TRANSFORMING PHARMACEUTICAL MANUFACTURING TO DRIVE SUSTAINABILITY AND COST EFFICIENCY

In this article, Michael Astle, Executive Director of Legal Affairs and Head of ESG, Gareth Jenkins, PhD, Vice-President of Science and Technology, and Edward Mayo, Engineering Project Manager, all at Quotient Sciences, explore current strategies to reduce carbon emissions and drive cost efficiency throughout the healthcare industry.

Transforming the healthcare industry's current manufacturing practices into more energy-efficient alternatives is a task of paramount importance. The industry, including pharmaceuticals, produces approximately 5% of global carbon emissions and must do its part to meet carbon reduction targets in line with the Paris Agreement.[1,2] Across the pharmaceutical industry, manufacturers are changing their operational strategies to help limit global warming to a temperature increase of 1.5°C above pre-industrial levels.[2] By reducing carbon outputs through energy-saving methods, these modifications are also helping to drive cost efficiency for manufacturing lines, which has become increasingly necessary as energy prices rise.

Maintaining regulatory compliance when altering current operating systems to meet sustainability demands can be a complex task. The industry is highly regulated and must meet GMP guidelines to ensure that its products are safe for patients. Any changes to drug substance (DS) or drug product (DP) manufacture must be strictly monitored, ensuring that there is no impact on quality as a result, and that the process remains compliant and the product safe.

OVERCOMING CHALLENGES TO SUSTAINABLE SOLUTIONS

The pharmaceutical industry prioritises patient safety, and GMP guidelines define stringent safety standards that all products intended for patients must meet. Implementing the changes required to meet sustainability targets without compromising regulatory compliance can be challenging. To help overcome these barriers, an effective strategy is essential, taking into consideration any possible implications that could occur as a result.

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Completing extensive risk assessments to pre-empt the potential effects of any alterations allows for mitigative measures to be implemented, de-risking sustainable practices for a smooth transition. This, coupled with an effective electronic monitoring system and a robust quality control (QC) testing programme, offers assurance that any changes made will have minimal to no impact on product quality. As revalidation will be required, an opportunity to improve GMP compliance also arises, implementing techniques to further improve DS and DP safety and efficacy while reaching sustainability targets. Effective partnering with colleagues in quality assurance is vital to delivering improvements in sustainability while maintaining elevated quality standards.

TRANSITIONING TO SUSTAINABLE MANUFACTURING

Many changes can be made to current operations to improve environmental sustainability and reduce operational expenditure, some of which are discussed here.

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Optimising Current Operations

Examining current manufacturing processes and operating procedures can help to identify inefficient methods that could be optimised to reduce carbon emissions and make processes more cost efficient. This could include:

- **Process optimisation:** Analysis of current processes to identify suboptimal practices that could be improved to minimise resource usage and waste, as well as further streamline reactions.
- **Supply chain sustainability:** Ensuring that sustainability objectives are shared across the entire supply network contributing to a company's greenhouse gas emissions.
- **Personnel training:** Educating employees on sustainable practices and offering guidance on how they can help reach sustainability targets.

Through this evaluation, small changes can be made that can have large impacts on helping to reach sustainable solutions.

Modifying HVAC Systems

Heating, ventilation and air conditioning (HVAC) systems in particular have high energy consumption, accounting for 60–90% of cleanroom energy usage.[3] As a core component of cleanroom systems, the use of HVAC systems is vital to ensure that the environmental conditions of the cleanroom meet those required for sterility and stability. However, with such high energy costs, HVAC systems offer a prime opportunity for introducing more energy-efficient methods to meet sustainability targets.

The use of HVAC systems can be enhanced by adjusting the settings to meet DP needs while consuming the minimum energy possible. With an in-depth understanding of DS and DP, the manufacturing process and the regulatory requirements, a compromise can be made to meet the needs of both.

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A recent innovation has led to an advancement in HVAC systems, forming reactive airflow systems. These HVACs induce a variable, demand-based airflow supply. Instead of working at fixed airflow rates, these modified HVAC appliances use a robust environmental monitoring system to respond to changes in the environment. For example, a shift in particulate concentration would "switch on" the airflow system to ensure the environment remains within acceptable levels. This reactive feature circumvents the need for fixed airflow rates.[4]

As an example of the impact that implementing newer HVAC technologies can have, in a real-life example three obsolete rooftop HVAC units were replaced with brand new units at a pharma development facility. The existing obsolete units all had a seasonal energy efficiency ratio (SEER) rating of 10.8 or less, while the new units all had an SEER of 14. This equates to the new units using 21% less energy per year while maintaining equivalent or better temperature and humidity control in critical processing areas.

Aside from energy consumption, much of the potential environmental impact of HVAC equipment can come from refrigerant leaks. Effective preventative maintenance and intelligent operation of HVAC equipment are key elements of reducing the total environmental impact. As it is a large contributor to carbon emissions, optimising HVAC usage significantly reduces energy consumption, helping the move toward sustainability.

Harnessing Technological Advancements to Enhance Manufacturing

Technological advancements have had a significant impact on sustainable manufacturing capabilities to streamline production. Through more efficient working practices, such as building automated workflows, the time and cost associated with drug development, scale-up and manufacture can be significantly reduced.

One example is the use of continuous manufacturing. Although an understanding of the chemical reaction is required, with continuous flow chemistry, reaction components are seamlessly transferred into, and products removed from, a reactor. This leads to a highly efficient and scalable process, which removes the need to produce large quantities of unneeded material and reduces the timelines for scale-up. With this accelerated approach, costs are reduced and energy consumption is minimised, all while quickly and reliably delivering increasing quantities of DS. Integration of automation into earlier drug development stages can help to further accelerate production and reduce carbon emissions.

With the increased availability of online analytics and accessible process data modelling, robust approaches for developing new sustainable chemical processes can be adopted. A recent example is the optimisation of a catalyst system to work in environmentally benign solvents, scoring 77 out of 100 using the GreenMetric assessment against the 12 Principles of Green Chemistry.[5]

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A PARTNERSHIP TO DRIVE SUSTAINABLE SOLUTIONS

To help implement manufacturing changes to reach sustainability goals, a partner with technical knowledge, experience and a proven track record can help to provide solutions for decarbonisation and improving cost efficiency while maintaining regulatory compliance. When deciding on a partner, it is essential to ensure that sustainability goals align. Choosing partners with a commitment to sustainable practices and the appropriate expertise will be vital for businesses in meeting their sustainability targets.

ABOUT THE COMPANY

Quotient Sciences is a drug development and manufacturing accelerator providing integrated programmes and tailored services

across the entire development pathway. Cutting through silos across a range of drug development capabilities, Quotient saves precious time and money in getting drugs to patients. Everything Quotient does for its customers is driven by an unswerving belief that ideas need to become solutions, and molecules need to become cures, fast, because humanity needs solutions, fast.

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ABOUT THE AUTHORS

Michael Astle is the Executive Director of Legal Affairs and Head of Environment, Social and Governance (ESG) at Quotient Sciences, with over seven years of experience in the pharmaceutical industry. In this role, he oversees both the organisation's legal team and its ESG activities. As well as being a qualified lawyer, Mr Astle studied Business Sustainability Management at the University of Cambridge's Institute for Sustainability Leadership (UK). He is passionate about partnering with others to find solutions for business and the environment.

Dr Gareth Jenkins, PhD, is the Vice-President of Science and Technology at Quotient Sciences, with over 25 years of experience in the pharmaceutical services industry spanning drug discovery, drug development and drug product manufacture. Dr Jenkins brings a passion for science and innovation built on a broad and deep knowledge of medicinal chemistry, process development, industrial biotechnology, synthetic biology, continuous manufacturing, process analytical technology and process engineering. He uses this experience to guide drug development roadmaps from candidate selection, through pre-clinical and across clinical development phases. Dr Jenkins holds a degree and PhD in Organic Chemistry from Imperial College London (UK) and an MBA in Entrepreneurship from Manchester Business School (UK). He is also a Fellow of the Royal Society of Chemistry.

Ed Mayo, is the Director of Site Engineering at Quotient Sciences, with over 10 years of experience in pharmaceutical manufacturing. Mr Mayo's background as a manufacturing engineer and consulting process engineer gives him a unique perspective in understanding the needs of both internal and external customers. He is responsible for the leadership of the site engineering team and facilitates capital projects. He brings with him a strong focus on data driven continuous improvement and organisational discipline.