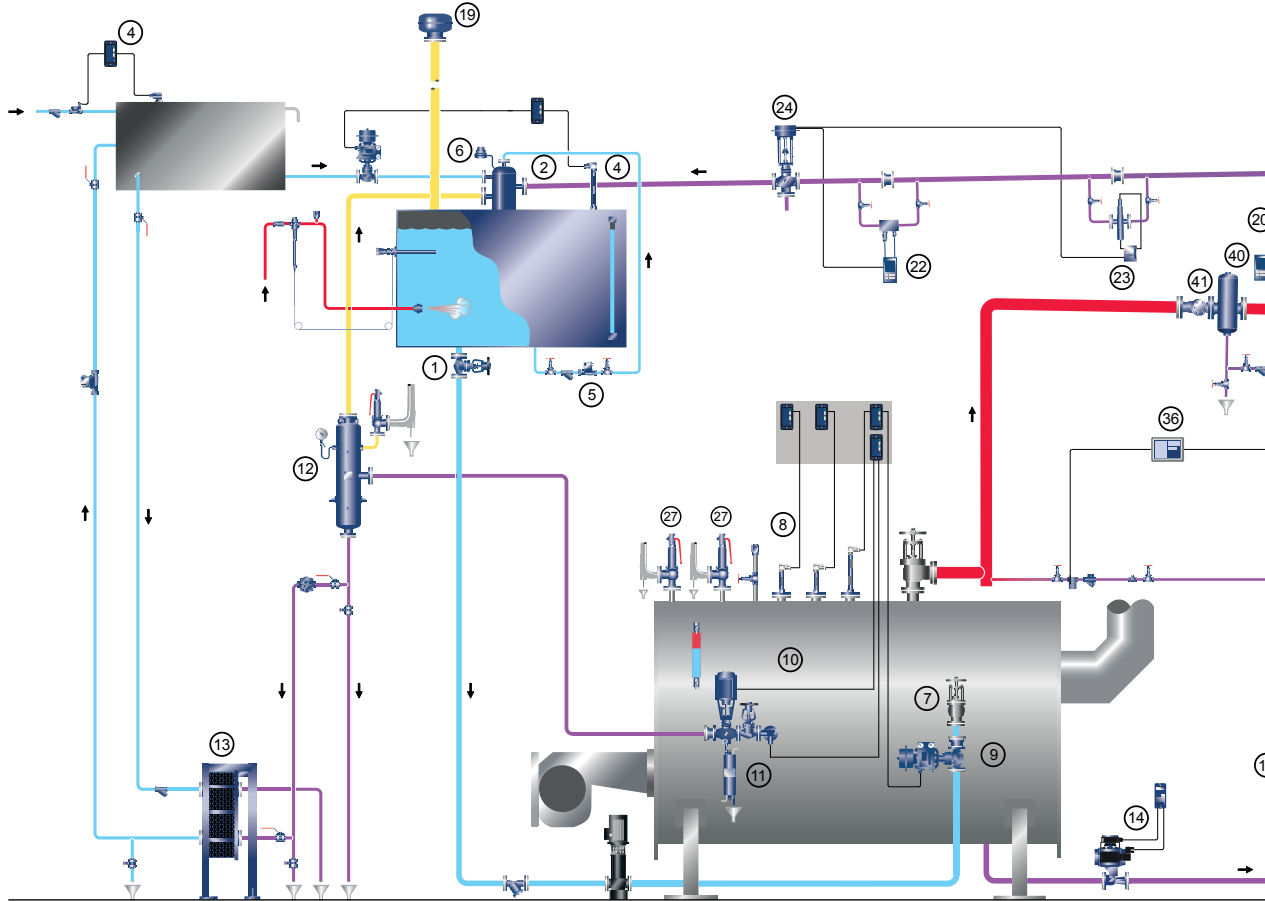
Spirax Sarco relentlessly strive to exceed customer expectations across our process steam system offerings, through good manufacturing practices, continuous improvement, and meticulous attention to detail.

Our world class ISO 7 cleanroom manufacturing capabilities ensure our sanitary process steam offerings are fully compliant, with supporting EN 10204 3.1 validation documentation traceability as part of our manufacturing process.

Spirax Sarco actively embrace and uphold current Good Manufacturing (cGMP), Engineering (cGEP), Documentation (cGDP) Practices throughout our production facilities.

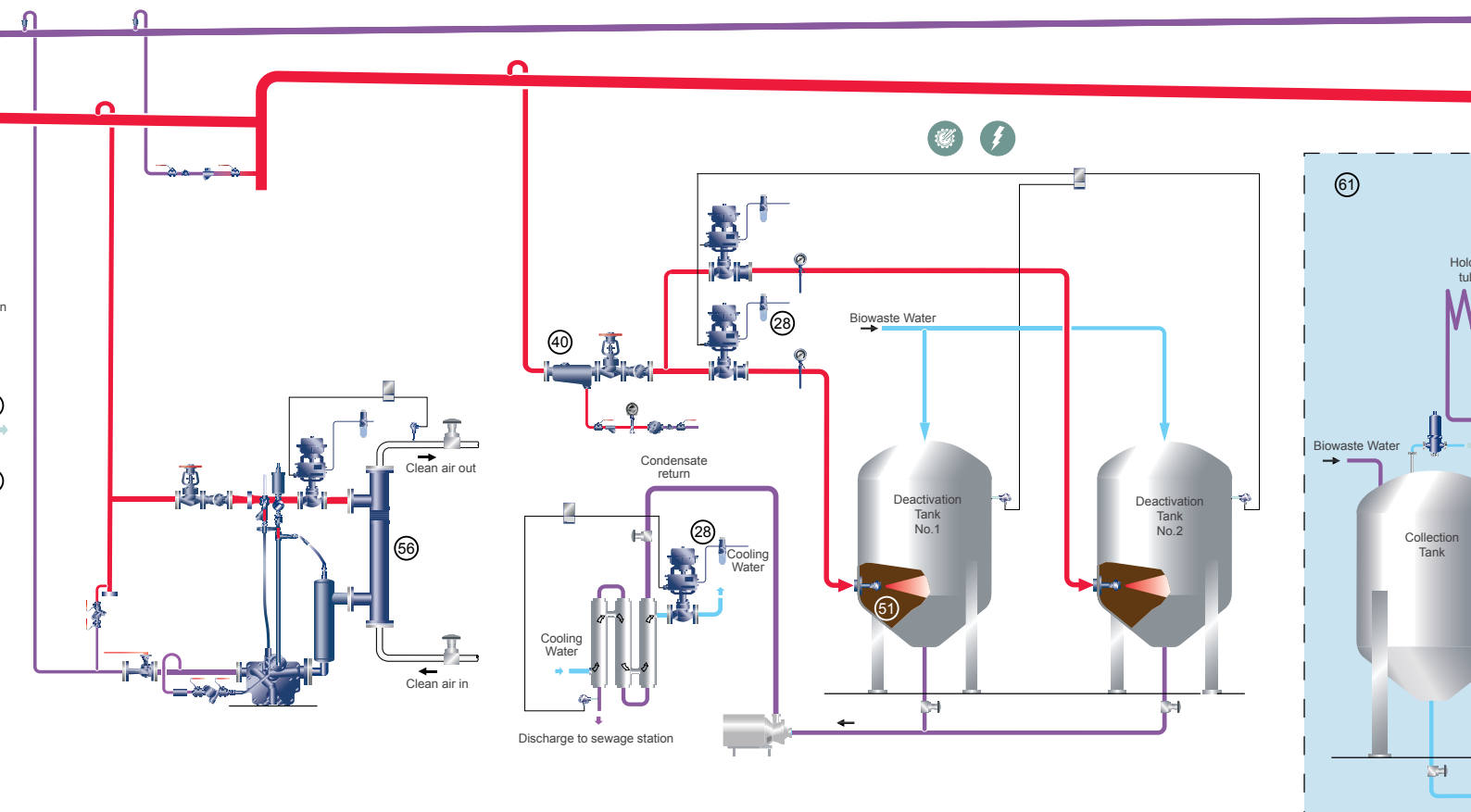
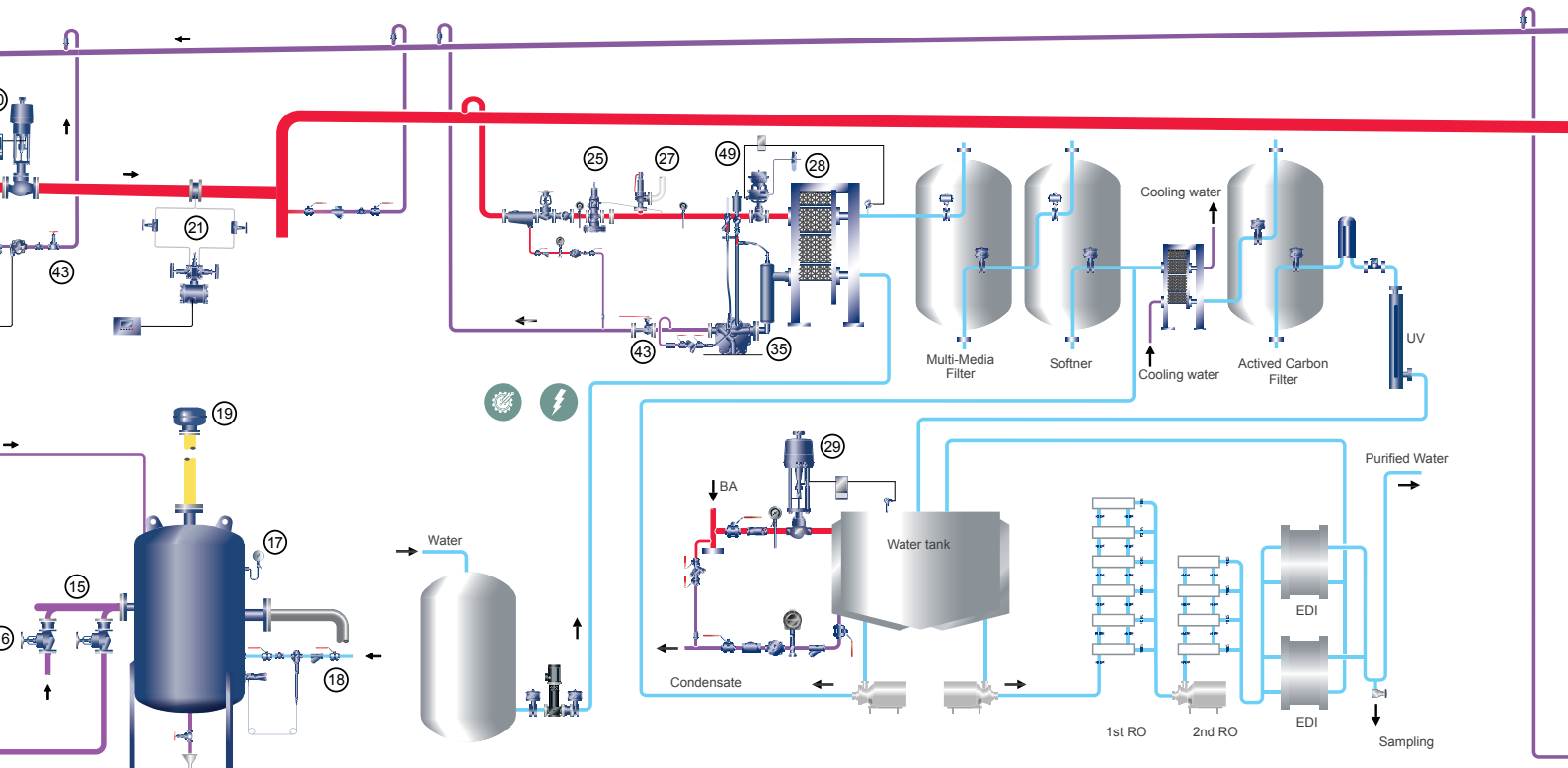


# Plant utility steam generation and distribution



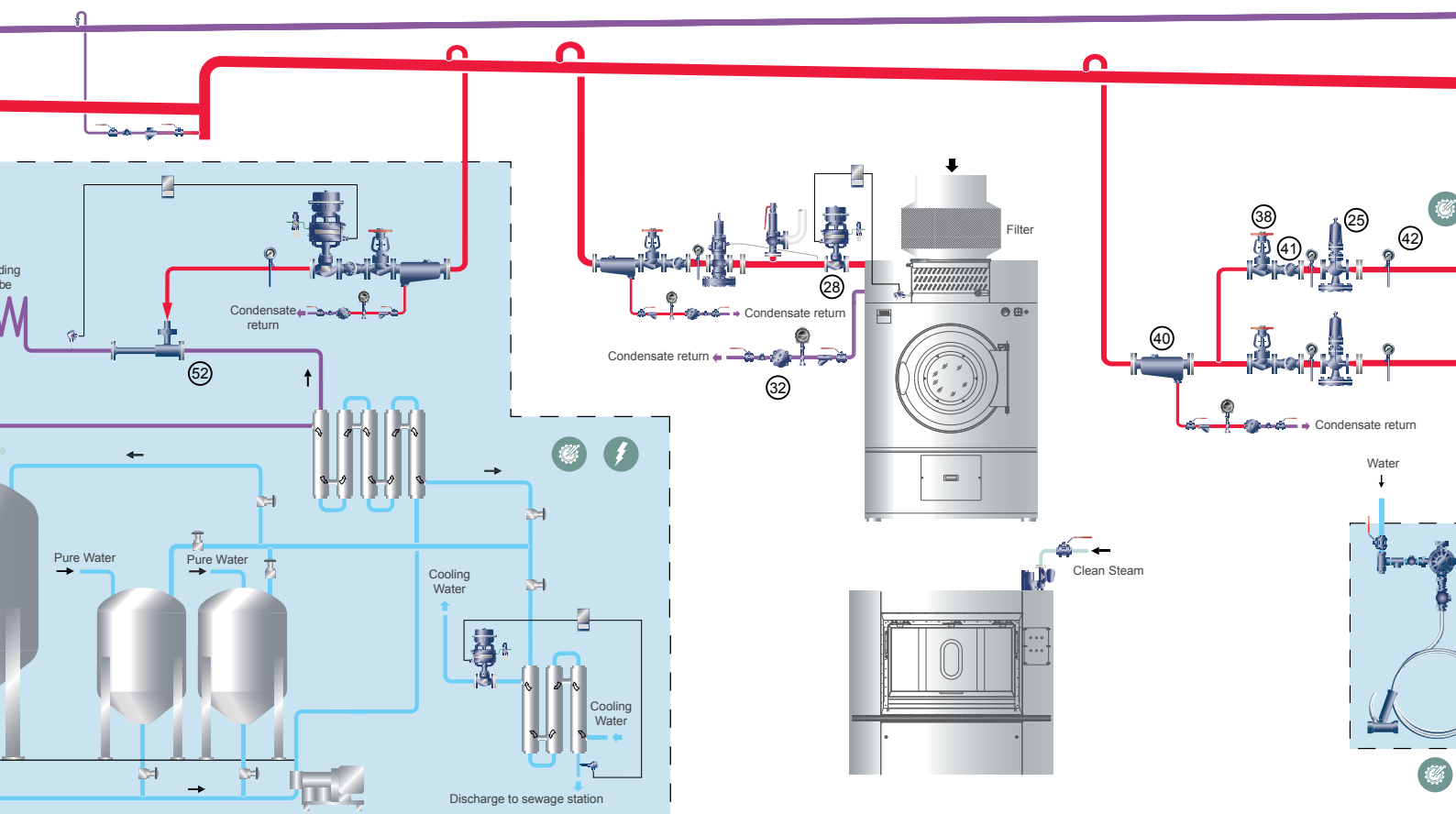
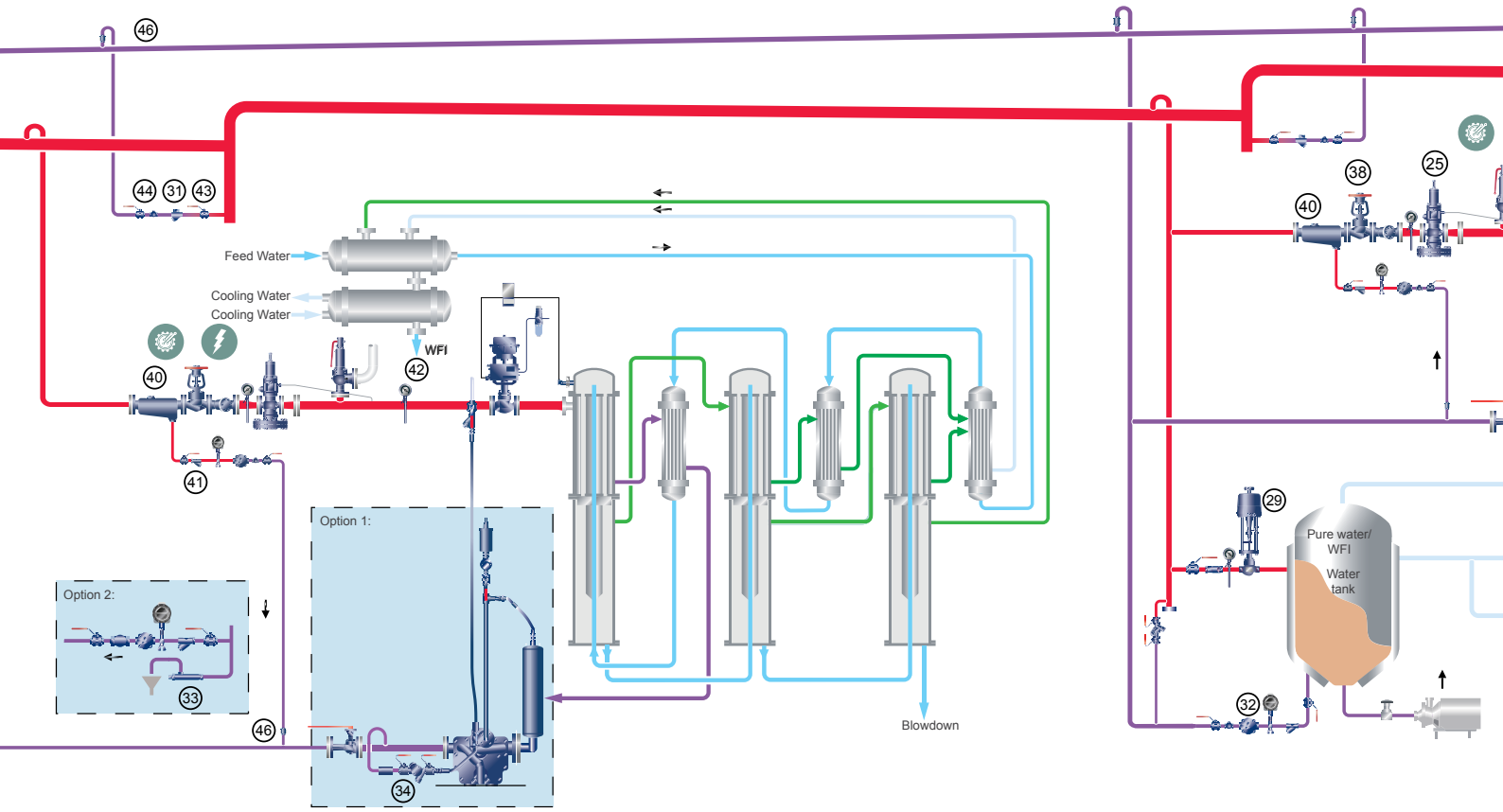
# Clean-In-Place (CIP) station

# Preparation of pure water



Air heating for drying

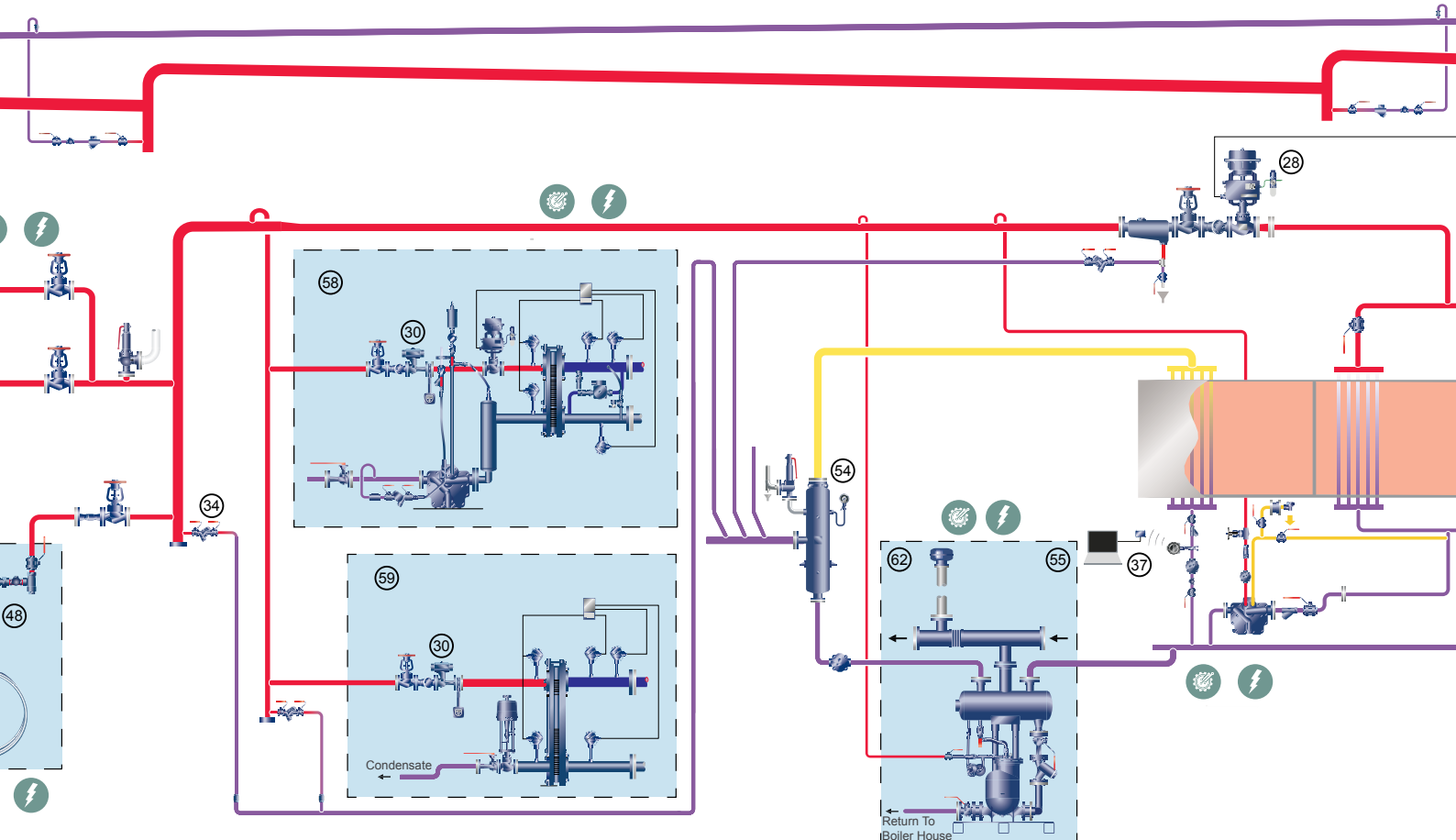
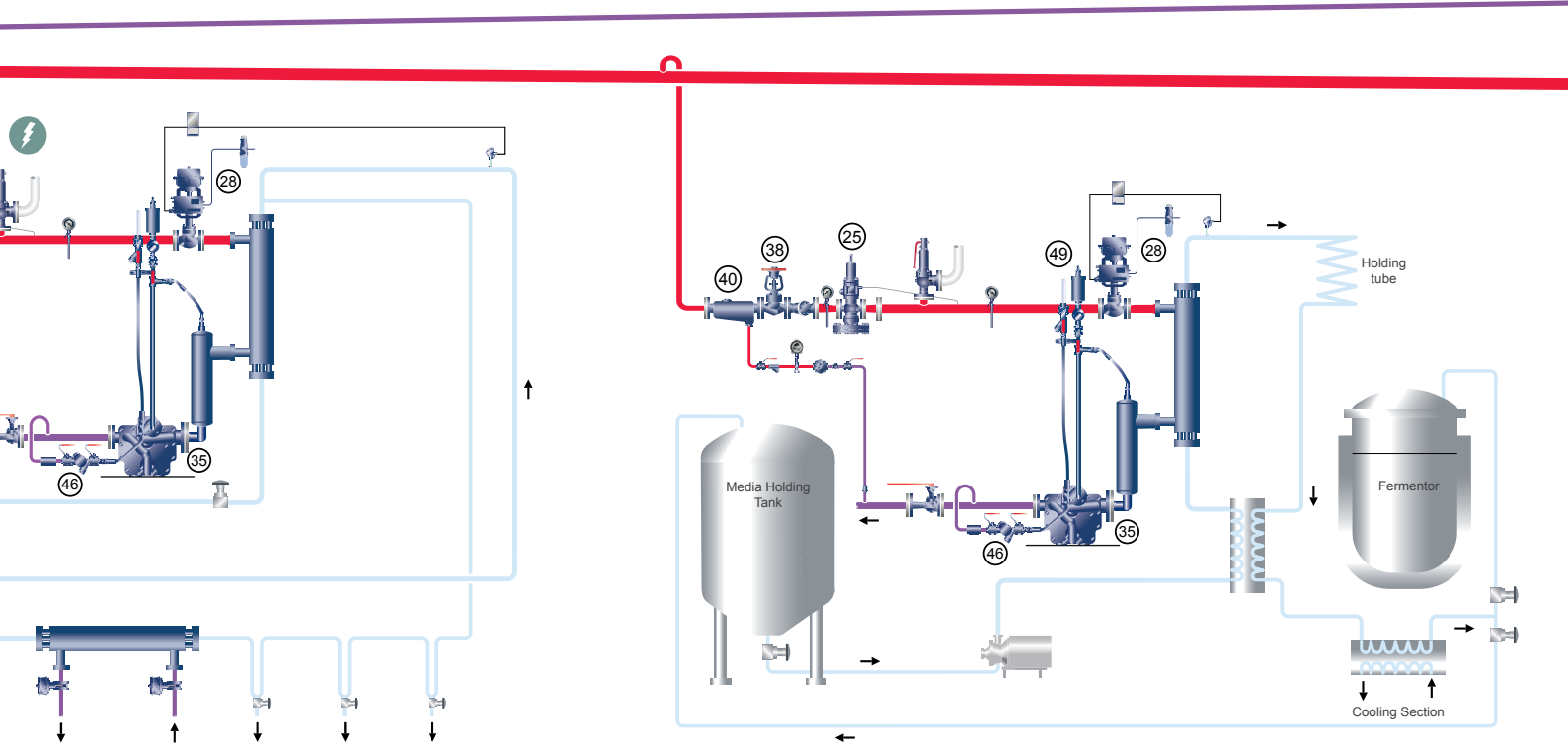
Inactivation of viruses in a biological wastewater treatment system - sequencing batch

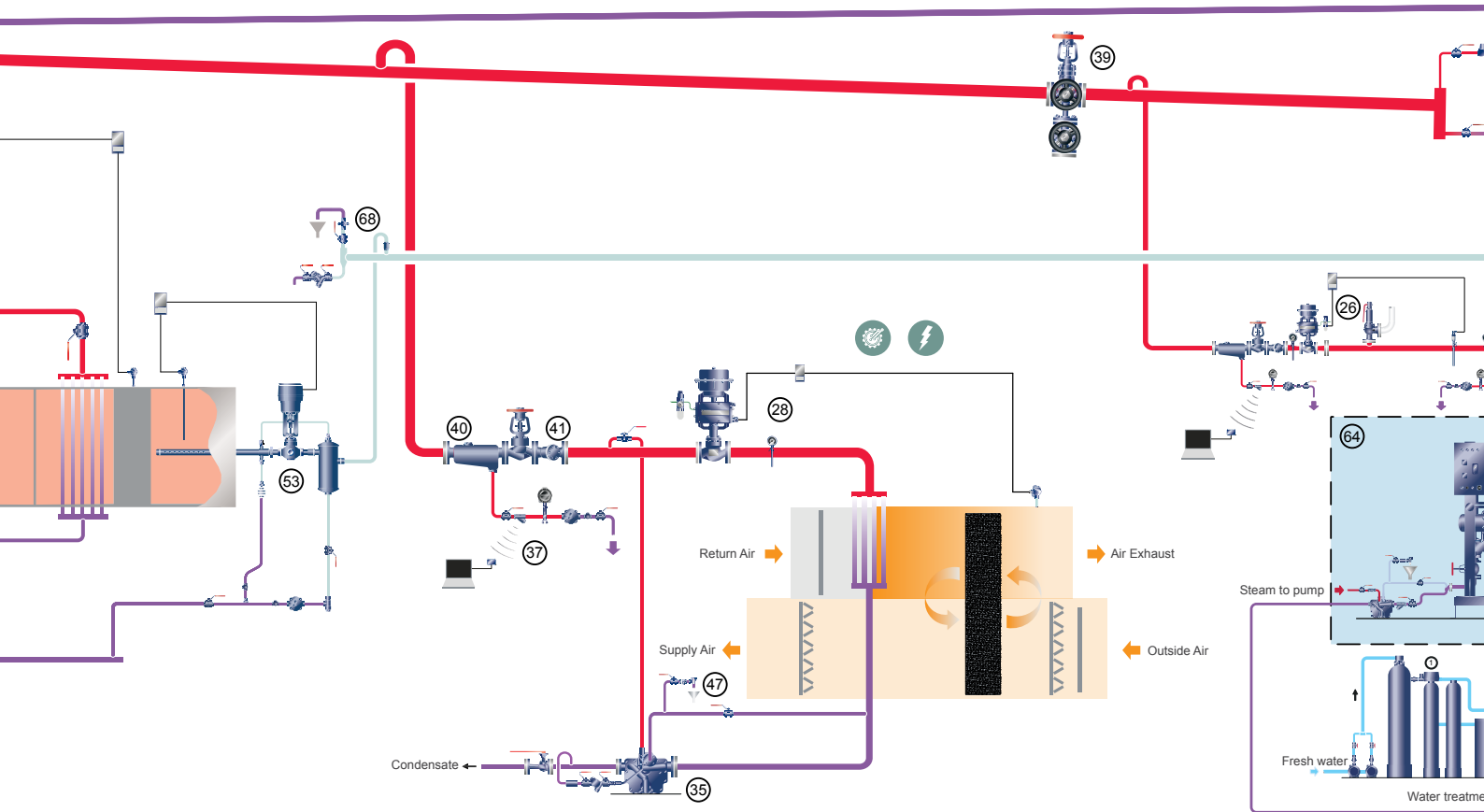
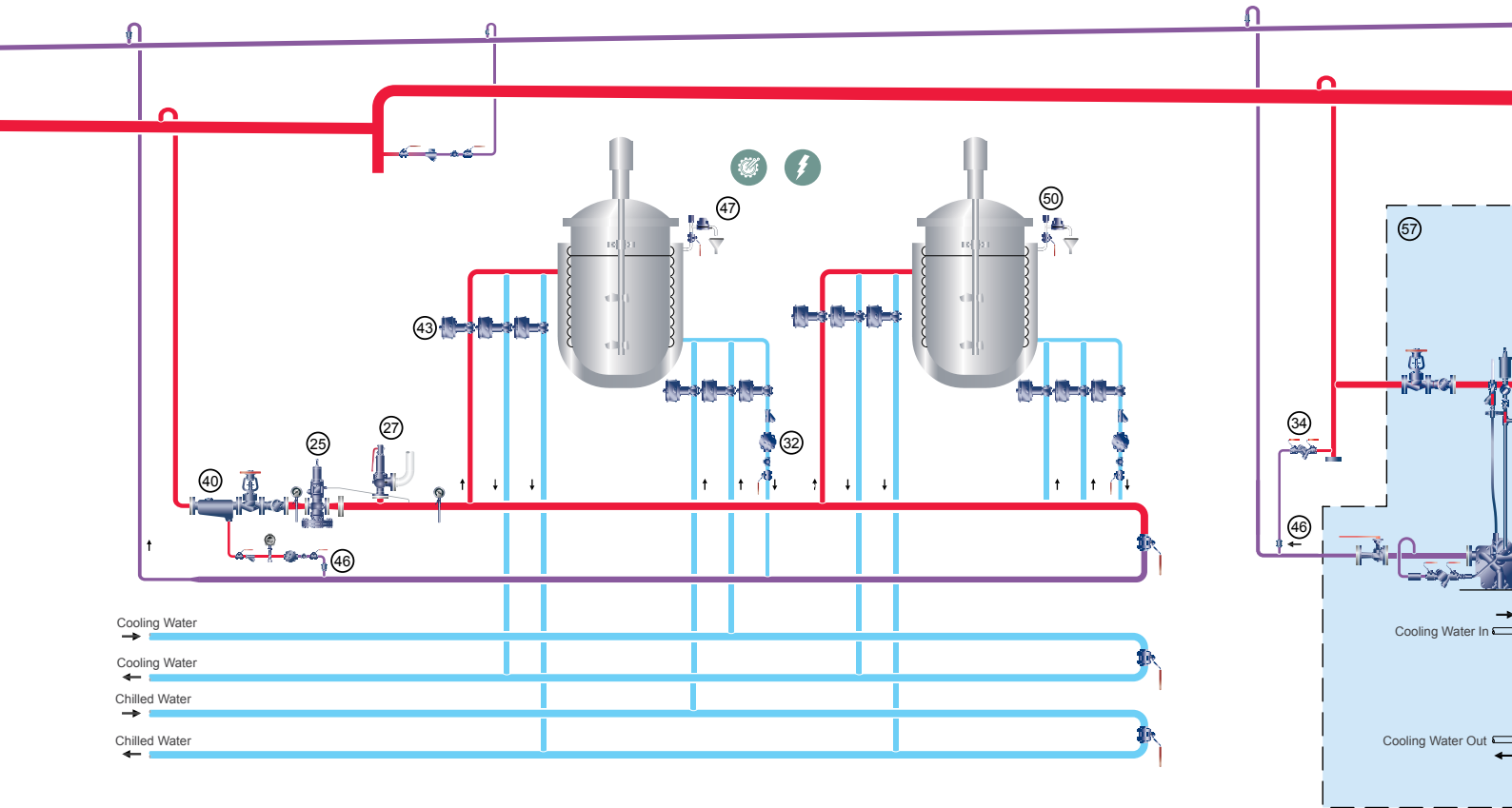


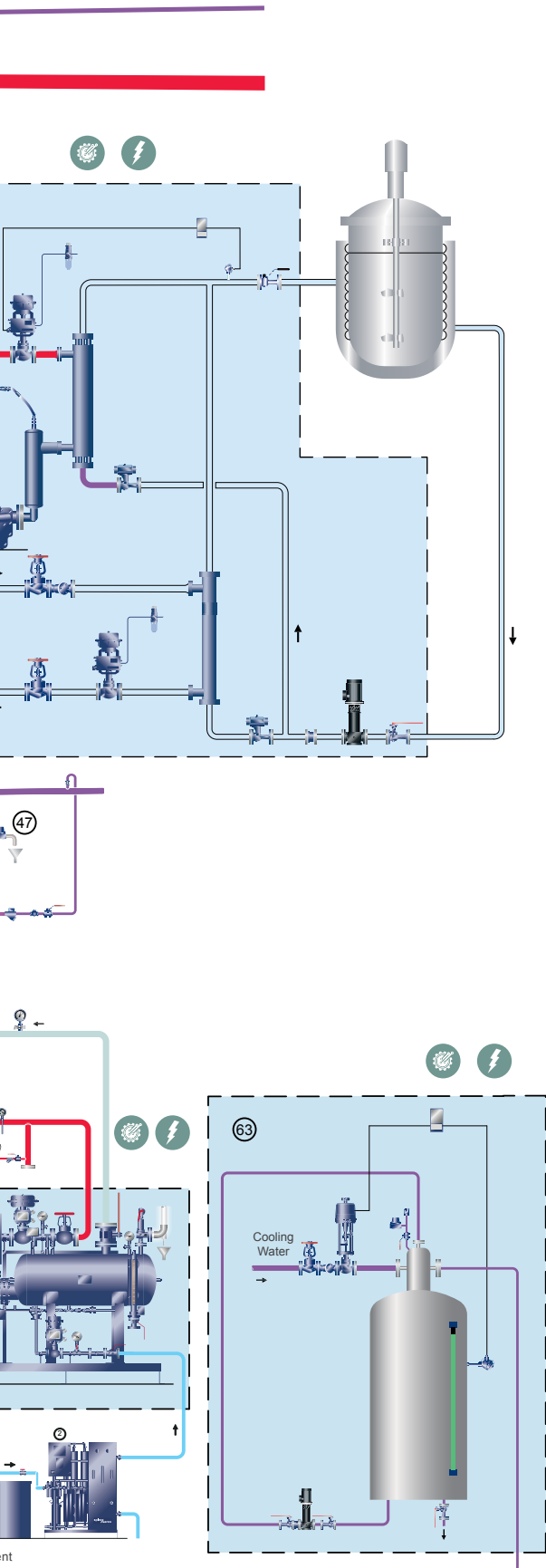
Inactivation of viruses in a biological wastewater treatment system - continuous

Ultra clean washer and dryer

Pressure reduction system and cleaning station







## Boiler room water supply and water supply treatment

- 1 Water supply tank
- 2 Deaerator head
- 3 Steam injection and temperature control system
- 4 Liquid level control
- 5 Recirculating system
- 6 Blowoff valve and vacuum breaker

## Boiler room water supply and boiler liquid level control

- 7 Proportional water supply control
- 8 High and low liquid level alarm
- 9 Liquid level regulating valve and check valve

## Continuous blowdown system for the boiler

- 10 TDS automatic control system
- 11 Sampling cooler

## Blowdown heat recovery

- 12 Flash tank
- 13 Heat exchanger for waste heat recovery

## Bottom blowdown system

- 14 Boiler bottom drain valve
- 15 Water harvesting pipe
- 16 Stop valve and check valve
- 17 Blowdown tank
- 18 Cooling water temperature control system
- 19 Steam vent cap

## Steam start and metering

- 20 Steam mains start-up system
- 21 ILVA flowmeter system

## Condensate contamination detection

- 22 Conductivity detection system
- 23 Turbidity detection system
- 24 Condensate flow divider

## Pressure control system

- 25 Pilot operated pressure reducing valve
- Pneumatic pressure reducing valve
- 26 Safety valve
- 27

## Temperature control system

- 28 Pneumatic temperature control system
- Electric temperature control system
- High temperature cut-off protection
- 30

## Steam trapping and testing

- 31 Thermodynamic trap
- 32 Ball float trap
- 33 Shutdown drain trap
- 34 Ready-package trap station
- 35 Automatic trap valve/pump
- 36 Wired system for trap detection
- 37 Wireless system for trap detection

## Piping attachment

- 38 Bellows sealed cut-off valve
- 39 Dual flow shutoff valve
- 40 Steam-water separator
- 41 Filter
- 42 Pressure gauge
- 43 Manual or pneumatic ball valve
- 44 Check valve
- 45 View mirror
- 46 Silencer
- 47 Air vent valve
- 48 Steam-water mixing station
- 49 Air vent valve for the liquid system
- 50 Vacuum breaker
- 51 Steam ejector
- 52 Steam ejection heater

## Steam humidifier

- 53 Steam injection humidifier

## Flash steam and condensate recovery system

- 54 Flash tank - used to convert high-pressure water into usable secondary steam for preheating air duct heaters
- 55 Flash steam condenser

## Heat exchanger

- 56 Tubular heat exchanger

## Skid-mounted system

- 57 Temperature control unit
- 58 Domestic hot water heater
- 59 Air conditioner water heater
- 60 Process hot water system
- 61 Continuous inactivation system
- 62 Closed condensate recovery system
- 63 Condensate and flash steam cooling units
- 64 Chemical free steam from a CSG

## Pure steam system

- 65 Exhaust gas filter
- 66 Sanitary steam trap for CIP/SIP
- 67 Sanitary steam trap for CIP/SIP
- 68 Sanitary air vent



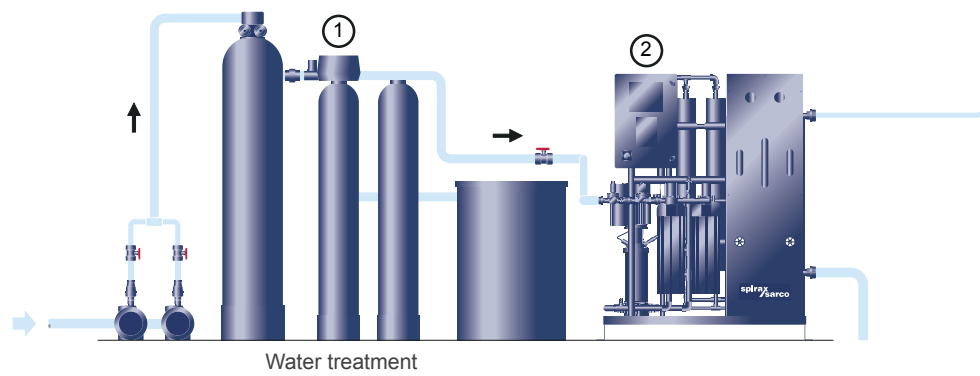
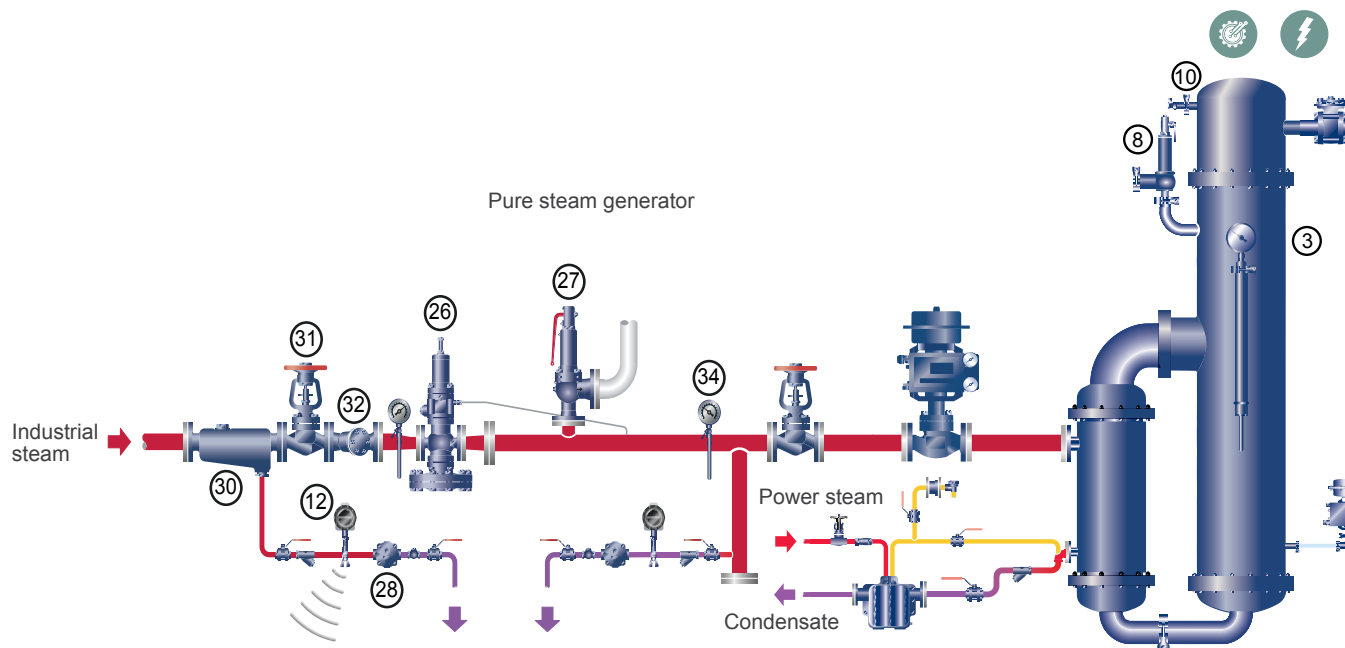
Critical control point

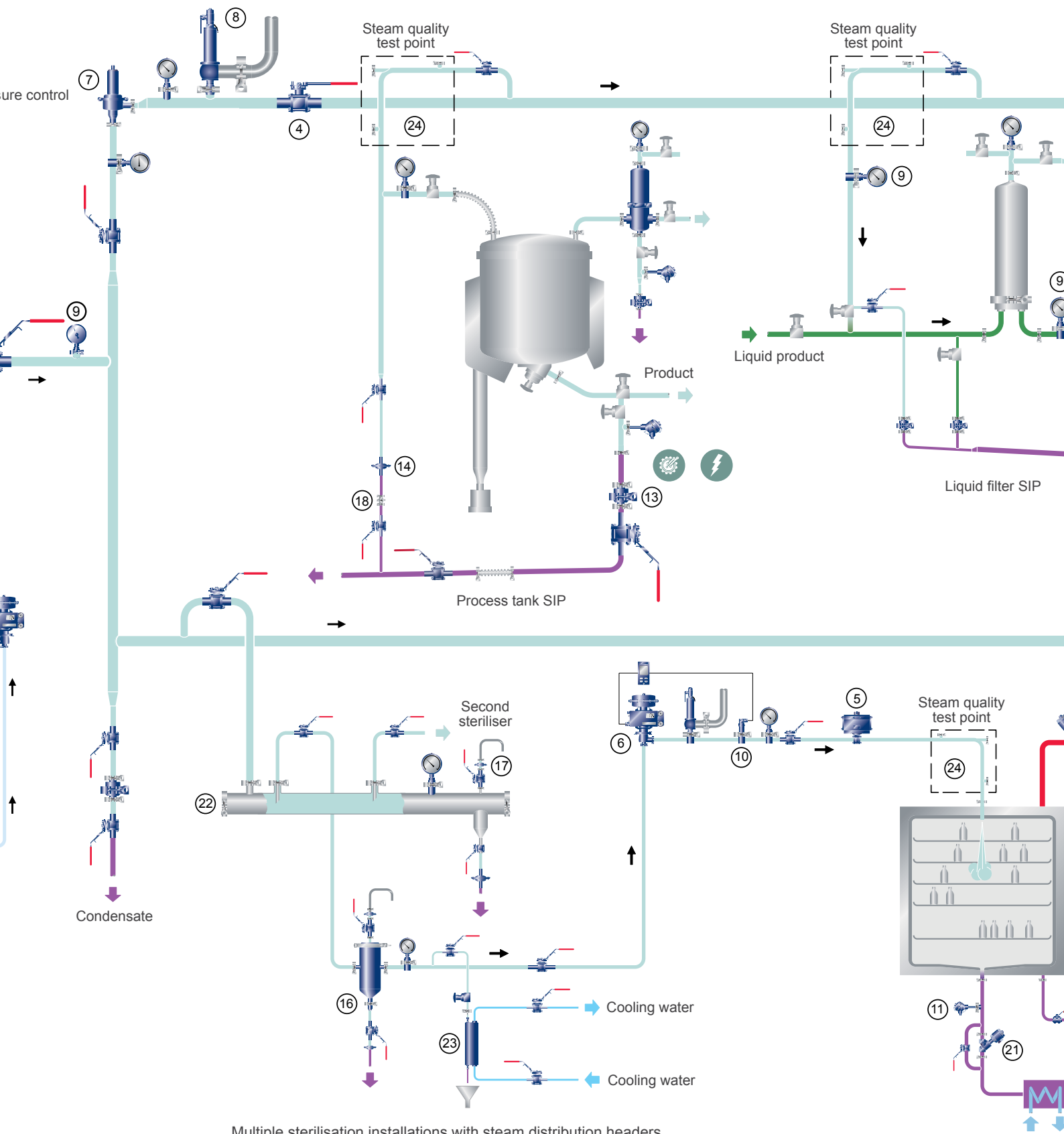


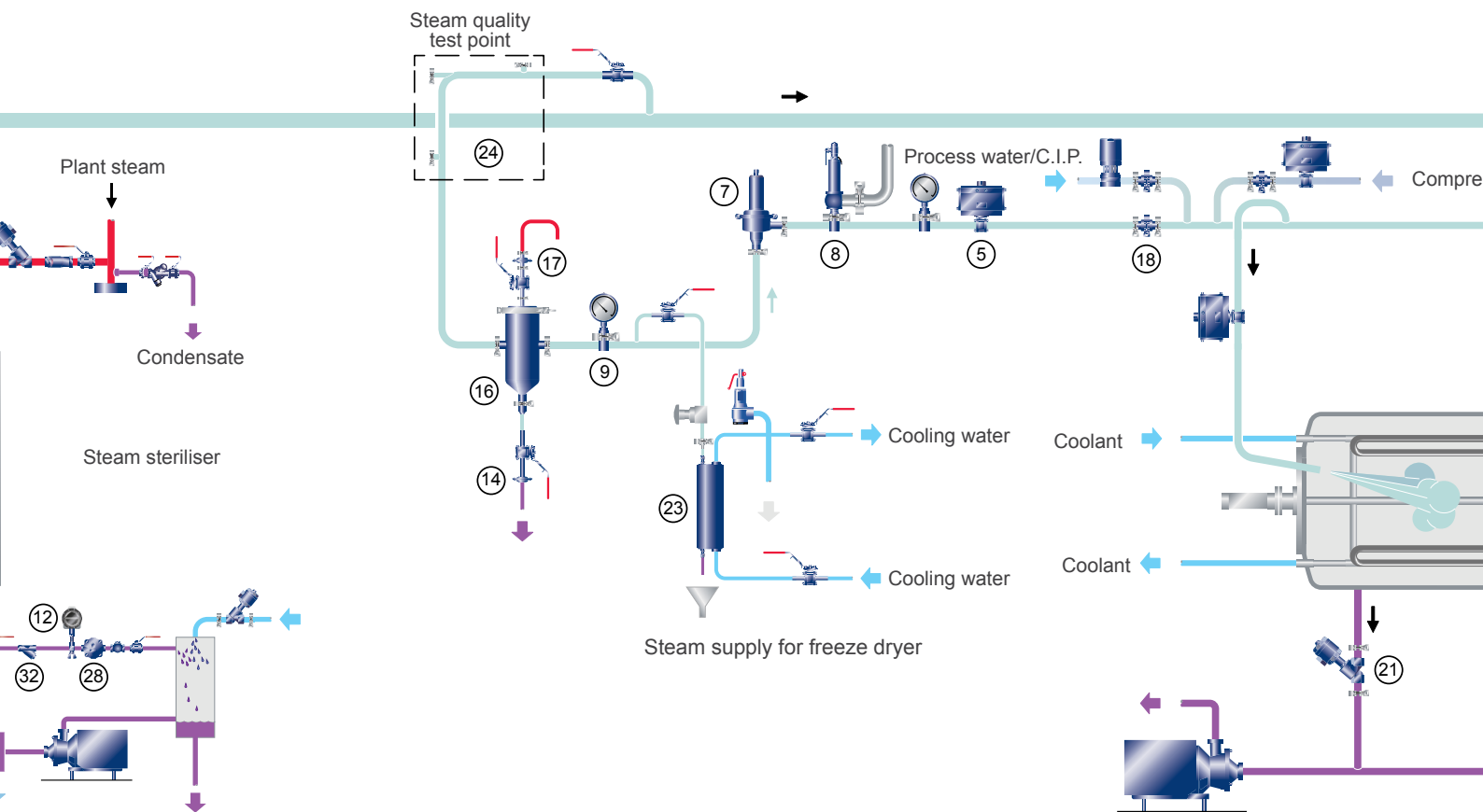
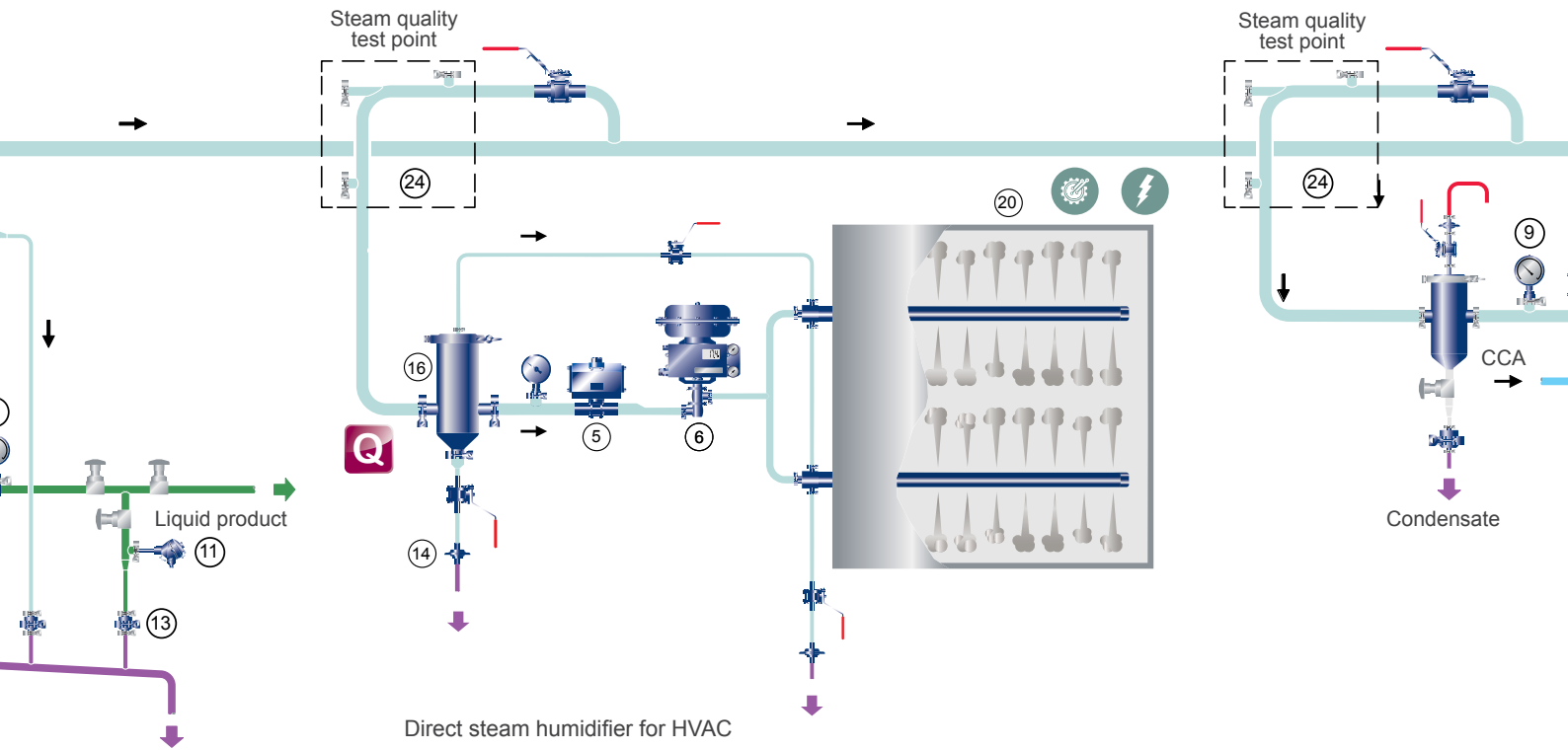
Risk point

# Pure steam generation

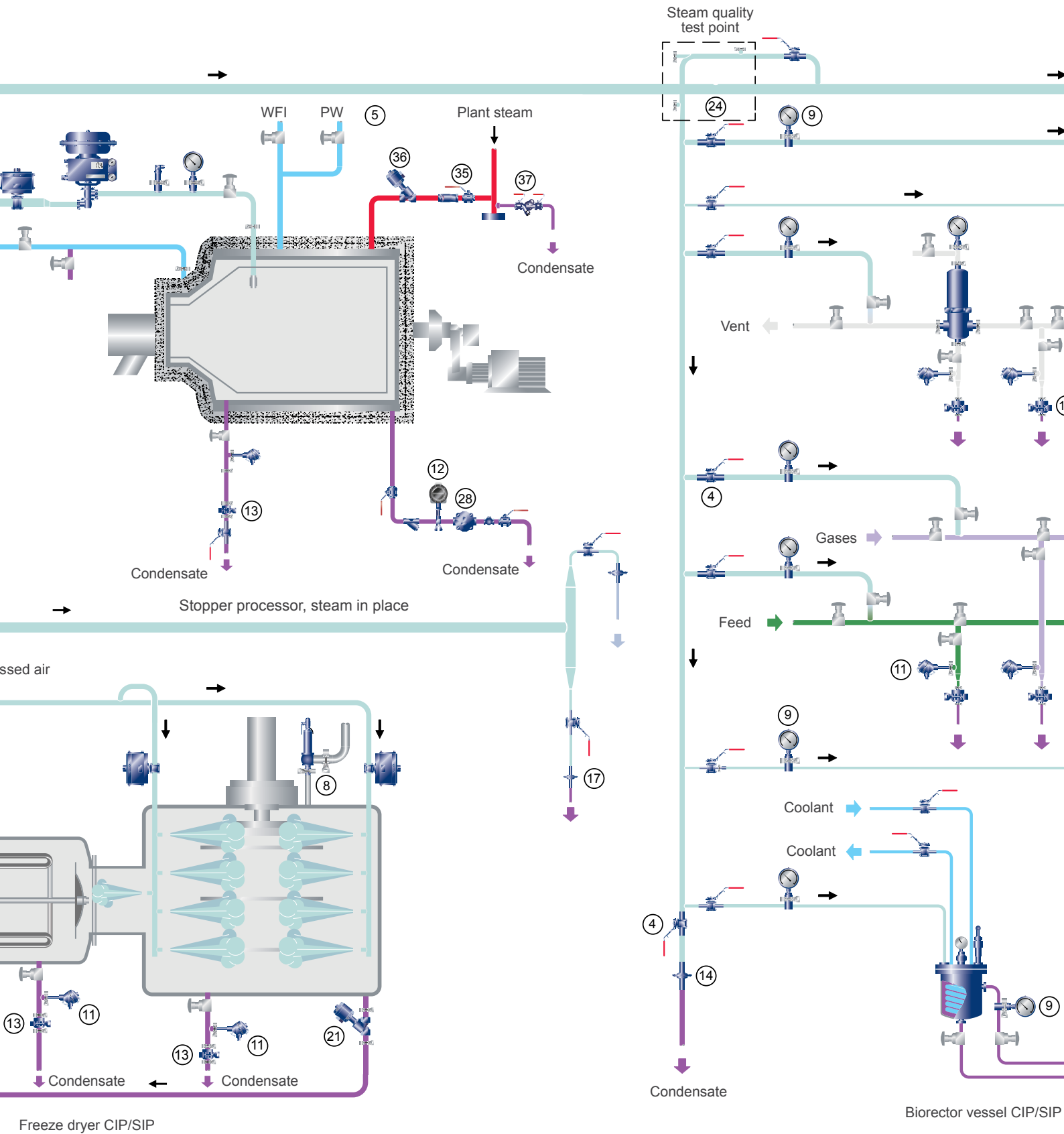
Press

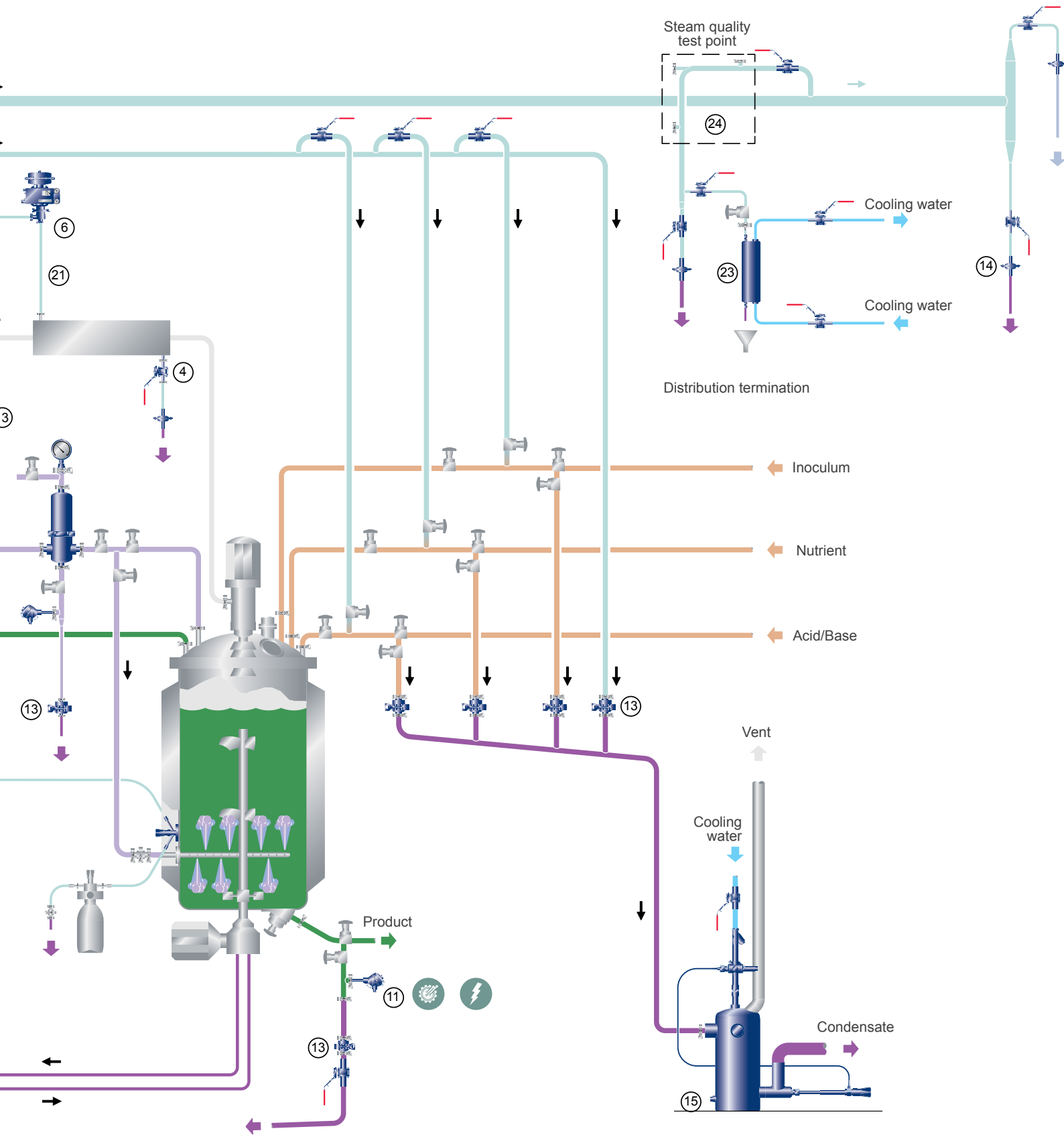






# Generation and points of use





## Equipment room

- 1 Water softener/water pre-treatment
- 2 RO water dispenser
- 3 Pure steam generator

## Pure steam system valve

- 4 Sanitary isolation ball valve (non-cavity fill)
- 5 Sanitary isolation ball valve (non-cavity fill)
- 6 Sanitary rising steam control valve
- 7 Sanitary self-acting pressure control valve
- 8 Sanitary safety valve

## Pure steam instruments

- 9 Sanitary pressure gauge
- 10 Sanitary pressure transmitter with hygienic pocket
- 11 Sanitary temperature transmitter with hygienic pocket
- 12 Wireless monitoring of STAPS trap

## Pure steam condensate

- 13 Sanitary steam trap
- 14 Sanitary steam trap
- 15 Flash steam/condensate cooler (non sanitary)

## Pure steam system accessories

- 16 Sanitary separator
- 17 Sanitary air vent
- 18 Sanitary check valve (available with hard and soft seat options)
- 20 Sanitary steam injection humidifier
- 21 Sanitary angle valve
- 22 HTM compliant steam header

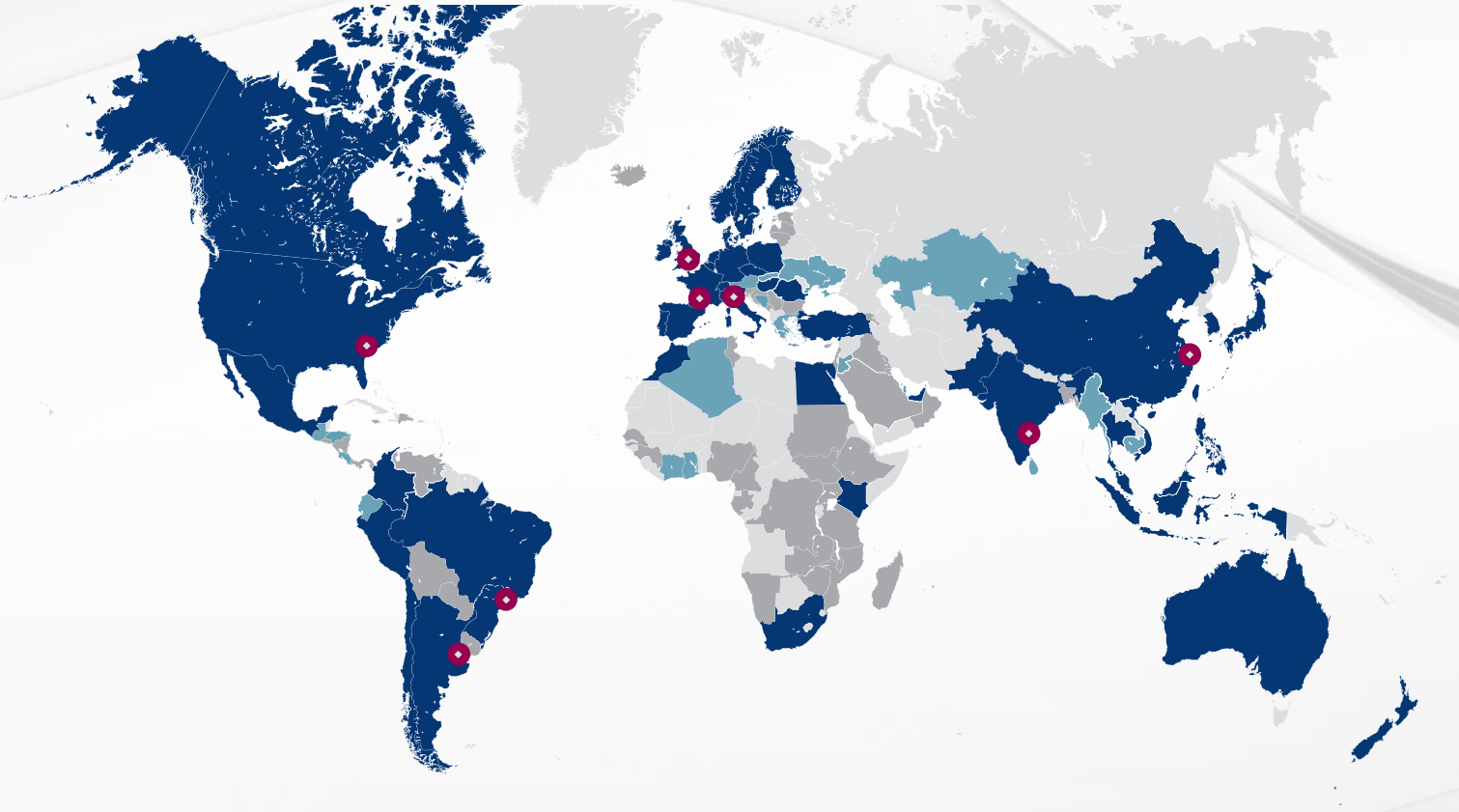
## Pure steam sampling to EN 285

- 23 Sanitary sample cooler for EN 285 steam quality testing
- 24 Sanitary steam quality testing points to EN 285 standard (pre-fitted to distribution/point of use pipework).

## Plant utility steam & condensate system

- 25 Pneumatic/electric control valve
- 26 Pilot operated pressure reducing valve
- 27 Safety valve
- 28 Ball float trap
- 29 Automatic trap valve/pump
- 30 Steam-water separator
- 31 Stop valve
- 32 Filter
- 33 Air vent valve
- 34 Pressure gauge
- 35 Ball valve
- 36 Pneumatic valve
- 37 Integrated steam trap station

**IMPORTANT NOTE:** Plant steam quality has a direct impact on process steam quality (whether pure steam for sterile manufacturing, and chemical free steam for non-sterile manufacturing)



**Operating Companies**

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