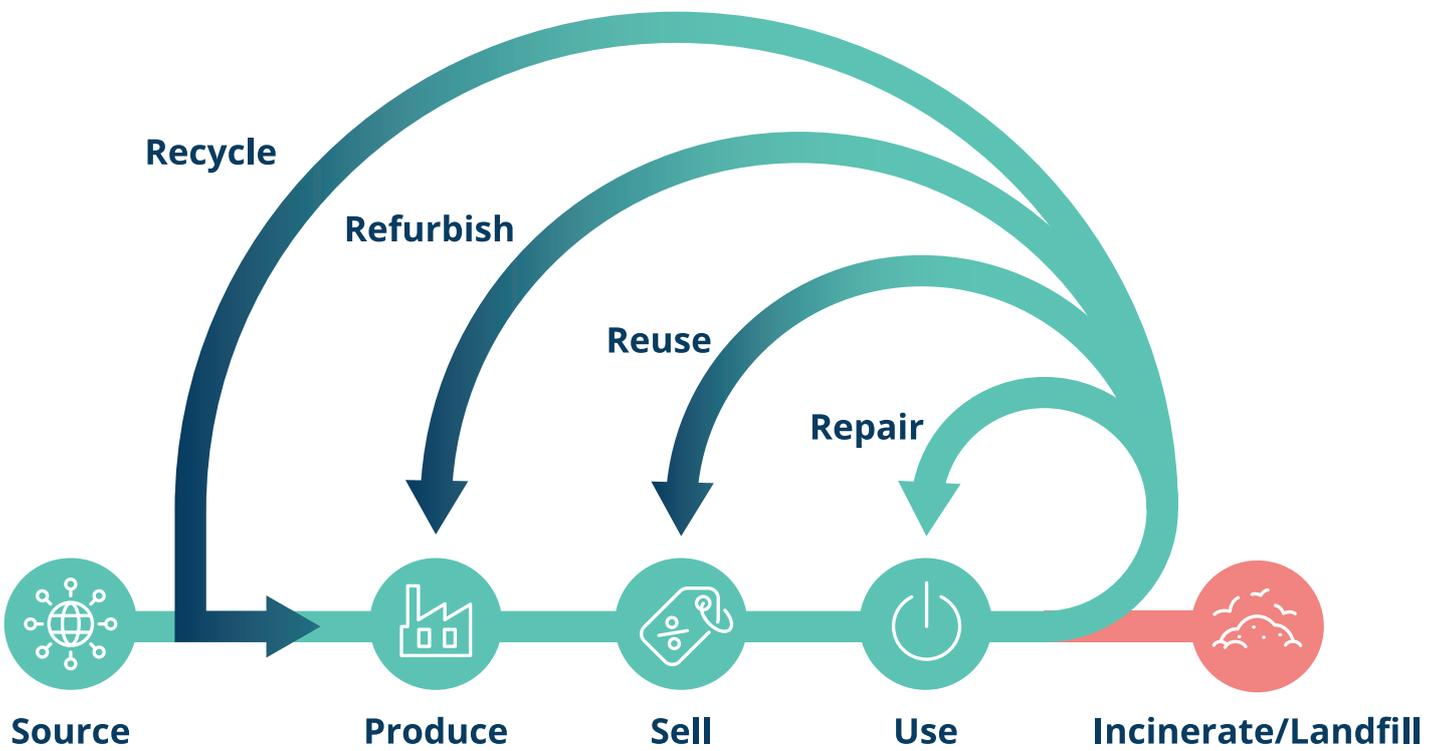


DRUG DELIVERY & ENVIRONMENTAL SUSTAINABILITY



SMC[®] Ltd.

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SUSTAINABILITY CONSIDERATIONS FOR END-TO-END DRUG DELIVERY DEVICE SOLUTIONS

In this article, Barbara Lead, Chief Executive Officer of Cambridge Pharma and Oval Medical Technologies, outlines the sustainability efforts undertaken by SMC Group associated companies, including facilitating the transition from hospital to at-home treatment and investment in greener facilities.

At the 2021 COP26 summit in Glasgow, further cuts to carbon dioxide emissions were agreed to accelerate action on climate change over the course of this decade. The aim is to keep the average global temperature increase to less than 1.5°C, as recommended by scientists to prevent a climate catastrophe. Beyond legislative requirements, businesses must innovate and act smartly to support this objective.

The SMC Group, comprised of Oval Medical Technologies, SMC Ltd and Cambridge Pharma, is mindful of this. SMC Group provides an end-to-end solution for sterile injection devices, including autoinjectors. This end-to-end solution includes customisation of the appropriate device platform to meet the specific user requirements, component manufacture, filling of the primary drug container, and assembly and integration to produce the final device. In addition, process development from laboratory scale to clinical scale can be provided, as well

as quality control and stability testing. Further process development, scale up and technology transfer to commercial quantities can be provided for product launches.

In the provision of this end-to-end solution, the Group's sustainability strategy has four key components:

1. Replace high carbon footprint plastics with lower carbon footprint alternatives
2. Develop autoinjectors that facilitate at-home treatments that reduce the need for patient travel and day care hospital beds
3. Cambridge Pharma uses dynamic heating, ventilation and air conditioning (HVAC) systems, which reduce energy usage, and green energy suppliers
4. Cambridge Pharma offers pharmaceutical development services in the UK, enabling customers to reduce transport miles in their supply chains.

The aim of SMC Group's strategy to minimise the carbon footprint of its facilities and products is to, in turn, reduce the carbon footprint associated with drug delivery. SMC Group seeks to achieve this not only through device manufacture but also by delivering innovations that enable the reduction of the carbon footprint associated with patients' treatments. To realise the goal of providing an end-to-end solution while minimising the carbon footprint of the final drug-device combination, it is necessary to perform an analysis of the value chain and trends in patient treatments.

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DEVICE DESIGN AND MANUFACTURE

There are several ways of minimising the carbon footprint of a drug delivery device. Oval's devices use a novel primary drug container made of cyclic olefin polymer instead of glass. Plastics are better for the environment as the manufacture and shipping of glass uses more energy. Oval also aims to use grades of plastic that have low carbon footprints.

SMC Ltd manufactures the plastic components for all its drug delivery devices and has attained a bronze award from EcoVadis for its environmentally friendly manufacturing processes and energy minimisation strategies. Oval is following SMC Ltd's lead on this front and aims to achieve an EcoVadis award with the next year.

While biodegradable materials are becoming available, they are not yet suitable for medical devices. However, Oval does use these materials for rapid prototyping during the development process as part of its environmental policies.

Furthermore, Oval is now following SMC Ltd's example with respect to energy use minimisation. The company's electricity provider uses clean energy, lighting is controlled by movement sensors and the company uses local UK suppliers wherever possible.

MOVING FROM HOSPITAL TO HOME AND EXTENDING TIME BETWEEN TREATMENTS

The carbon footprint of a drug delivery device can be dwarfed by that of the patient journey involved in providing treatment. Many drug treatments, such as chemotherapy, are provided in a hospital, either as an outpatient treatment or, on occasion, requiring an overnight stay.

The covid-19 pandemic led to healthcare providers (HCPs) visiting patients in their homes. Additionally, many clinical trials were taken out of the clinic and moved into patients' homes. This change in treatment provision during the pandemic has led to a change in HCPs' perspectives on at-home treatment, with many seeking to move more treatments from hospital to home.

The movement of treatment from hospital to home frequently involves a change in a drug's route of administration from intravenous to subcutaneous. Many pharma companies are reformulating existing products and formulating new products to allow for subcutaneous or intramuscular administration for use by outreach HCPs or patients themselves. As a result, there is increasing demand for autoinjectors that can deliver 5–20 mL of drug formulation, some of increasingly high viscosity. There is also a trend towards extending the time between treatments using long-acting injectables. These formulations are often gel-like suspensions or ultra-high viscosity, which are challenging to deliver.

Oval has platforms that can deliver large volume, ultra-high viscosity formulations, including gels and suspensions. These formulations are delivered by devices containing powerful springs and Oval's proprietary cyclic olefin primary drug containers, which have been designed with high burst strength to facilitate such deliveries. These devices are designed to be intuitive to use, and studies have shown very low levels of user errors even without training, ensuring treatment efficacy. For frequent administration or multiple injections in a home setting, reusable devices can reduce a treatment's carbon footprint even further.

By facilitating self-administration, Oval's autoinjectors reduce the travel required to and from the hospital and reduce the need for beds for day patients and overnight stays. The ability to deliver long-acting injectables reduces the number of devices required per year to treat a

“The ability to deliver long-acting injectables reduces the number of devices required per year to treat a patient, greatly reducing the consumption of materials in manufacturing and the impact of their supply chain on the environment.”

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SUSTAINABILITY AT CAMBRIDGE PHARMA

Cambridge Pharma is a new pharmaceutical services business, specialising in process development, sterile fill-finish, quality control and stability testing of small-batch sterile products for clinical trials and launch volumes. The process development team has experience with fill-finish of difficult-to-fill formulations and has the capability to fill vials, syringes and cartridges, as well as custom primary drug containers.

The company's new fill-finish facility has two cleanrooms equipped with isolators for aseptic fill-finish. Each filling suite has independent HVAC systems that use dynamic air control to maintain room classifications and reduce air flow when the room is not in use overnight and at weekends. This intelligent cleanroom control system delivers a demonstrable change in energy consumption – a reduction in excess of 60% in previous projects when compared with static systems. This is extremely important when cleanroom energy consumption accounts for 65–70% of cleanroom costs. The facility uses green energy and lighting is controlled by movement sensors.

Based in Cambridge (UK), this new business offers UK customers an opportunity to reduce their carbon footprint still further by reducing transport. The ability to fill ultra-high-viscosity formulations, gels and suspensions in the UK has the potential to reduce product transport requirements by miles, as well as reducing travel distance for customers working with Cambridge Pharma's teams.

SUSTAINABILITY AT SMC LTD

SMC Ltd has its headquarters in Somerset (WI, US) and six manufacturing locations, four in the US, one in Costa Rica and one in India. The company provides contract manufacturing services to three primary market sectors, medical devices, diagnostics and pharma in drug delivery. Sustainability has been an SMC Ltd focus for many years, primarily in the tracking and reporting of greenhouse gas emissions. Improvements have been driven in all facilities across various areas:

1. Installing LED lighting and motion sensors
2. Installing more efficient air compressors
3. Switching to servo-driven moulding machines versus hydraulic-driven, which require up to 70% less energy
4. Use of solar panels in select locations
5. Using variable frequency drives on water chillers (based on building demand).

For the past four years SMC Ltd has been a part of the EcoVadis programme. EcoVadis is a third-party company that provides holistic

sustainability ratings for companies to incorporate and use as part of their sustainability programmes, focusing on four key areas:

- Environmental
- Labour and human rights
- Ethics
- Sustainable procurement impacts.

SMC Ltd achieved an EcoVadis “Bronze Sustainability Rating” for 2021, which places it among the top 50% of all companies assessed by EcoVadis.

ABOUT THE COMPANIES

Oval Medical Technologies specialises in the development of patient-centric autoinjectors that meet the most challenging requirements arising from diverse patient groups and novel drug formulations. Oval’s technology platforms can be customised to deliver a wide range of drug formulations, including fragile molecules, biologics for both subcutaneous and intramuscular injection with high viscosities and large volumes. Oval’s patented primary drug container technology provides the design freedom to create truly optimised devices for patient benefit.

SMC Ltd, with more than 33 years of experience, provides product services from initial concept to the final packaged device, including programme management, design and development, product

manufacturing, clinical/commercial manufacturing, electronics integration and global supply chain management. SMC Ltd has global GMP manufacturing sites in the US, the UK, Costa Rica and India.

Cambridge Pharma specialises in pharmaceutical services, sterile fill-finish batches of 100–10,000 units for a range of presentations including its own primary containers, as well as syringes, cartridges and vials. The company works with a wide variety of formulations including small molecules, proteins, peptides and biologics. Its flexible, broad service offering includes development and scale-up of the fill-finish process, including development of container closure integrity test methodology, analytical method development for QC release, and stability testing.

ABOUT THE AUTHOR

Barbara Lead is the Chief Executive Officer of Cambridge Pharma and Oval Medical Technologies. Ms Lead has held senior positions in three pharma companies and has experience in R&D and industrialisation. Working in the field of asthma and allergy, she has experience working with a variety of drug-device combination products and in solving manufacturing and design issues with drug delivery devices. Over many years, Ms Lead has come to realise the importance of good device design, risk assessment and human factors in the development of delivery devices to ensure effective drug delivery and correct use by patients.



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