Net-Zero Pledge: CDMOs Go Greener

Sustainability goals to redefine partnering. *This is the sixth of a nine-part series of articles addressing pharmaceutical outsourcing industry trends.*

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In the year 2021, when COP26 was held in Glasgow, Sterling Pharma Solutions came out announcing an ambitious target: to reduce the CDMO's overall emissions by 50% by 2025 and by doing so, joining the international community's fight against climate change.

The CDMO Recipharm expanded its pressurized metered dose inhalers (pMDI) product development the following year to accommodate the switch to new propellants, which have 90% to 99.9% lower global warming potential than HFA134a.

In the same year, WuXi STA won top scores from EcoVadis, a provider of business sustainability ratings, for their API and formulations factories located in China.

Again, in January, Samsung Biologics was awarded the 2022 Sustainable Markets Initiative's Terra Carta Seal in recognition of its commitment to achieving net zero greenhouse gas emissions across its direct operations and supply chain by 2050 or earlier.

Similarly, Cytiva says its goal is to eliminate polystyrene from the company's packaging materials and supply chain by 2025.

These are just a few examples of a growing trend.

A number of CDMOs are accelerating their environmental drive setting themselves far more ambitious targets than these as sustainability goals are now becoming one of the most urgent business strategies facing pharma companies.

Presently, analysts say that there is a move away from sustainability being seen as something that is nice to have, to something more fundamentally important to businesses.

"Sustainability commitments are no longer just desirable," says Jon Peers, director of sustainability at Hovione. "They are becoming mandatory, both directly by our regulatory authori-

ties and indirectly by the regulatory and financial requirements faced by our customers."

Hovione, a leader in spray drying and particle engineering, became a Certified B Corp in 2017 integrating an innovative community of companies that use the power of business to solve social and environmental problems.

PHARMA'S OUTSIZED IMPACT

Medicine making leaves an environmental impact which is quite massive. Estimates show that the pharmaceutical sector is accountable for as much as 4.4% of worldwide emissions—and if no action is taken—its carbon dioxide, a greenhouse gas (GHG), emissions are predicted to triple by 2050.

Not only manufacturing but the distributing and transporting of medicines from the factory to the patient also carries a substantial environmental footprint.

According to the Sustainable Markets Initiative's (SMI) "Decarbonizing Healthcare Supply Chains" whitepaper, the biopharma industry is responsible for 4–5% of global GHG emissions, with most of its carbon footprint coming from supply chain, manufacturing, retail, and logistics.

Having felt the heat, many leading pharma companies are already ahead of the curve on the path to net-zero carbon emissions. They have made carbon neutrality and net-zero pledges, some for as early as the next decade.

SUSTAINABILITY METRICS: HIGH ON THE AGENDA

CDMOs demonstrate a strong determination to reduce their carbon emissions as environmental performance is being added to the list of demands by their clientele.

Industry reports show that full waste recycling, green power percentage and green chemistries currently play a crucial role during negotiations between pharmaceutical companies and the CDMOs.

These "sustainability metrics" are becoming increasingly important even as technology, track record, capacity, and cost are still the most important criteria for selecting CMOs/CDMOs.

"Recognizing our commitment and progress made towards our sustainability targets, clients will seek out not only providers of CDMO services but also those companies with the competence to execute these services in harmony with the client's respective sustainability goals," says Paul Zuechner, director, sustainability and reliability engineering, pharma services, Thermo Fisher Scientific.

Thermo Fisher, which offers end-to-end solutions to small molecules as well as biologics, announced an acceleration of the target to reduce scope 1 and 2 GHG emissions to more than 50% by 2030.

Zuechner maintains that the increasing focus on sustainability, resource and decarbonization quantifications is now elevating sustainability towards an equal project deliverable on par with cost, quality, and timelines.

The sustainability initiatives by CDMOs are not only driven by customer preference but also by regulatory requirements, according to Peers of Hovione. Regulated and standardized reporting is there. The European Corporate Sustainability Reporting Directive (CSRD) together with the European Sustainability Reporting Standards (ESRS) is significantly raising the required levels of compliance.

On top of this, businesses must meet their stakeholder's requirements to provide material information that stands up to scrutiny.

Headquartered in Loures-Portugal, Hovione believes that it is simply not possible to meet the challenging goals that have been set by the companies themselves on sustainability without further innovation, particularly through process intensification and the greening of pharmaceutical intermediate and API manufacturing.

SAFETY VIA PROCESS EFFICIENCY

Without question, manufacturers are aggressively pursuing various strategies to enhance processes as it becomes a business imperative for the service providers.

"Olon tries to optimize plants' performances, in order to reduce the amount of energy, materials and natural resources they need," says Giorgio Bertolini, senior vice president of R&D, Olon Group, a global leader in the development and production of APIs, headquartered in Milan, Italy.

Olon is working on cutting-edge R&D processes applied both to chemistry, in terms of flow chemistry, photochemistry, and electrochemistry, and to biotechnologies. Investing in and developing technological advances allows the organization to combine well-established practices with new ones, to guarantee efficient and successful manufacturing processes, at the same time ensuring safe, fast and cost-effective commercial processes.

"We consider climate protection and the related reduction of GHG emissions to be a top priority," emphasizes Bertolini. To increase efficiency and reduce the energy required for production, especially in the functioning of reactors, Olon is implementing several continuous manufacturing processes, investigating both the flow chemistry approach and the continuous stirred tank reactors (CSTR)

These approaches entail leaving no batch reactors with loading and unloading phases but keeping constantly active production units—either microreactors or small classical reactors. The outcome is that, at the same levels of production, continuous manufacturing processes can reduce the footprint of the manufacturing process in comparison with standard methods.

This innovative production technique, he explains, enables a double positive impact in terms of sustainability. Indeed, it allows for the use of smaller amounts of material for the unit time, therefore resulting in increased local temperature control and in the possibility to avoid extreme temperatures, making the

manufacturing process less energy intensive. It also provides greater safety for operators.

The industry is now facing a change of paradigm, avers Bertolini, in which there is a continuous exchange of knowledge and information between the chemical and engineering sectors, which eventually results in the creation of new specific know-how and business synergies.

Olon started constructing a new facility at its Rodano site (Milan, Italy) dedicated to ultra-potent compounds, used for antibody-drug conjugates (ADCs).

Circular business models that combine a responsible use of natural resources and raw materials with a responsible waste management approach are what Olon strives to promote, according to Bertolini.

GREENING THE SUPPLY CHAIN

To reduce effluents and design safer alternatives to hazardous processes organizations extensively explore the use of safer and more sustainable chemicals.

This green chemistry approach can minimize the risk of impact on the environment to a great extent.

Olon, for instance, is focusing on green chemistry projects for the replacement of chlorinated solvents and the reduction of critical substances which could be particularly toxic, especially in new manufacturing processes.

Not only in manufacturing, quite a few companies are investing in greener biofuels (rather than diesel) for vehicles. As mentioned, distributing and transporting medicines from the factory to the patient also leaves a large carbon footprint. Temperature-sensitive products are loaded onto refrigerated vehicles to maintain cold-chain which require a considerable amount of energy to power.

Environmental credentials are now integral to all supply chain decisions. There is almost a universal consensus on this approach, shows the CPHI sustainability sentiment index.

In data released ahead of CPHI Frankfurt 2022, 95% of industry executives suggest it is either "important" or "extremely important" (52%) to have visibility on supply chain partners.

SCOPE 3 EMISSIONS: KEY CHALLENGE

In comparison to the scope 3 tally that falls not within the organization's boundary, scopes 1 and 2 emissions are relatively minor. However, within these scopes, electrical energy consumption in manufacturing and the fugitive emissions from hydrofluorocarbons (HFC) released during pMDIs product lab testing are the highest.

pMDIs and anesthetic gases can be particularly serious for global warming. The UK and several countries in the EU block including Belgium, and the Netherlands are now promoting dry powder inhalers in prescription guidelines. Meanwhile, the common general anesthetic desflurane is being replaced by lower-carbon alternatives in countries like Sweden.

Scope 3 emissions, however, make up the majority of the pharma sector's carbon footprint. Even though many CDMOs have set ambitious targets like striving for carbon neutrality across the entire value chain already by 2030, many are still simply focusing on scope 1 and 2 emissions.

Observers say that this is largely because the need for sustainability in the pharmaceutical industry has become more apparent only in recent years.

Another concern is the cost factor.

According to Peers of Hovione, decarbonization costs in particular can be very expensive and require strategic planning and commitment from senior management to meet associated capital and operational costs.

The sustainability challenge, he says, needs to be considered throughout the drug development life cycle, starting from simple assessments against sustainability principles and metrics early on and growing in detail and robustness as the drug progresses through the cycle.

SHIFT IN FOCUS

Experts, however, see a shift across the industry. Discussions about sustainability are taking place at the highest levels. An increasing number of pharmaceutical companies are prioritizing it when discussing projects with their CDMO partners.

"Be it the fulfillment of new technical capabilities, increased production capacities, advancing regulatory compliance and now sustainability target introductions—it's natural for us to solve for and achieve our customers' product development, manufacturing, and corporate goals in partnership," says Zuechner of Waltham, Massachusetts-headquartered Thermo Fisher.

It will be essential for drug makers and their CDMO partners to work together on questions of sustainability, and to be ready with a sustainability agenda before starting to work on the project, in the coming years.

It is important for CDMOs, says Peers, that their clients and suppliers share the same vision of a more sustainable industry as collaboration across the value chain is key to leveraging knowledge and driving change. **CP**

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