

WFI Reverse Osmosis Generation



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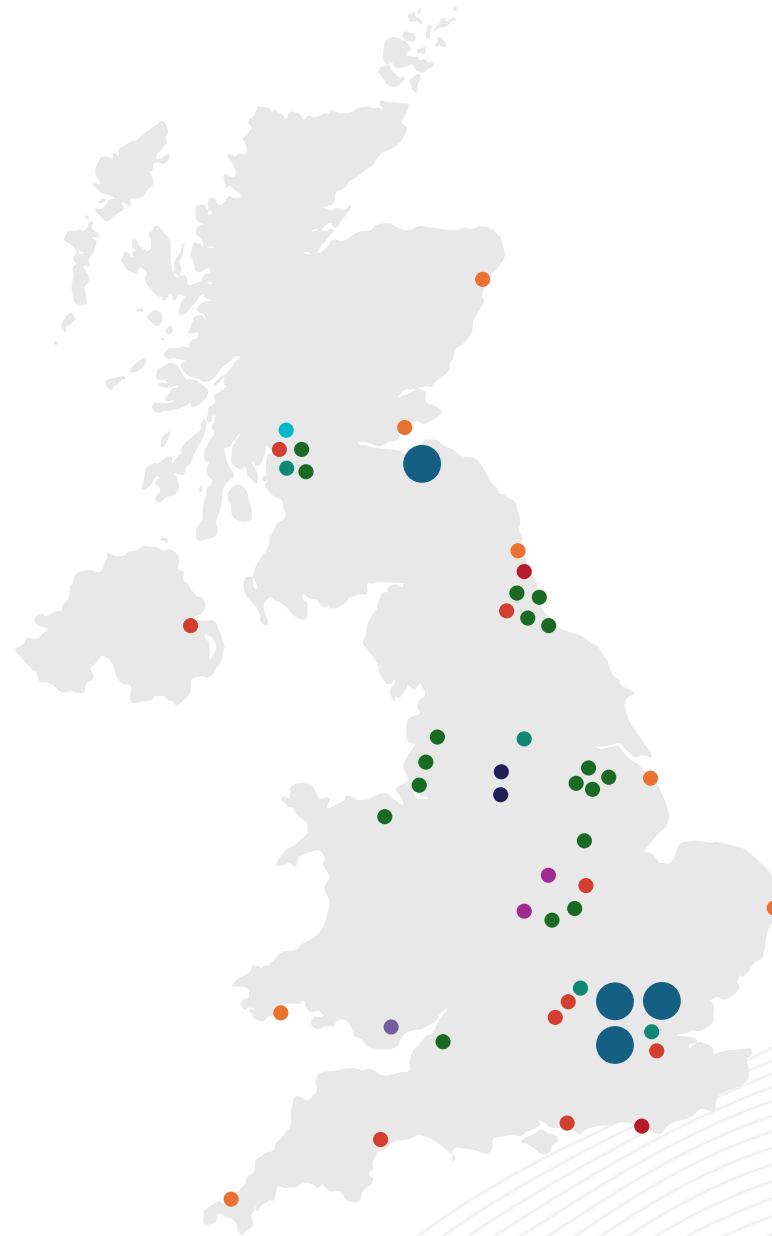
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The Catapult Network

£9.0 billion of pharmaceutical R&D was performed by the business enterprise sector in 2022, which was equivalent to 0.36% of the UK's GDP. Pharmaceutical R&D accounted for 18% of all R&D performed by businesses in the UK in 2022, the highest of any product area.

Department for science, innovation and technology
Life sciences competitiveness indicators 2024: summary
Published 11 July 2024



CGTC BMIC was identified as a vaccine support facility during the COVID-19 Pandemic

Various technologies were considered requiring a large scale WFI supply

Assessment to purchase vs investment on site was undertaken

Cost associated with purchasing large volumes of WFI were not deemed economically viable

Decision was taken to invest in an onsite WFI system leading to our Mission Statement

Delivery of a WFI generation system capable of 2000L/hr. with bulk storage and distribution infrastructure to point of use outlets within clean rooms and labs

Innovation and sustainability needs are core features in CGTC redevelopment and were key drivers to our decision making and solution identified

Our research identified three potential Technology options:

Distillation – Multiple Effect (most common) & Vapour Compression

Distillation is the tried and tested method used to obtain pharmaceutical grade WFI.

Water is heated via industrial steam or electricity with the generated steam vapour converted back to water, producing WFI.

Membrane Technology

Reverse Osmosis (RO) with Ultra-filtration.

RO technology pumps water at high pressure through semi-permeable membranes, followed by continuous electrode ionisation and finally ultra-filtration

CGTC looks to improve sustainability within the industry through innovation and the adoption of novel solutions where possible.

Membrane RO cold loop systems were approved for WFI generation under EU Pharmacopoeia in **2016**, uptake has been slow in a risk averse industry.

There are perceived risks with membrane technology. This is mainly because the WFI produced by membrane technology isn't produced hot (+ 95°C) like distillation but is produced at ambient temperatures. The perception is that the formation of biofilms is much more likely.

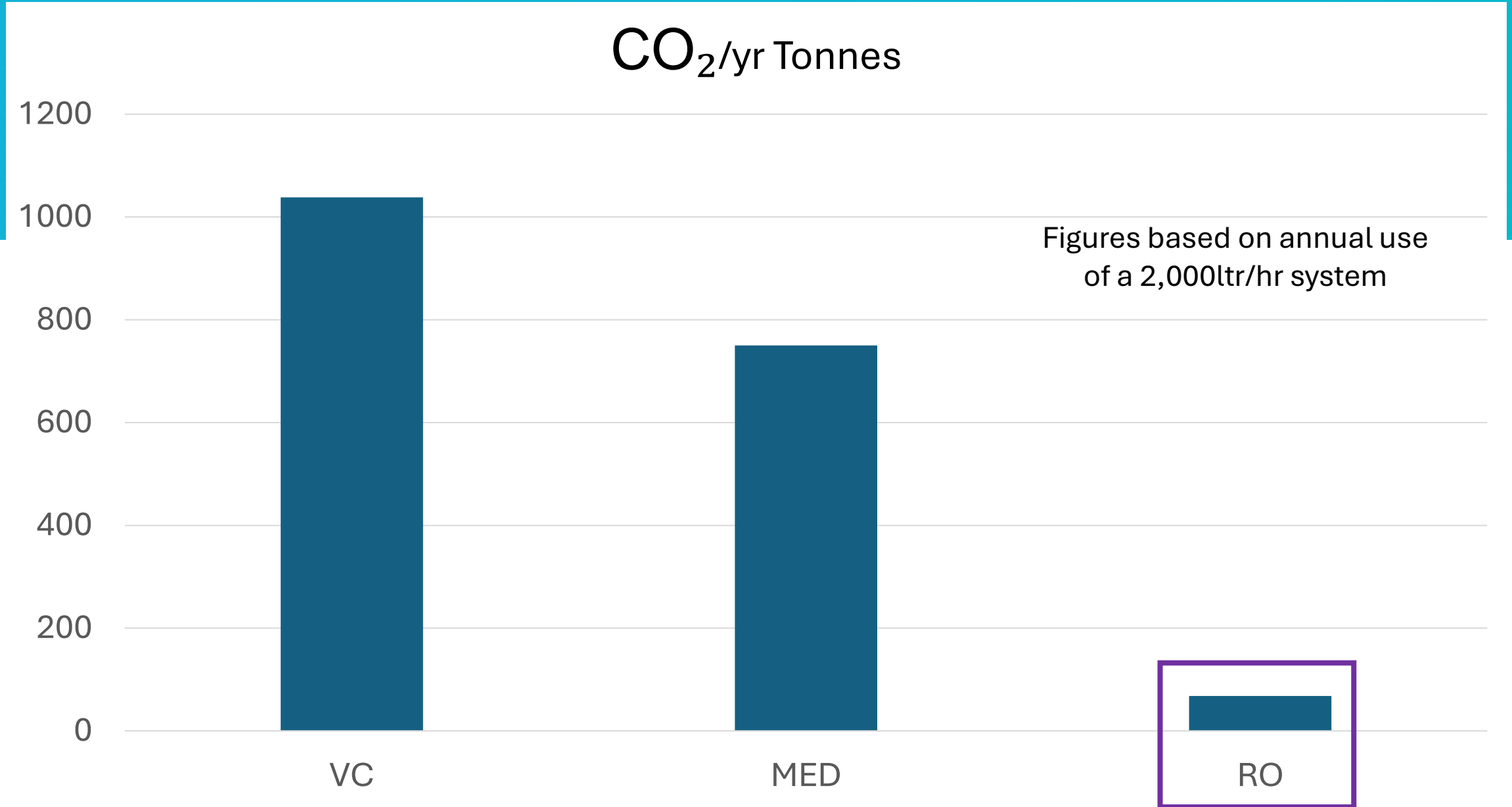
Our RO system design has been positively reviewed by both the MHRA and an independent GMP auditor. The system design performance delivers high quality WFI.

Our system comprises a:

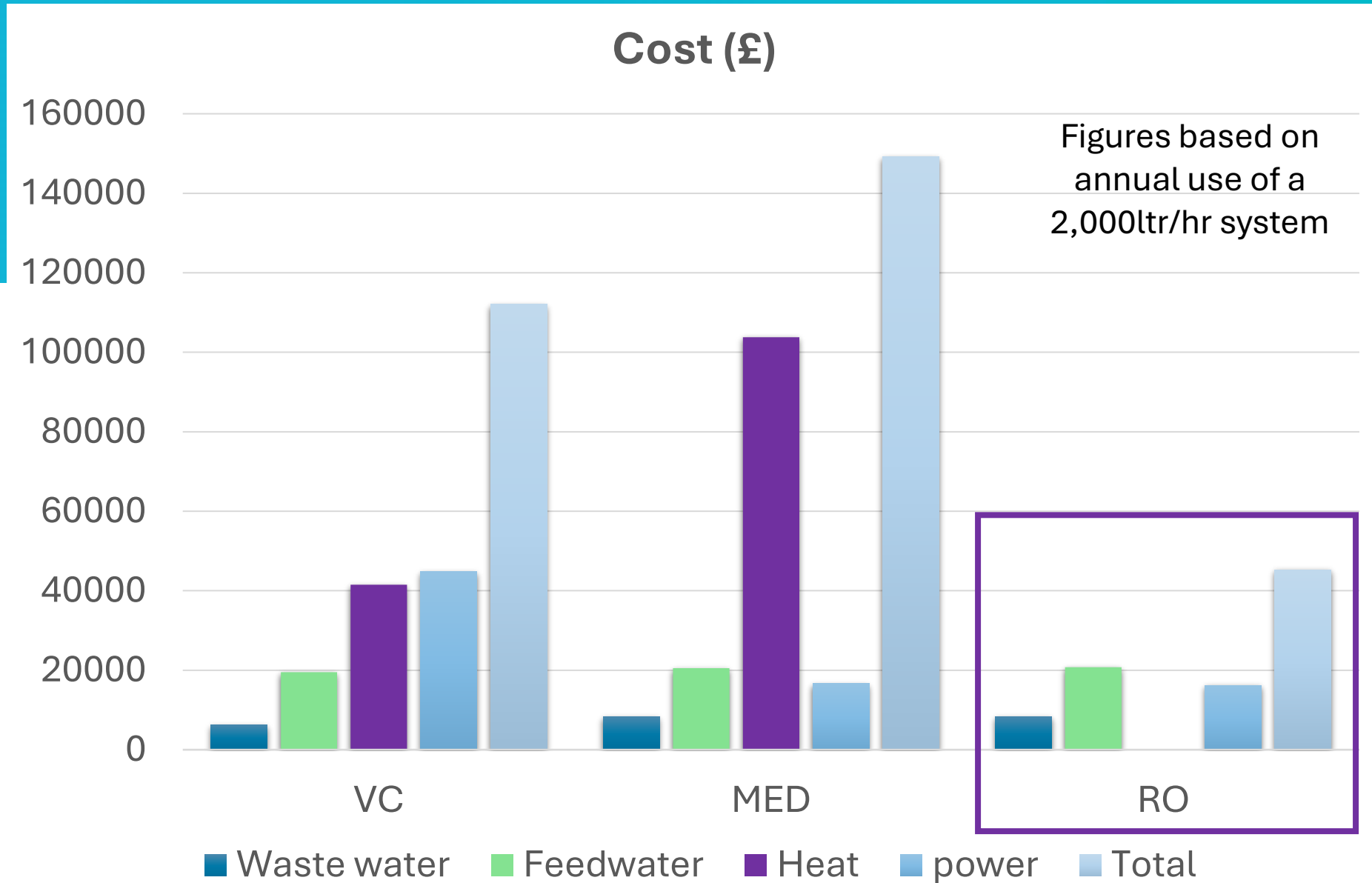
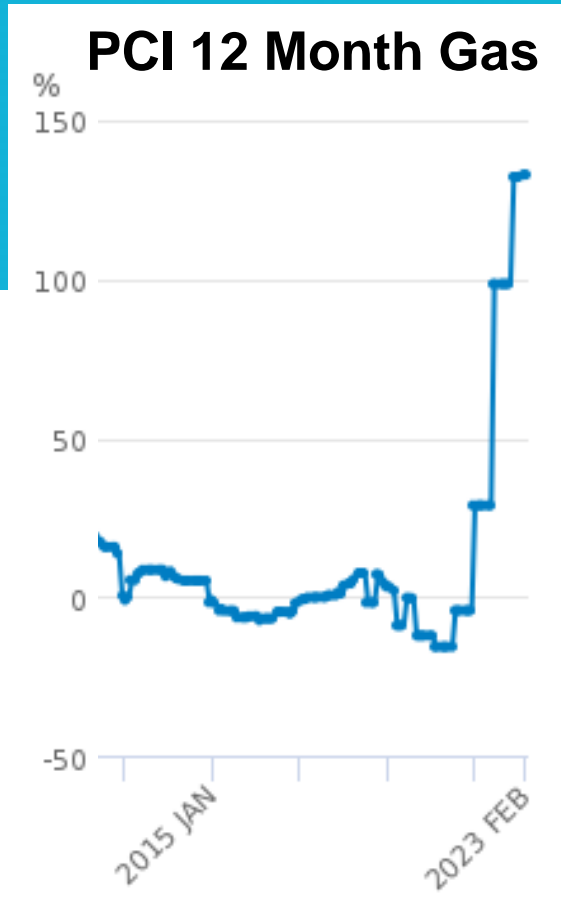
- Pre-treatment system
- Modular system utilising global leading technologies
- Twin-pass RO membrane for increased safety
- Ultrafiltration as standard with additional Ultraviolet

Typical product water quality			
Attribute	Genesys ^{WFI}	US Pharmacopoeia	European Pharmacopoeia
Conductivity (µS/cm)	<0.1	<1.3 @ 25 C (Stage 1)	<1.1 @ 20 C
TOC (ppb)	<20	<500	<500
Nitrate	<0.01 ppm	N/A	<0.2 ppm
Bacteria (TVC CFU/100ml)	<1	<10	<10
Endotoxins (EU/ml)	<0.05 (UF option)	<0.25 EU/ml	<0.25 EU/ml

CO₂ reduction utilising RO vs other technologies



Cost reduction utilising RO vs other technologies



Cost & CO₂ savings

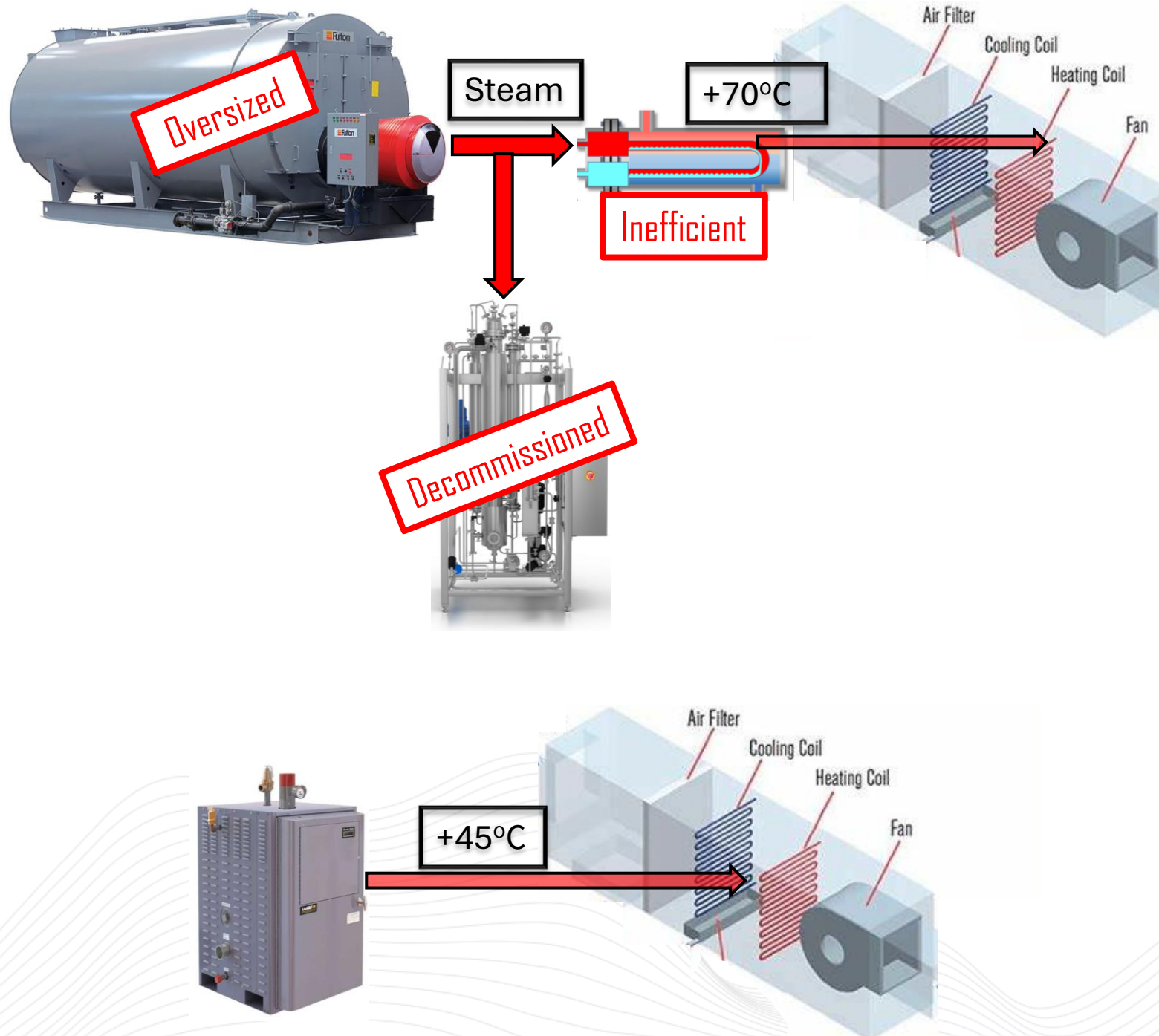
Under our commitment to Energy Savings Opportunity Scheme (ESOS) we have identified several areas of improvement which will reduce site utility costs and CO₂ reductions.

Improved sustainability for WFI production compared to other methods available.

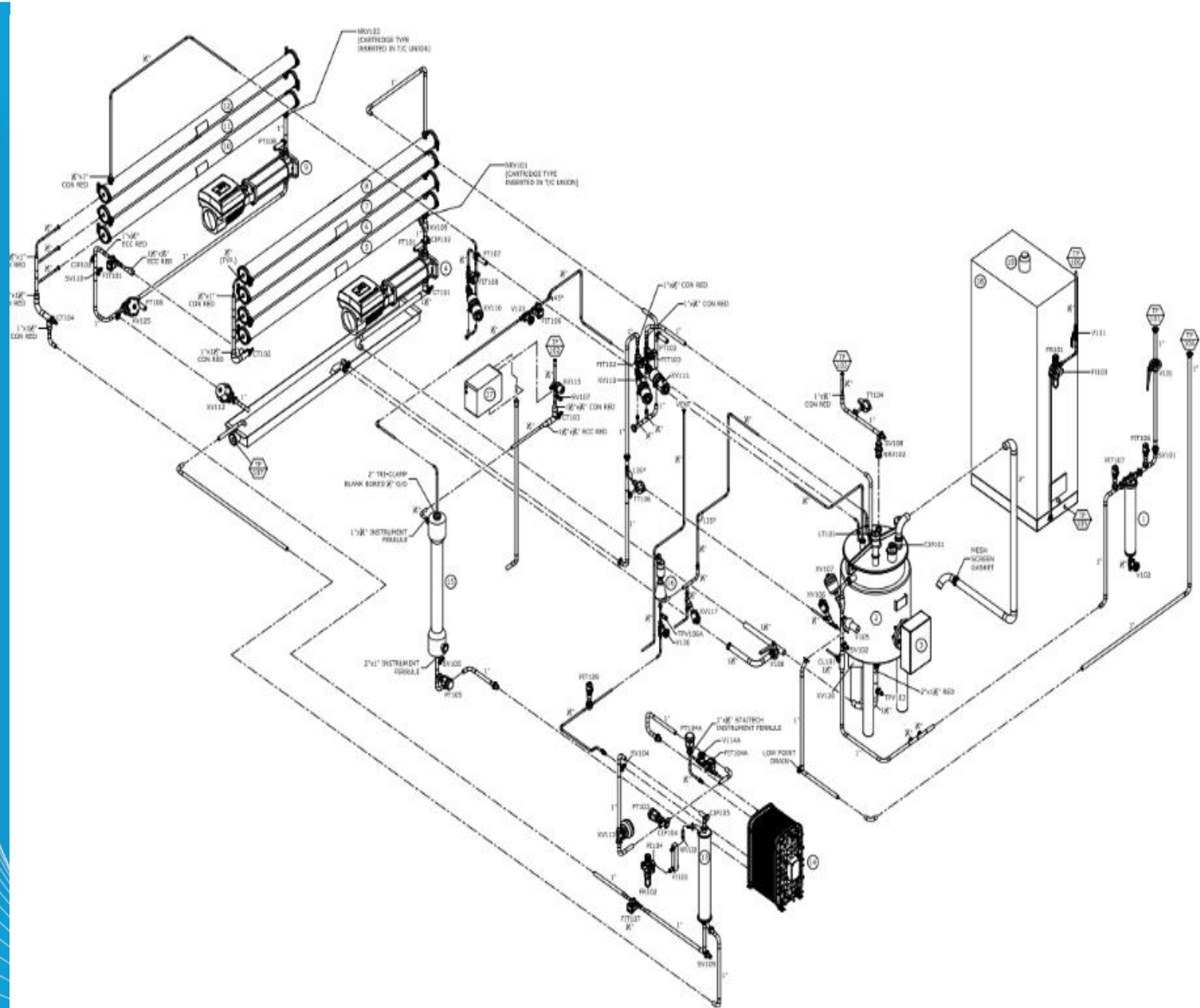
The removal of an existing steam boiler.

The replacement of AHU heating coils.

The installation of lower temperature boilers.



A large, complex industrial machine, likely a water treatment or filtration system, is shown in a laboratory or industrial setting. The machine is constructed from stainless steel and features a large cylindrical tank, various pipes, valves, and a control panel. It is situated on a tiled floor, and the background shows other industrial equipment and overhead lighting.



Our Company mission statement - **“Advancing the cell and gene therapy industry through powerful collaborations”**

We believe this project helps realise the following benefits:

- Aligns with our site sustainability improvement strategy
- Delivers robust capability for vaccine and large volume batch manufacturing
- Reduces operating cost of manufacture
- Reduces EHS risks on site relating to steam generation
- Delivers on our approach to consider innovation and novel technologies
- Provide performance data for RO membrane technology to the industry





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Thank you



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