

ADOPTION OF SUSTAINABILITY PRACTICES WITHIN SUBCUTANEOUS DRUG DELIVERY: INDUSTRY INSIGHTS

Conor O'Neill, Duncan Paterson and Dr Monica Adams of the Subcutaneous Drug Development & Delivery Consortium come together to discuss a recent study conducted by the Consortium among its member organisations, digging into the pharmaceutical industry's progress and priorities when it comes to improving the environmental impact of subcutaneous medicines.

“THE OBJECTIVES OF THE STUDY WERE TO INFORM FUTURE INITIATIVES OF THE SUSTAINABILITY SUB-TEAM, AS WELL AS TO IDENTIFY OPPORTUNITIES FOR BROADER COLLABORATION ON ENVIRONMENTAL SUSTAINABILITY EFFORTS ACROSS THE BIOPHARMA AND PHARMACEUTICAL INDUSTRIES.”

The pharmaceutical industry is making substantial efforts to reduce its environmental impact and contribute towards global climate goals. Most pharma companies are aligned with international initiatives such as the Paris Agreement and the United Nations’ “Race to Zero” campaign, and have made public commitments to reduce carbon emissions across the entire value chain by 2045, with interim targets set between 2025 and 2030 to ensure progress, according to a survey of various company websites.

While there is a clear drive for change, realising pharma companies’ ambitions

will require greater collaboration and industry alignment towards implementation of sustainability efforts across the subcutaneous (SC) product value chain, from raw materials through to end use. Currently, environmentally oriented solutions are limited and often only occur at the local product or company level, thereby minimising the opportunities available and their effectiveness.

Against this backdrop, the Sustainability Sub-Team of the Subcutaneous Drug Development & Delivery Consortium (SC Consortium) conducted a study of its member organisations to benchmark

SC Consortium Member Organisations (N=12)	Survey Respondents (N=12)	Interview Participants (N=29)
AstraZeneca	1	3
BD	1	3
Biogen	1	1
Boehringer Ingelheim	1	2
Bristol Myers Squibb	1	3
GlaxoSmithKline	1	3
Halozyme	1	1
J&J Innovative Medicine	1	4
Merck	1	3
Novartis	1	3
Pfizer	1	1
Sanofi	1	2

Table 1: Number of representatives for each SC Consortium member organisation participating in the sustainability benchmarking study.

environmental sustainability-related commitments, ambitions and perspectives across the industry. The objectives of the study were to inform future initiatives of the Sustainability Sub-Team, as well as to identify opportunities for broader collaboration on environmental sustainability efforts across the biopharma and pharmaceutical industries.

The study was conducted in two phases. The first was an online quantitative pre-work questionnaire completed by representatives from each member organisation (with the support of subject matter experts within their organisations as needed). The second phase involved in-depth, qualitative, discussion-based interviews with the respondents of the first phase together with other expert representatives of each participating company.

The discussion was designed to collect qualitative, contextual information about the quantitative ratings provided in the first phase and more generally about adoption and implementation of sustainability improvement practices within the member companies. Responses from individual interview participants were then reviewed and consolidated to achieve industry insights. While the majority of respondents were employed in packaging or device development functions within their companies, experts from environmental sustainability, drug development, commercial and regulatory affairs were also included. Companies varied with regard to the number of individuals providing responses (Table 1).

COMMON THEMES ABOUT SUSTAINABILITY COMMITMENTS AMONG MEMBER ORGANISATIONS

Strong, corporate-level sustainability commitments aimed at achieving major reductions in environmental impact have been made across the SC Consortium's member organisations. However, the study results indicate that, despite this corporate-level commitment, the transition to less environmentally impactful practices is lagging across all participating companies (Figure 1).

Qualitative discussions suggested that, to date, most member companies have concentrated their sustainability efforts

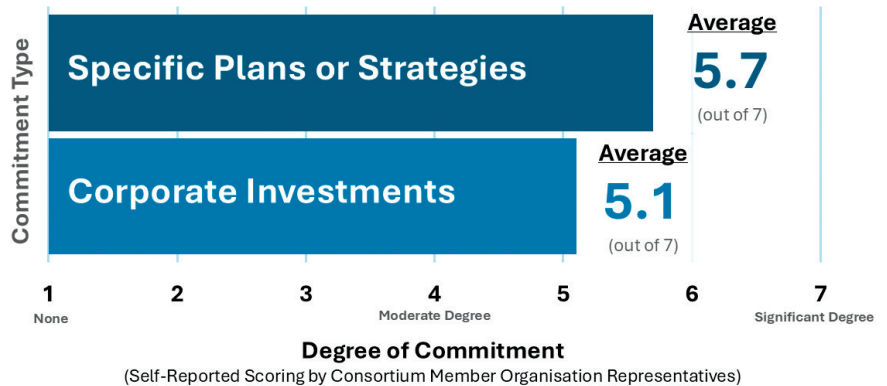


Figure 1: Existing commitments of Consortium member organisations towards future implementation of sustainable practices in product development.

"QUALITATIVE DISCUSSIONS SUGGESTED THAT, TO DATE, MOST MEMBER COMPANIES HAVE CONCENTRATED THEIR SUSTAINABILITY EFFORTS ON AREAS THAT ARE COMPARATIVELY EASIER TO ADDRESS, SUCH AS SECONDARY AND TERTIARY PACKAGING."

on areas that are comparatively easier to address, such as secondary and tertiary packaging. In contrast, more complex domains – such as drug product formulation, device redesign and supply chain transformation – remain less advanced. A second theme concerned the regulatory environment, which participants described as both a challenge and an enabler; regulations can create prohibitive burdens for implementation, yet they are

also viewed as essential for establishing a level playing field and compelling the industry to adopt more difficult but necessary changes.

Companies have identified that packaging is an area where environmental improvements can be implemented with lower complexity and risk compared with the drug product or manufacturing processes (Table 2), which can serve as an enabler for broader sustainability

Product Development Process	Degree to Which Sustainable Transitions Are On Track*
Product Development Overall	5.6
Packaging	5.8
Procurement	5.5
Supply Chain	5.3
Product Development – Devices	5.2
Manufacturing – Devices	5.1
Product Development – Formulation	4.7
Manufacturing – Formulation	4.7

Table 2: Degree to which Consortium member organisations self-assess being on track with future transitions towards more sustainable practices. *Average score on scale from 1 (not at all on track) to 7 (completely on track).

transitions. Furthermore, respondents scored packaging transitions highest in terms of the degree to which they were on track with corporate sustainability goals and targets.

Table 3 highlights that secondary and tertiary packaging are the areas where green credentials are most likely to be considered compared with other aspects of product development. Table 4 shows that energy consumption, supplier selection and waste reduction are the key factors influencing selection decisions during development and process selection.

CONFLICTING PRIORITIES IMPACT IMPLEMENTATION OF REUSABLE AND MULTIDOSE DEVICES DESPITE ACKNOWLEDGED ENVIRONMENTAL BENEFITS

The study confirmed that the environmental benefits of reusable and multidose SC delivery devices over single-use devices are widely recognised because of the significant reduction in material use, waste and emissions per dose. However, despite these compelling benefits, there is not yet widespread adoption of these more complex devices, especially of those that require additional training or operational steps. Study responses confirmed that Consortium member organisations are hesitant to adopt these technologies because of the possible use-related risks they are perceived to bring. Furthermore, when considering reusable devices, factors such as the intervals between doses and use-risks – such as “memory-decay” known to occur after training with more complex systems – are barriers to adoption.

ALTERNATIVE MATERIALS AND PROCESS APPROACHES TO REDUCE ENVIRONMENTAL IMPACT

The study indicates that alternative approaches to achieving sustainability goals are seen as easier to adopt, such as adjustments to material selection and sources of energy for the production of glass, plastic and metal components. Alternative plastics, for example, bio-sourced resins, can be used for packaging and device components to reduce environmental impact; however, to date, member

Product Development Process	Degree to Which Green Credentials Are Considered*
Secondary/Tertiary Packaging	5.2
Devices – Product Design	4.3
Primary Packaging	4.1
Devices – Manufacturing Processes	3.9
Drug Product – Formulation Development	3.9
Drug Product – Manufacturing Processes	3.9

Table 3: Degree to which green credentials are considered in Consortium members' product development processes. *Average score on scale from 1 (not at all considered) to 7 (significant consideration).

Green Credential Selection Factors	Importance When Selecting Green Credentials*
Energy Consumption	5.5
Supplier Selection	5.5
Waste Reduction	5.3
Device Material Selection	5.1
Container Selection/Primary Packaging	4.8
Drug Product Formulation Ingredients	4.4
Selection of Excipients	4.3
Automation	3.7

Table 4: Perceived importance of factors when selecting product development and manufacturing processes with green credentials. *Average score on scale from 1 (not important) to 7 (highly important).

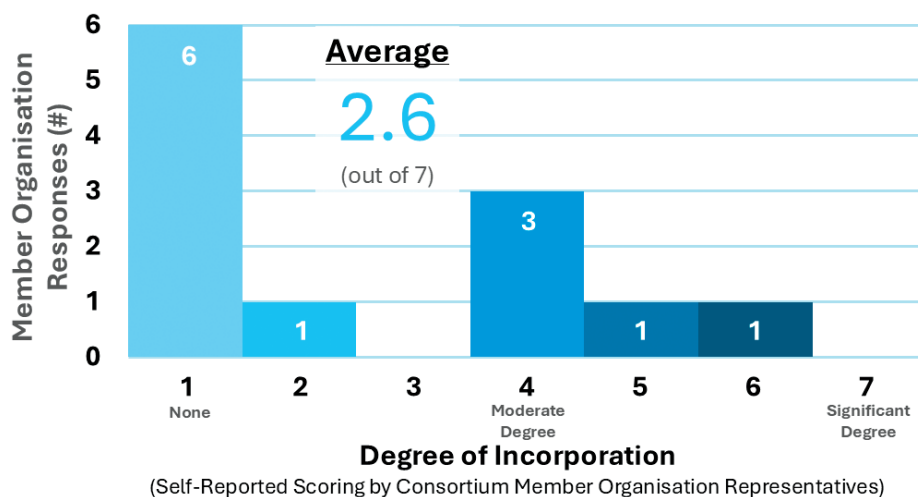


Figure 2: Current incorporation of non-fossil-derived or recycled polymers in Consortium members' SC delivery devices.

Polymer Type	Importance for Achieving Sustainability Goals*
Bio-based Polymers	5.2
Virgin Petrochemically-Derived Polymers	5.2
Biomass Polymers	4.5
Chemically Recycled Polymers	3.8
Carbon-Captured Polymers	3.7
Mechanically Recycled Polymers	3.0

Table 5: Importance of plastic material types for achieving Consortium members' sustainability goals. *Average score on scale from 1 (not important) to 7 (highly important).

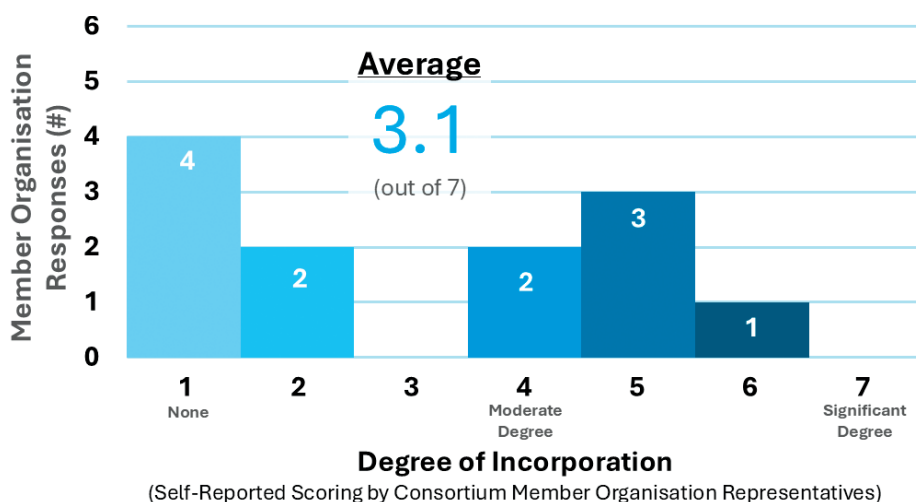


Figure 3: Current incorporation of circularity in Consortium members' product-development processes.

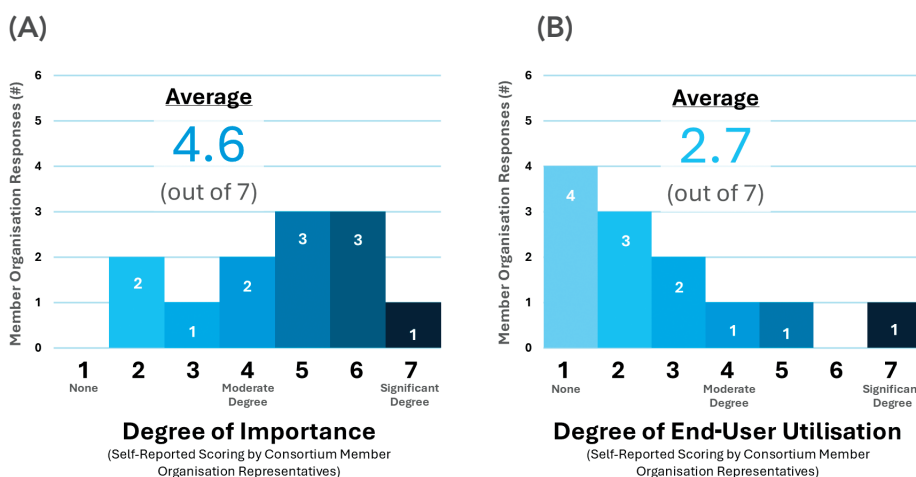


Figure 4: (A) Importance of take-back programmes to achieving Consortium members' sustainability goals; (B) Current end-user use of Consortium members' take-back programmes.

organisations report limited incorporation of non-fossil-derived or recycled polymers in their products (Figure 2). These changes can be challenging to implement, given the regulatory implications, stringent safety and quality requirements, and concerns related to ethical sourcing. However, study responses indicate that alternatives to petrochemical-derived resin materials are considered to be important for achieving sustainability goals (Table 5).

Lower scores for the importance of certain available polymer options may be down to a lack of familiarity or experience with these newer materials or feedstock flows. Moreover, qualitative responses indicated that companies remain cautious due to supplier dependency and uncertainties related to quality and consistency, as well as broader environmental impacts, including biodiversity and land use.

The qualitative responses from the second phase of the study indicate that companies consider the ethical concerns that accompany bio-derived feedstock sources for bio-based plastic resin production, specifically including risks related to the displacement of agricultural land at the expense of food production and of impacts to rainforests. Nevertheless, there is some expressed interest from companies in the introduction of lower-impact plastics through alternative hydrocarbon sources or mechanical recycle. Provided that outstanding concerns related to consistent material quality control, relative availability, cost and true environmental benefit can be addressed, we may start to see a reduced reliance on non-renewable resources in the industry.

Circularity

Consortium member organisations are conscious of the loss of high-value materials contained within injection devices upon disposal. However, most struggle to translate circularity ambitions into real action to prevent loss to landfill or incineration (Figure 3).

Safe retrieval of used devices for reprocessing of materials is important to achieving circularity, but study responses indicate that perspectives on take-back schemes are mixed (Figure 4). Consortium member organisations

generally acknowledge that successful implementation of reverse-logistics schemes can prevent material losses, but they also point out that they are challenged by high implementation costs and the need to take on greater downstream responsibilities that are beyond the typical reach of pharma companies, including redefining relationships with waste management organisations.

Historically, the success rate of medical device take-back schemes has been low,¹ and study participants commented that achieving greater return rates requires substantial upfront investment, making it difficult to make a sound business case to support their implementation. However, despite these challenges, some Consortium member organisations are interested in pursuing take-back schemes, especially if there is a stronger and more collaborative push across the industry.

LCAs and Eco-Design Principles

Although lifecycle assessments (LCAs) are conducted for fewer than half of Consortium members' products, study participants confirm that these assessments are currently used to both assess environmental impact and inform decisions. During development, some Consortium member organisations use internal tools to identify and evaluate opportunities for sustainability improvements. Results from these internal tools are generally not externally reportable but are intended to support decision-making during product design and development phases.

Comprehensive LCA methodologies are typically employed retrospectively for fully defined commercial products, when the overall environmental impact can be calculated and reported. At the time of the study, some Consortium members were not yet conducting LCAs for SC delivery devices. This may present a barrier to these organisations with respect to future collaboration opportunities,

Product Development Process	Importance of Eco-Design Considerations*	Formal Incorporation of Eco-Design Criteria**
Product Development Overall	5.3	4.8
Packaging	5.8	5.3
Product Development – Devices	5.7	4.9
Procurement	5.3	4.8
Manufacturing – Devices	5.1	4.2
Supply Chain	4.8	4.0
Product Development – Formulation	4.7	4.6
Manufacturing – Formulation	4.6	4.3

Table 6: Importance versus formal incorporation of eco-design criteria in various Consortium members' product-development processes. *Average score on scale from 1 (not important) to 7 (highly important) **Average score on scale from 1 (not implemented) to 7 (significantly implemented).

including learning best practices from other organisations and aligning on common industry practices for analyses and reporting.

Eco-design – a product-development approach that considers (and aims to reduce) environmental impact throughout a product's lifecycle – is a noteworthy approach for promoting environmental sustainability. Embedding good eco-design principles in product development can broadly improve sustainability outcomes when designing or updating subcutaneously delivered medicines, including enabling the adoption of less impactful materials; facilitating product recovery, disassembly and recycling; and establishing aligned LCA reporting across the supply chain.

Results from the study revealed that eco-design considerations are seen by Consortium members as important levers for packaging, drug delivery devices and procurement activities, but application of these considerations to formulation design and defining the supply chain is

perceived to be more challenging (Table 6). Qualitative responses indicated that applying eco-design principles to drug products and delivery devices is perceived as more complex than it is for packaging, due to regulatory requirements, the need for changes in fill-finish operations, and the inherent difficulty of adapting biologics and other formulations. Participants emphasised that such changes require more time, phasing and investment to implement compared with secondary or tertiary packaging.

Regulatory

Sustainability-led transitions must be managed within the context and constraints of existing and emerging regulatory frameworks. Study participants expressed that Consortium member organisations generally have good understanding of and compliance with regulations for topics such as zero emissions targets and pharmaceuticals in the environment, as these have been established for many

DEEP DIVE INTO TOMORROW'S DRUG DELIVERY INNOVATIONS



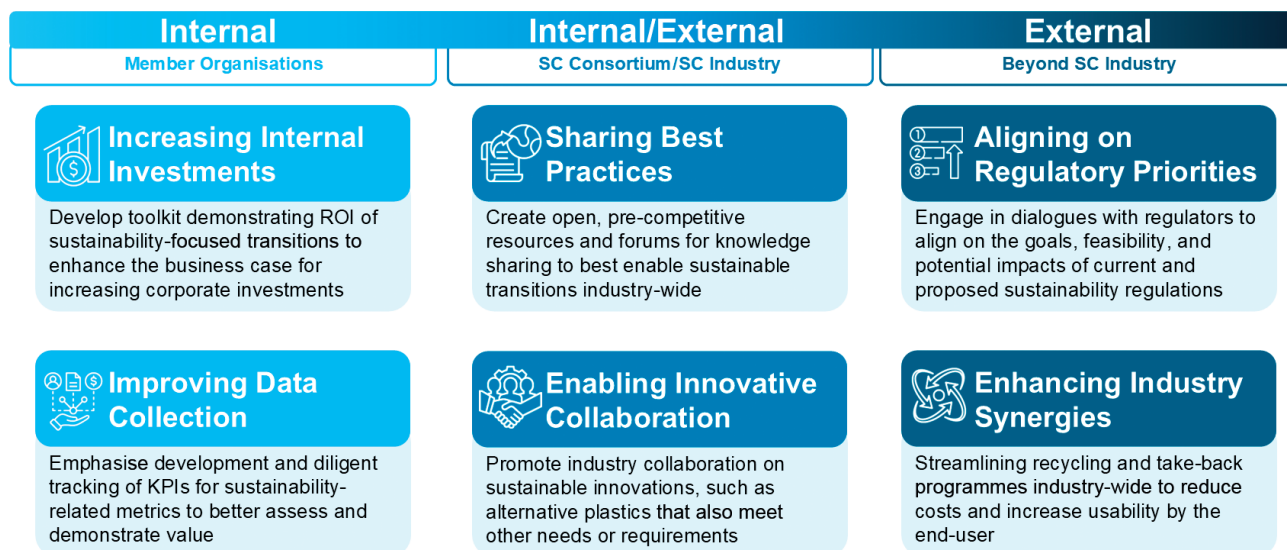


Figure 5: Recommendations following the SC Consortium sustainability benchmarking initiative.

years.^{2,3} On the other hand, greater difficulties can be experienced managing compliance with newer legislation and usage restrictions related to problematic materials, such as PVC and per- and polyfluoroalkyl substances.^{4,5}

The pace of regulatory change is increasing within the pharmaceutical industry and has the potential to impact shared supply chains. Newer regulations, such as the Packaging and Packaging Waste Regulation in Europe, are not always fully compatible with medical and medical device regulations.⁶ While temporary derogations can provide additional time for achieving compliance, these are typically time-limited and, ultimately, the industry must find ways to meet the growing environmental regulatory requirements. The study results suggest that environmental regulations are seen as either a positive stimulant for industry-wide progress towards environmental sustainability or as significant additional complexity for the industry to manage.

CONCLUSION

The sustainability benchmarking initiative led by the Sustainability Sub-Team of the SC Consortium found that there is strong commitment to sustainability among the Consortium's membership. However, while there is a measurable desire to achieve impact – from enhancing packaging sustainability to exploring bio-based materials and circularity – notable challenges remain. Many companies face a gap between ambitious corporate targets and the internal investment required to embed sustainability practices in SC product development, especially when balancing regulatory demands and patient needs. Moving forward, the Consortium will prioritise collaborative efforts towards industry-wide best practices, focus on aligning strategic sustainability ambitions with practical implementation, and encourage targeted investments to overcome the complex challenges of transitioning to less environmentally

impactful SC drug products (Figure 5). This collective approach will be essential for achieving meaningful environmental progress while continuing to innovate for improved patient outcomes.

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ABOUT THE COMPANY

The Subcutaneous Drug Development & Delivery Consortium was established in 2018 to fundamentally improve subcutaneous drug development and delivery. Motivated by this shared goal, the organisations within the Consortium's membership have come together to address key issues in the subcutaneous industry and expand subcutaneous technology use to improve patient outcomes.

REFERENCES

1. Murphy A et al, "Understanding the feasibility and environmental effectiveness of a pilot postal inhaler recovery and recycling scheme". *NPJ Prim Care Respir Med*,

"MANY COMPANIES FACE A GAP BETWEEN AMBITIOUS CORPORATE TARGETS AND THE INTERNAL INVESTMENT REQUIRED TO EMBED SUSTAINABILITY PRACTICES IN SC PRODUCT DEVELOPMENT, ESPECIALLY WHEN BALANCING REGULATORY DEMANDS AND PATIENT NEEDS."

- 2023, vol 33(1), art 5.
2. “Pharmaceuticals in the Environment (PIE)”. Web Page, EFPIA, accessed Sep 2025.
3. “Guideline on the environmental risk assessment of medicinal products for human use”. EMA, Aug 2024.
4. “Investigation Report on PVC and PVC Additives”. European Chemicals Agency, Nov 2023.
5. “EU PFAS restriction”. Web Page, Plastics Europe, accessed Sep 2025.
6. “Regulation (EU) 2025/40 of the European Parliament and of the Council of 19 December 2024”. Official Journal of the European Union, Jan 2025.



Conor O'Neill

Conor O'Neill, Director Packaging Development & Design, R&D at GSK, is a seasoned pharmaceutical expert with over 20 years' experience spanning oral, inhaled, intranasal and parental medicines. He spearheads GSK's "Pack of the Future" project aimed at reducing the environmental impact of its devices and packaging. A recognised thought leader, he actively contributes to industry groups and forums, advocating for sustainable practices and circularity in packaging and device development. He holds a BS in Applied Physics from the University of Limerick, Ireland.

T: +44 7920 28 4402
E: conor.m.oneill@gsk.com

GSK

Ware R&D, Harris's Lane, Ware, Hertfordshire, SG12 0GX, United Kingdom
www.gsk.com



Duncan Paterson

Duncan Paterson, Senior Director – Device Development at Astra Zeneca, has over 20 years of technical leadership experience in the development of inhalation and parenteral devices for pharmaceutical combination products. Currently a Senior Director with AstraZeneca, previously with Novartis and Nektar Therapeutics, Mr Paterson leads device development and chemistry, manufacturing and controls project teams across all stages of the product lifecycle, as well as strategic technology and sustainability related initiatives and working groups. He also co-leads the Sustainability Sub-Team of the SC Consortium.

T: +1 650 379 3073
E: duncan.paterson@astrazeneca.com

AstraZeneca

121 Oyster Point Boulevard, South San Francisco, CA 94080, United States
www.astrazeneca.com



Dr Monica Adams

Monica Adams, PhD, Global Head – Packaging, Device and Design Solutions at GSK, has over 20 years' experience across a range of product types, including oral, intravenous, subcutaneous and respiratory products. In her current role, she is accountable for packaging and device development across the GSK ecosystem. She also co-leads the Sustainability Sub-Team and is an Officer of the SC Consortium. Her prior work experience includes product development and chemistry, manufacturing and controls leadership at Janssen, Bristol-Myers Squibb and NanoCarrier.

E: monica.x.adams@gsk.com

GSK

1250 S Collegeville Rd, Collegeville, PA 19426, United States
www.gsk.com