tks publisher event organiser media agency

chimica oggi CHEMISTRY TODAY
+ regular section: PHARMA HORIZON

Enabling Sustainable Manufacturing – From a CRDMO Perspective

Xiaoyong Fu, Ph.D.
CTO and Head of API Business, WuXi STA

CDMOs and CMOs are the key players in the ecosystem of the pharmaceutical industry. They specialize in providing manufacturing services, including active pharmaceutical ingredients (APIs) and intermediates, which require large scale chemical synthesis. As a result, they contribute significantly to energy consumption and waste emission within the industry. In recent years, there has been a growing emphasis on sustainable manufacturing practices among CDMOs and CMOs. Consequently, sustainability has become an important criterion for assessing responsible service providers.

As a unique CRDMO for new drug development, sustainability is one of WuXi STA's top priorities in our daily operations. Our primary focus is on four main approaches: carbon emission management, water resource management, solid waste management, and, most importantly, process mass intensity (PMI) management.

We prioritize controlling air emissions and energy consumption to reduce our carbon footprint. To address air emissions, we have implemented a series of approaches from source control, process control, to terminal control. For instance, organic solvents used in chemical synthesis are a significant source of carbon waste. By transitioning to milder or aqueous solvents, we can greatly enhance the environmental friendliness of the synthesis process, ultimately reducing the carbon footprint. When designing reactions, selecting green solvents based on the guidelines provided by the American Chemical Society Green Chemistry Institute Pharmaceutical Round (ACS GCIPR) is one of our key considerations.

In terms of process control, we employ fully contained equipment with proper seals and enclosures throughout the manufacturing process. We also utilize Local Exhaust Ventilation (LEV) to capture non-organized waste gases at their source. Terminal treatments, such as activated carbon absorption, scrubbers, and regenerative thermal oxidizer (RTO), are particularly effective in mitigating certain types of hazardous gas emissions. For example, the resin absorption technology implemented in all of our API manufacturing facilities collects over 2.2 tons of HCl every year, protecting the environment from acidification.

Energy consumption management is another crucial component of carbon emission management. We are committed to building a green and low-carbon campus through various energy-saving initiatives. One example is the utilization of a vapor absorption refrigeration (VAR) system, which generates steam for manufacturing by incinerating waste materials. This system has resulted in an annual savings of over 100,000 tons of commercial steam at our Changzhou API manufacturing site alone.

Natural energy sources, such as solar and geothermal energy, also contribute to building a green facility. Our drug product manufacturing site in Couvet Switzerland benefits from several geographical advantages that have transformed it into an exemplary green site. The site harnesses the rich geothermal energy emitted from 266 geothermal piles 100 feet below the ground to power the HVAC system, supplying heat to the facility. Additionally, the site takes advantage of the undisturbed atmosphere, optimizing solar power utilization. Through the implementation of fully automated shades and a reinforced façade, the facility minimizes the need for air conditioning. As a result of these initiatives, the site reduces CO_2 emissions by 70% compared to an equivalent-sized facility in the industry.

publisher
event organiser
media agency

chimica oggi
CHEMISTRY TODAY
+ regular section: PHARMA HORIZON

Water resource management is another crucial aspect of manufacturing sustainability. Similar to carbon management, designing greener processes with less water consumption is a primary focus for our process scientists in chemical synthesis. Furthermore, we implement systems to segregate rainwater, groundwater, and wastewater, along with wastewater classification and collection for reuse, as practical measures to preserve water resources.

Moreover, to ensure compliance with wastewater discharge regulations, we employ comprehensive pretreatment for sewage, including a biological treatment system and distillation of organic solvents from process wastewater.

Solid waste management relies heavily on meticulous management and planning. While careful process design helps reduce the generation of hazardous waste, it is crucial to have stringent classification and collection systems in place for proper waste treatment. Here, hazardous wastes are appropriately packaged, labeled, and transported to certificated third-party waste treatment facilities for disposal. Additionally, recyclable packaging materials are prioritized for use when applicable.

Last but not least, PMI management is one of the most important methodologies for achieving sustainable manufacturing. PMI serves as a key metric to measure the efficiency of manufacturing processes. In the new drug process development and manufacturing, synthesis routes and manufacturing processes are often not optimized to reduce PMI. To address this, for nearly a decade we have been proactively exploring and implementing green chemistry and engineering technologies in every aspect of process development and manufacturing. Our focus has primarily been on biocatalysis, continuous processing (also known as flow chemistry), direct isolations, and other applicable technologies in the field of process chemistry.

In order to standardize our approach, we have developed a multi-cascade bottom-up control system for each individual project. This strategy we adopt to achieve greener API processes started by evaluating the applicability of a variety of innovative technologies. Biocatalysis and chemocatalysis, together with new chemistry domains including photochemistry, electrochemistry, etc. are deeply assessed for the synthetic route design at the entry point of process chemistry.

When it comes to the reaction process development, we would use either flow chemistry as an enabler to achieve yield and process safety improvements and reduce waste generation, or high-throughput screening to quickly develop greener process conditions for batch processes. During this stage, we have a gate control for the use of environmentally unfavorable solvents and reagents and a well-defined target PMI for each individual step.

In the work-up stage, we would take direct isolation, continuous processing, and crystallization optimization to minimize waste generation. After manufacturing is completed in the plant, the PMI data are recorded for every step and evaluated as a direct measurement of our progress toward sustainability.

In addition to our well-established and proven strategy, WuXi STA remains committed to investing in our capability and capacity enhancement for biocatalysis, flow chemistry, and direct isolations.

As an industry-leading CRDMO, we face high expectations for ESG management from our clients and the public. We are dedicated to meeting these expectations and making a positive impact by protecting the environment through sustainable technologies and operations. Ultimately, our goal is to create a more sustainable world while improving the health of the patients within it.