Sustainability in Pharmaceutical Manufacturing

A comprehensive Steam System Audit approach to Steam Quality Management

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The world is beginning to grasp with the huge challenge of achieving Net Zero (CO_2) by 2050

As the world tackles the COVID-19 pandemic, we must be resolved to address our behaviours which negatively impact climate change with ever increasing pace and purpose. Around the world many countries have committed to achieve carbon neutrality, or Net Zero (CO_2) emissions, by 2050. As a major global industry, the pharmaceutical sector has a vitally important role to play.

For thermal energy intensive industries, such as pharmaceutical manufacturing, the long-term future options to maintain current manufacturing processes are few, and look to significantly increase energy costs. Whether electrification, hydrogen, bio-fuel, or even synthetic fuels, each will require significant investment in production, distribution, and infrastructure both at a national, local, and individual site level.

The journey to achieve Net Zero must therefore include our focused and deliberate efforts to minimise infrastructure investment cost and timeline to delivery, by treating energy as a highly valuable resource and establishing best practice in energy efficiency, eliminating waste, and recovering and reusing waste heat from existing processes.

For the avoidance of doubt, we reach Net Zero when the amount of carbon dioxide we add is no more than the amount taken away. These goals guide us to significantly reduce our absolute emissions and find ways to sequester any residual carbon emissions - so to avoid a net increase in CO_2. Over the next decade, our actions, as we strive to achieve Net Zero, will have a major impact on the world we live in. This will reach every corner of the economy.

In the future our reliance upon renewable sources of energy, particularly electricity, will increase and with that reliance power supplies will become more inflexible as the weather and daylight influence generation. Energy storage, both thermal and electrical, will become increasingly important to ensure 24-hour economical production as industry competes with electric vehicles, buildings, and housing for economic access.

From vitamins to vaccines, the pharmaceutical industry is fundamental as we strive to improve the world's health by advancing cutting-edge and innovative solutions.

Every step taken by the pharmaceutical industry to address our clear and present sustainability imperatives demonstrates a positive commitment to get ahead of the challenge, moving towards a Net Zero business with pace and purpose, with the added benefit of limiting emissions more quickly.

Underpinning such critical endeavours are vital utilities, such as steam, enabling manufacturing processes to run safely, whilst mitigating contamination risk, and managing efficient thermal energy transfer from boiler to plant and process points of use. However, with carbon footprint reduction becoming an increasing focus for energy-intensive manufacturing processes, pharmaceutical utilities & facilities management teams continue to apply a laser focus to reduce energy consumption and wastage.

Taking this into account, Professor Jeremy Miller, Research Fellow, and James Heseltine FRSC, Global Market Development Manager, Spirax Sarco, explain the steps pharmaceutical utilities & facilities managers can take to improve steam system efficiency, through steam quality management, so to maximise process and final product quality, and optimise overall productivity.

Setting the scene as we embark on our shared journey towards Net Zero (CO_2) by 2050

At this time it may be prudent to attempt to summarise the hugely impactful challenge ahead.

Greenhouse gas emissions are categorised into three groups or 'Scopes' by the most widely-used international accounting tool, the Greenhouse Gas (GHG) Protocol. Scope 1, 2 and 3 is a way of categorising the different kinds of carbon emissions a company creates in its own operations, and in its wider value chain.

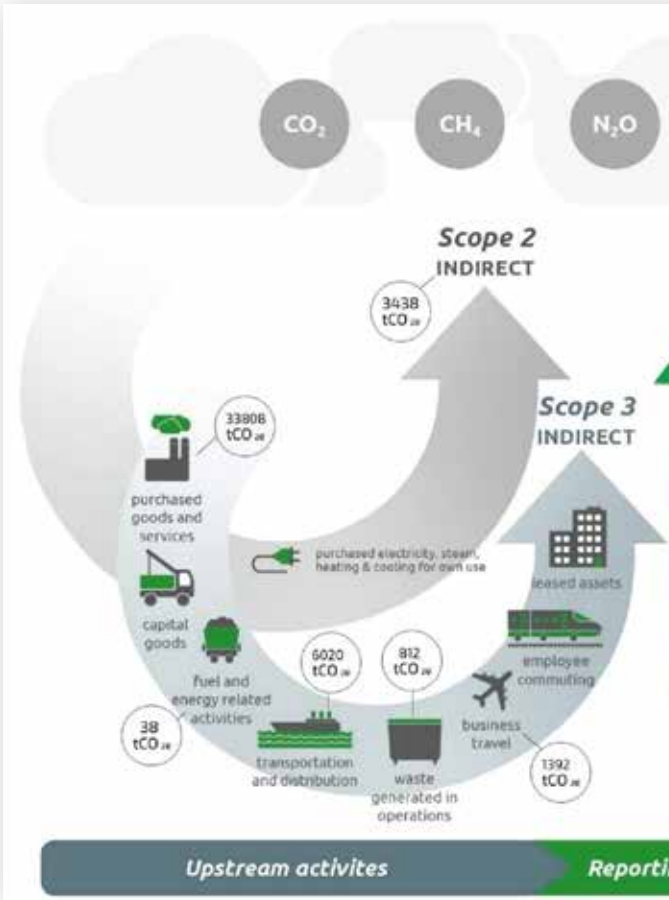
It is possible to think of 'Scopes' in terms of three categories of emissions:

- **Scope 1** - Covers the Greenhouse Gas (GHG) emissions that a company makes directly, for example whilst running its boilers (including steam), manufacturing utilities, and its vehicles.
- **Scope 2** - Covers emissions a company makes indirectly, for example when the electricity, steam or energy purchased for heating/heat transfer, cooling buildings, and manufacturing utilities, is being produced on the company's behalf.
- **Scope 3** - Covers all the emissions associated, not with the company itself, but that the organisation is indirectly responsible for, up and down its value chain. For example, from buying products from its suppliers, and from its products when customers use them.
  – Scope 3 emissions will be a highly impactful concern.

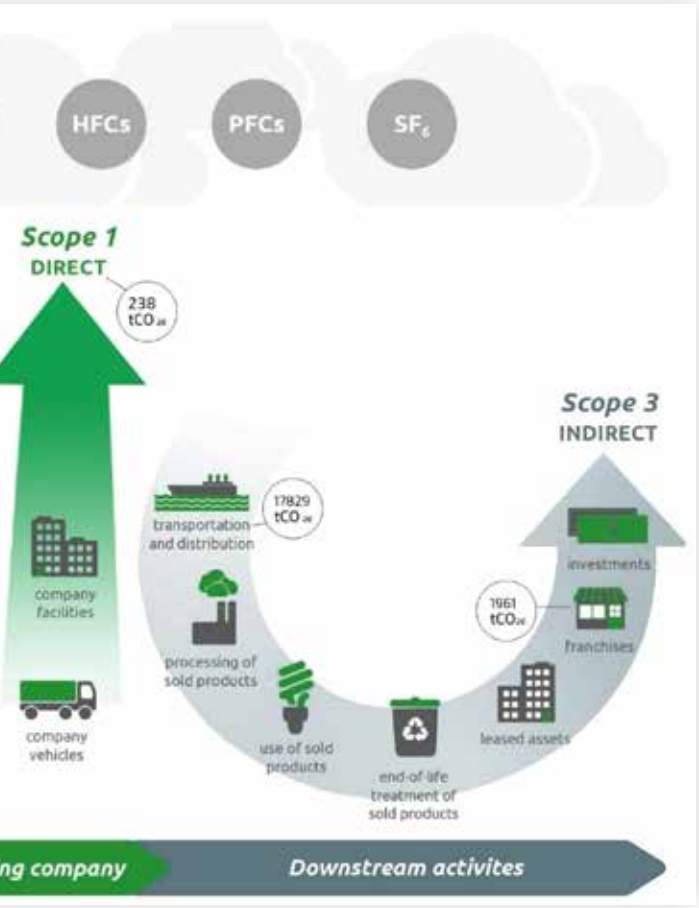
Furthermore some key themes begin to emerge when thinking about the 'Scopes':

Scope 1 and 2 emissions are often within an organisation's control

- It is highly likely that an organisation will have access to the source data needed to convert direct purchases of gas, steam and electricity into a value in tonnes of GHGs. This information may sit with procurement, finance, estates management, utilities & facilities management, or in a sustainability function.



Source: www.carboncredentials.com



In some cases, the solutions exist to deliver Net Zero for Scope 1 and 2 emissions

- For example, an organisation can source renewable electricity, renewable gas, renewable steam, or electrify (or suitable renewable) the source of its energy transfer/heat demand, or transition to electric vehicles.

Scope 3 is often where the impact is

- For many businesses, Scope 3 emissions will account for more than 70% of their carbon footprint. For example, for an organisation that manufactures products, there will often be significant carbon emissions from the extraction, manufacture, and processing of the raw materials and finished goods.

Organisations may have less control on how Scope 3 emissions are addressed

- Businesses can offer to collaborate on solutions to reduce emissions with current suppliers, or consider changes to their own supply chain. However, in most areas, businesses' current suppliers will have considerable influence on how emissions are reduced through their own purchasing decisions, and product design.

Committing to reach Net Zero will involve significant focus on Scope 3 emissions

- Definitions for what constitutes net zero ambition are evolving, but businesses looking to adopt best practice will commit to focus on Scope 3 emissions as part of their plans. Mapping company emissions footprint by scale, and how much control a company will have over the source of such emissions will be a good way to start addressing them, as well as bringing the emissions hotspots within reach to effect change.

Taking the above into consideration, it is prudent to specifically address the pharmaceutical industry's need to raise, distribute and bring steam of the correct quality and quantity to each and every plant and process point of use.

An important question to answer, why does the pharmaceutical industry use steam at all? Why indeed?

Why is steam used in the pharmaceutical industry?

Firstly we should pose the fundamental question – Why is steam used in pharmaceutical manufacturing, across plant utilities, and process? The answer is simple, but with a very compelling and insightful outcome.

Steam is widely recognised as a powerful and highly efficient thermal energy transfer fluid, steam itself is a natural fluid and environmentally benign, after all when one has used all available heat from steam one is left with water, in the form of condensate, which can be reused through the steam and condensate loop. However, it should be noted that it is not best practice to recover condensate from pure process steam systems employed within sterile pharmaceutical manufacturing sites, due to contamination risk. It is the current general method to raise steam by burning fossil fuels, a significant source of carbon intensity.

A rhetorical question would be which comes first safety, product quality, compliance, or energy efficiency? The pharmaceutical industry is founded on safety, quality, and compliance, it is therefore correct and appropriate that the thermal energy transfer attributes of steam should be actively managed - Steam Quality to EN 285 standard. Complete steam quality management will enable a safe, contamination free, compliant, and energy efficient system – sustainability by design, if you will.

From boiler, to plant and process points of use, it is critical to maintain the complete steam system in a mechanically correct condition, adhering to steam system engineering best practice, to ensure steam of the correct quality and quantity is raised, distributed, and arrives at point of use. Then, and only then, should one consider optimising the energy efficiency of the system. In short each and every point of use is 100% reliant upon steam of the correct quality and quantity in order to ensure full and appropriate energy transfer to the process.

One such example is Heating, Ventilation, and Air Conditioning (HVAC). HVAC systems have always been an integral part of pharmaceutical manufacturing, across comfort and current Good Manufacturing Practice (cGMP) areas. Many large multinational pharmaceutical companies estimate that HVAC demands account for 60-70% of total

operational energy consumption. In fact, operating costs of cGMP HVAC in cleanrooms are often 20 to 100 times larger per square foot than those employed in typical comfort areas, such as offices.

With such large numbers in mind, it is understandable that reducing overall consumption and improving efficiency is an area of importance for utilities & facilities management teams. Indeed, there has been considerable focus on ‘demand reduction’, and the complete steam system represents an interesting area where efficiencies may be identified and implemented.

Therefore is critical to embed stepwise and pragmatic sustainability initiatives into day to day operations, as well as the overall business model, so to enable positive and impactful change, which can be felt across the entire pharmaceutical community. Such leadership will set the tone, up and down an organisation, that robust cross-functional investments are needed to drive change.

Enabling sustainability through Steam Quality Management

From boiler, through distribution, and to each and every plant and process point of use, a complete steam system audit approach to steam quality management will address the many areas pharmaceutical utilities & facilities management teams may consider when looking to improve steam system efficiency. Some of these steps can be very simple, for example steam quality testing to EN 285 standard, to understand steam's thermal energy transfer attributes at critical test points, and steam trap surveys to establish a complete inventory of all plant and process steam traps, taking into account status, condition, maintenance record, and validation/compliance documentation. In summary, such information enable stepwise and pragmatic recommendations to be made based on steam system engineering best practice, ensuring a safe and compliant system meeting stringent local legislation.

On the subject of steam quality, it should be said that the physical tests for steam quality (dryness, superheat, and non-condensable gases) are a requirement of EN 285. Furthermore the EN 285 standard, at its core, is applied to large steam sterilisers, and forms part of the recommended test schedule to demonstrate the performance of sterilisers using saturated steam cycles (Porous Load Cycles). As such, steam quality should form part of the validation of any steam steriliser, bioreactor, or point of use where steam is to be used for immediate heat transfer within the process, particularly Clean-in-Place followed by Sterilise-in-Place. Moreover EN 285, the European Large Steam Steriliser standard, is the world's baseline authority for steam quality acceptance criteria, and referenced in many national standards, such as ISO 17665.

Furthermore it should be noted that isolating dead legs or processes which do not require steam is good practice, as keeping distribution lines hot when not needed wastes energy both in terms of steam production, and often again in the HVAC system when removing such heat from the production environment. Where isolation valves are located at height or in technical space making it difficult for access, thought should be given to the use of actuated valves that can be operated remotely or as part of the building management system.

Steam pipe insulation condition has an important role in reducing energy loss and reducing condensate levels in distribution piping. Often after a maintenance period, insulation and insulation jackets are removed for access and then are not replaced. This results in energy loss and excess condensate forming.

It should be said that poor insulation, dead legs, and sub-optimal steam trap performance can result in the formation of additional condensate, this can affect the dryness measurement component (Steam Quality to EN 285) at critical points. Therefore steam quality testing at critical points can also be a good qualitative measure of system performance and diagnostic indicator for thermal efficiency in addition to its primary role of ensuring and monitoring steam quality, especially relevant for steam sterilisation.

The boiler room may present a number of opportunities to reduce fuel consumption

Controlling boiler Total Dissolved Solids (TDS), and using an associated heat recovery system is one such example. Another is to capture thermal energy in the boiler flue gases using an economiser, which is typically used to pre-heat feed water going into the boiler. Flash recovery from the condensate blow-down vessel can also be used to pre-heat water reducing energy consumption, and fuel savings from each can typically be between 3% and 5%, lowering emissions whilst improving efficiency.

The boiler room will be the area most affected and changed by the transition to Net Zero

Boiler manufacturers are already diversifying and offering both electric and hydrogen fuelled boilers. Again as energy supplies become less flexible, energy storage will be key in providing uninterrupted process heat.

A new innovation in early commercialisation that addresses this problem is a combined electrically heated boiler and thermal energy accumulation system developed by Spirax

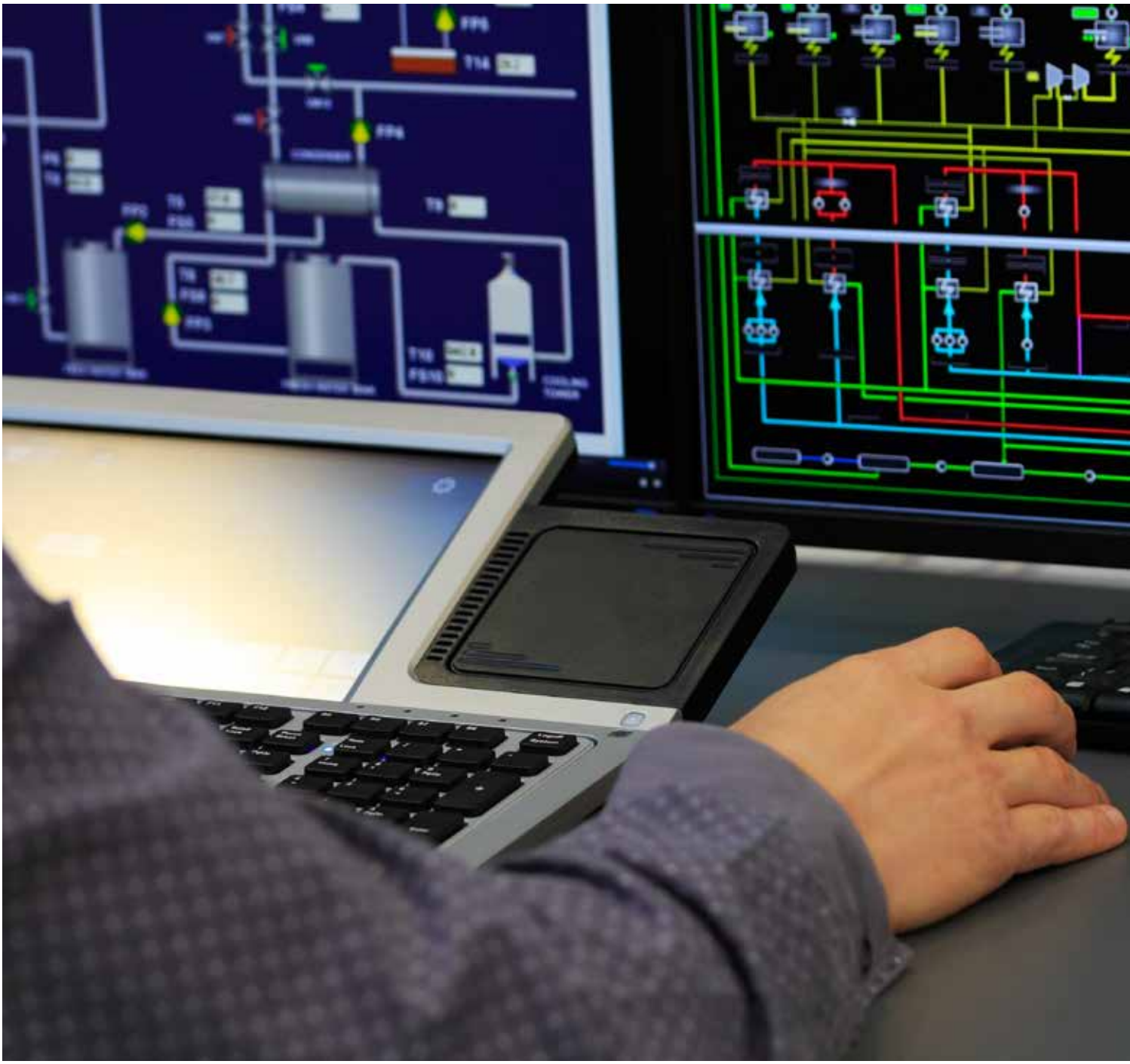
Sarco Ltd in partnership with our sister companies Chromalox and Gestra (Patent Pending).

Electrically generated steam is 15% to 20% more thermally efficient than conventional natural gas boilers, with zero flue gas emissions. Combining electrical heating within a steam generator and subsequent accumulator allows thermal energy, in the form of steam, to be stored when electricity is available or when it's available at low cost when there is oversupply in the grid. Storing the energy as heat and discharging as steam as required for the process. It's also possible to charge and discharge at the same time providing flexibility and peak shaving for any process.

Another advantage is that such energy accumulation can be placed closer to the process, reducing pipeline losses and maintaining steam quality. Furthermore such technology lends itself perfectly to plant steam indirect heating applications, using a standard accumulator vessel, as well as chemical free steam used in non-sterile pharmaceutical manufacturing processes, using a suitable stainless steel accumulator vessel.

Such technology is important to demonstrate Spirax Sarco's commitment to sustainable energy, supporting our customers as they strive to reduce the carbon intensity of their steam systems, and ultimately providing a zero carbon energy source as the grid receives more and more sustainable energy from renewable sources such as solar, wind, hydrogen, and even nuclear.

Sustainability improvements through the implementation of energy monitoring systems



Such technology is invaluable to establish service demand, and consumption patterns, enabling key stakeholders to know where, when, and how action should be taken.

Those responsible for energy use across the complete plant and process steam system, often use burner efficiency to track overall efficiency, but this method does not take into account all aspects of the boiler operation. Factors such as fouled heat transfer surfaces, carryover, radiation losses, and excessive boiler blowdown rates all impact on overall boiler room efficiency, which in turn may lead to an overestimation of actual boiler room efficiency. It is critical to remember that plant steam quality has a direct impact upon process steam quality, due to the thermal energy transfer attributes of steam at critical heat exchange points, such as a sanitary heat exchanger prior to a Pure Steam Generator (PSG) or a Water for Injection (WFI) system.

Through the use of dedicated technology, a complete overview of the plant and process steam system is possible, so to measure overall boiler room efficiency, distribution efficiency, and point of use quality, targeting improvements and associated savings. The utilities and facilities management team may consider using measured inputs from fuel, feed water, steam output, condensate return, and blowdown to build a true picture, helping to yield energy reductions and increasing overall efficiency.

Remote monitoring and control of steam systems will play a key role in steam's sustainability journey. Over and above inefficient reactive responses to everyday problems, digitalisation brings early alerts, predictability, and rapid problem-solving, with new levels of control.

Greater efficiency is built-in; problems are detected and acted upon immediately, before more serves consequences present. Early problem detection means smarter maintenance and repairs.

Optimised steam systems yield a significant reduction of carbon intensity, as energy emissions are reduced. Moreover, rigorous thermal energy transfer management across the complete steam system will enable much improved process productivity.

The importance of comprehensive Steam System Audit approach to Steam Quality Management

Although the pharmaceutical utilities & facilities management teams may continue to make significant progress with some of the steps mentioned earlier, there will almost certainly be times when they need to engage with specialists outside of their organisation. Knowledge partners, such as Spirax Sarco, are available to provide expert advice, through the deployment of steam system engineering best practice, so to ensure complete steam quality management, through a comprehensive steam system audit approach.

Steam system audits are vital tools to understand the health and wellbeing of the complete plant and process steam system, making recommendations based on steam system engineering best practice, health & safety, stringent local legislation, and product quality.

Tier 1 Steam System Audit – Initial Assessment

- Steam quality testing capabilities (EN 285 standard) to understand steam's thermal energy transfer attributes at critical test points
- Steam trap survey capabilities to establish a complete inventory of all plant and process steam traps, taking into account status, condition, maintenance record, and validation/compliance documentation

Tier 2 Steam System Audit – Comprehensive Assessment

- A complete steam system overview, from boiler, to all plant and process points of use
- Comprehensive assessment will identify energy saving possibilities with immediate and future solutions

Tier 3 Steam System Audit – Energy Assessment

- A detailed steam and condensate loop thermal energy mapping to discover plant & process optimisation possibilities
- Strive to understand and address energy demand reduction possibilities across the complete steam and condensate system
- Spirax Sarco's Energy Assessment approach is taken on case by case basis, as the scope of such an assessment is often very broad, with multiple variables and site specific details

In addition it should be noted whilst respecting the challenges of COVID-19 and social distancing, it is possible to conduct remote steam system audit capabilities with the use of video and images, to identify areas for improvement.

Steam system engineering best practice……in practise!

Optimising the skillset of those focusing on steam system efficiency on-site can also assist towards a more sustainable operation. Seeking out training centres that provide accredited courses, such as Spirax Sarco's UK Steam Technology Centre, not only ensures safe working in-line with BG01 (Guidance on Safe Operation of Steam Boilers), but also equips key functions with the skills and knowledge required to maximise the efficiency and performance of the steam system, such as Spirax Sarco's City & Guilds Accredited Steam Quality Testing training course to EN 285 standard.

Again, as we adapt to a changing work environment, remote training and webinars are an increasingly effective way of ensuring that personal improvement can continue.

City & Guilds | Accredited Programme

SPIRAX SARCO STEAM QUALITY TESTING TRAINING COURSE TO EN 285 STANDARD

So to conclude…..

As pharmaceutical manufacturers continue to deploy global sustainability initiatives to reduce their respective carbon footprint, the focus upon energy saving solutions is now greater than ever.

With particular focus on steam systems critical to manufacturing processes, steam users in the pharmaceutical sector should be reassured that there are many steps to be taken to lower emissions whilst improving efficiency, and ultimately maximising the impact of existing steam infrastructure, whilst working in a safe, smart, and sustainable manner.

Steam is Natural Technology…

Steam is familiar in nature, and part of everyday life; yet this extraordinary fluid is a high efficiency, mission-critical tool for diverse and important industries, such as pharmaceuticals, and increasingly relevant as part of our sustainable future. Steam is too small a word for it; steam is Natural Technology.

Steam is an essential energy transfer fluid, and many critical industries rely on it to keep us safe, and to keep the energy flowing. Steam is powerful, with capabilities no other fluid can match; steam's high energy density enables efficient and effective thermal energy transfer, with precise temperature control (through steam's pressure/temperature relationship). Moreover, existing steam systems can be significantly optimised to perform far more efficiently that they currently do; the very definition of sustainability; to do more with less.

Increasingly sustainable: Steam – the transition to greener technologies

More and more industries and organisations are recognising steam as the Natural Technology that fits with their sustainability agendas. With new steam generation technologies, we are on a path towards carbon-free steam generation.

The COVID-19 pandemic has brought into sharp focus the desire to invest in greener steam technology, as the world's demand for heat continues to grow. Raising the efficiency of steam generation will make a significant sustainability impact in the long term; notwithstanding the immediate energy savings through superior maintenance and step-wise improvements of existing steam systems, through the rigorous deployment of steam system engineering best practice.

Future ready, now - Natural Technology for today's world

Industrial scale solutions are already in operation to generate steam in cleaner, more sustainable ways.

Renewable electric steam – carbon-free, emission-free, and 100% renewable steam

Higher capacity users in the pharmaceutical sector are able to decarbonise their steam generation today, thanks to the power of electric systems. Such systems align well with the portfolio of solutions driving progressive companies towards a truly sustainable business.

When coupled with 100% renewable power sources, such as hydroelectric, PV solar, and wind, electric steam generators are capable of 1 to 20 tonnes of steam production without emission or carbon generation. They are capable of converting renewable electricity into steam at 97% energy conversion efficiency.

Biomass steam boilers

Steam can be generated from combustion of organic waste materials such as olive pulp, rice husks, and palm kernel shells created from various manufacturing processes. Biomass can be used to generate electrical energy as well as heat, when used in a Combined Heat and Power (CHP) systems. The reduction of organic waste and the use of biomass, helps to improve environmental sustainability and lower energy bills.

Rapidly advancing technology will deliver on the promise of zero carbon steam generation

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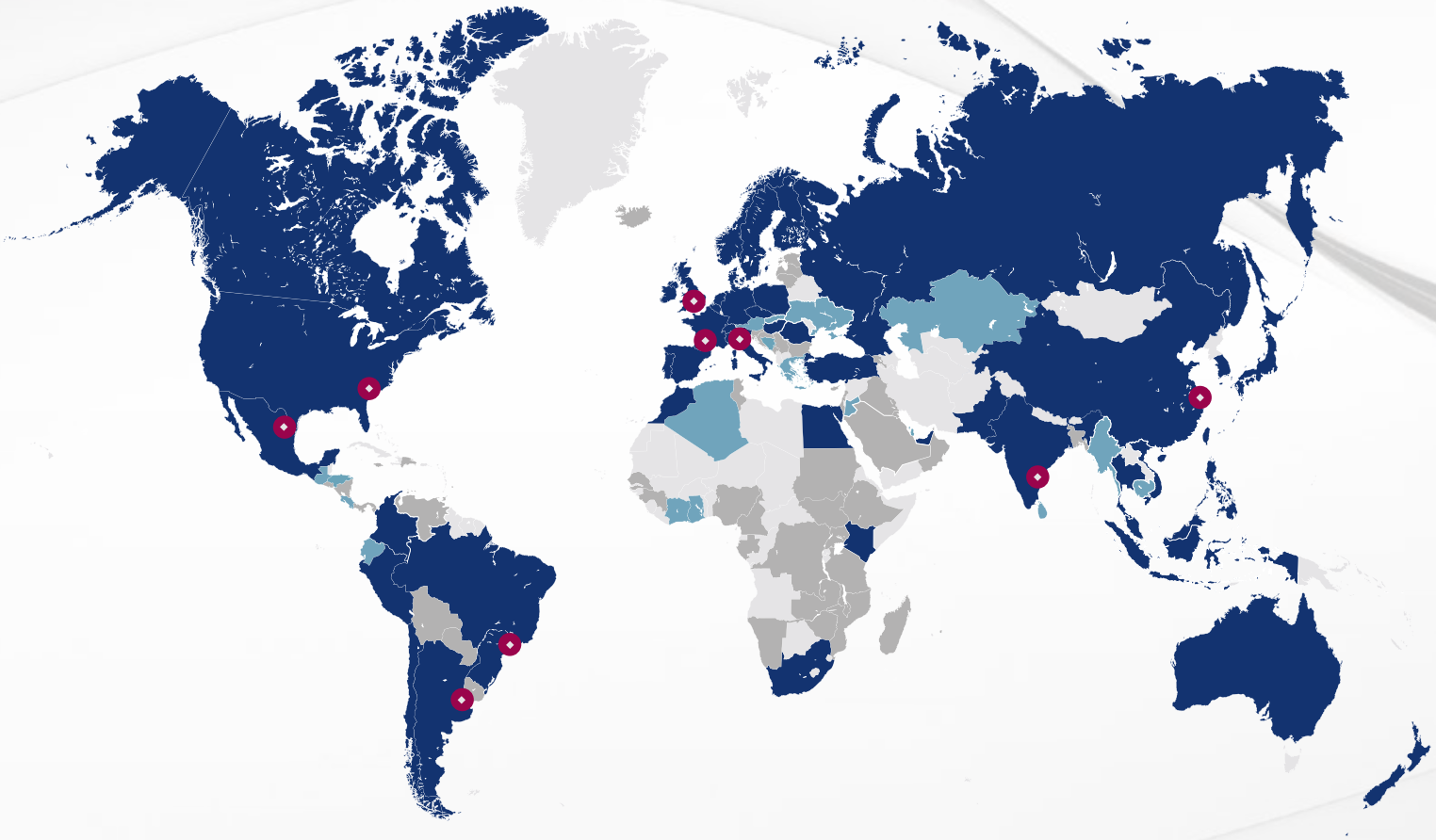
You see steam.
We see...
NATURAL
TECHNOLOGY



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