DCAT®

THE SUSTAINABILITY LEADERS

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nanoform
small is powerful®

NANOFORM: SMALL IS GREEN: UTILIZING INNOVATIVE NANOPARTICLE TECHNOLOGIES TO BUILD A MORE SUSTAINABLE PHARMACEUTICAL VALUE CHAIN

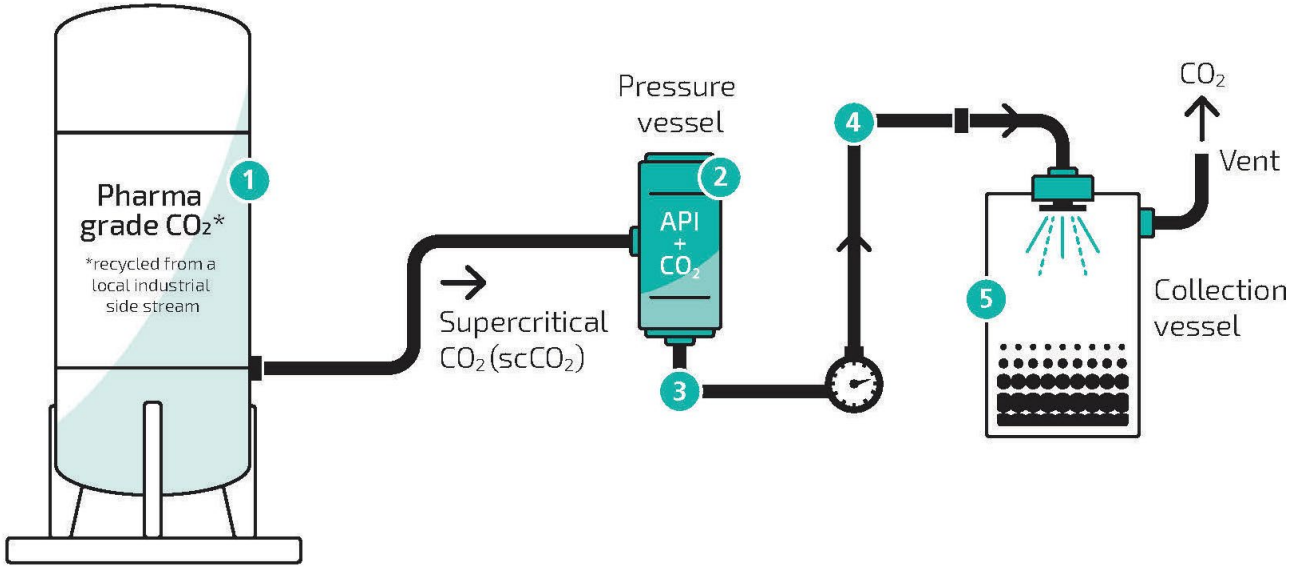
Climate change isn't just an environmental crisis, it's also a global health crisis. The healthcare sector accounts for nearly 5% of global greenhouse gas emissions—the equivalent of a small country. Patients are also increasingly seeking out treatments that align with their planet-conscious values. In response to this, the pharmaceutical industry is seizing the agenda and identifying new ways to make processes more sustainable. Merck, for example, has set an ambitious goal to achieve carbon neutrality across its operations by 2025. An Open Letter calling for suppliers to commit to joint, minimum climate and sustainability targets and to play their part in decarbonizing the healthcare value chain has also been signed by the CEOs of AstraZeneca, GSK, Merck, Novo Nordisk, Sanofi, Samsung Biologics, and the Chairman of Roche. By adopting transformative technologies that reduce waste and emissions, the pharma industry can help to forge a greener, healthier future for all.

Enhancing both sustainability and bioavailability

Nanoparticle engineering technology can both empower sustainability goals and lead to better patient outcomes. By increasing the bioavailability (referring to the extent and rate at which a drug substance reaches systemic circulation and its site of

action) of any given active pharmaceutical ingredient (API), the amount required to achieve the same therapeutic effect can be reduced, lowering dosages and thereby the overall manufacturing footprint of the given pharmaceutical.

Nanoform's proprietary Controlled Expansion of Supercritical Solutions (CESS®) nanoparticle engineering technology produces excipient-free, dry API nanoparticles directly from solution. The technique works by dissolving bulk API powder in supercritical



Steps involved in the CESS® nanoparticle enginering process.

carbon dioxide ($scCO_2$) and then recrystallizing under controlled temperature and pressure to produce uniform nanoparticles that are tuneable in size, shape, and morphology. By reducing the size to as small as 10 nm, which CESS® is able to achieve, specific surface area is dramatically increased. This facilitates greater contact with the solvent and improved dissolution, leading to greater bioavailability. This approach results in a high success rate, addressing a leading cause of drug development failure.

By producing API nanoparticles that are small enough to cross previously impassable biological membranes, CESS® can even open up new, local delivery routes, facilitating the creation of drug products with fewer side effects and improved compliance. Not only does this result in better patient outcomes, but it can also reduce downstream waste. With one in six US adults reporting difficulty swallowing, driving alternative delivery routes enables more patients to finish their drug courses and results in fewer discarded medicines at point of use by patients.

Nanoform supports all dosage form development, and our particles are amenable to multiple administration routes. Our pharmaceutical development team has expertise in a wide range of formulations, including oral, inhaled, injectable and ophthalmic.

Finding greener alternatives

Improving the bioavailability of APIs can help them to achieve the desired therapeutic effect at a lower dosage—cutting down on the manufacturing footprint for life-changing drugs. Particle engineering pathways such as CESS® can also help labs move away from utilizing common bioavailability-enhancing techniques such as spray drying of amorphous solid dispersions, which uses large quantities of polymers and environmentally damaging organic solvents.

Research suggests that organic solvents make up 60% of mass consumption in the pharmaceutical industry. Due to this widespread usage, they are commonly identified as an environmental concern. This is why CESS® utilizes GMP-grade CO_2 recycled from local industrial side streams as a solvent instead—it can help eliminate environmental concerns for users.

Innovative tools for the drugs of tomorrow

With recent advances in AI, interest is growing in its usage within pharmaceutical R&D. This includes roles such as identifying target proteins, de novo drug design and virtual drug screening. Only by embracing the latest game-changing technologies can API manufacturers stay ahead of the curve while also keeping sustainability at the forefront.

Digital twinning and AI can be utilized with particle engineering technologies to inform decision-making, ruling out drug design pathways that would otherwise have failed. This can reduce waste associated with drug development and de-risk the application of novel particle engineering techniques.

Nanoform's STARMAP® Online platform, for example, can be used alongside CESS® to pick winners among large libraries of candidate molecules. Our tool augments experimental results with detailed expert knowledge to drive the rational design of patient-centric drugs. STARMAP® Online ensures that labs only dedicate resources to projects with the greatest chance of success, reducing waste and minimizing the resources expended on API projects.

Selecting a partner focused on sustainability

Transitioning the pharmaceutical industry to a greener future is no small feat, but the challenge is not insurmountable with the right approach. This is why it's critical for companies to select partners who are aligned with the same environmental priorities. Patient- and planet-centricity are deeply interconnected, and one can't be achieved without the other.

Sustainability is an integral part of Nanoform—it runs through nearly everything we do. Our company roots are in Finland, a country that has committed to one of the earliest net zero targets. This steadfast obligation to a greener future is woven deeply into our company culture.

CESSilia, the patient statue at the heart of Nanoform's headquarters in Helsinki.

At the very heart of our Helsinki campus stands the bronze statue of a child reaching out to a nanoformed medicine. "CESSilia" serves as our reminder that everything we do is for our patients and their futures.

Our state-of-the-art GMP nanoforming suites have recently been expanded to triple our manufacturing capabilities. Furthermore, our GMP activities are regularly inspected by the national competent authority, the Finnish Medicines Agency, Fimea. This ensures all processes and materials produced are compliant and positioned for the manufacture of multiple clinical APIs. In June, Nanoform submitted an application to Fimea to update our Manufacturer's Authorization (MIA) to include our new production facilities and equipment, including GMP lines 2 & 3, our new GMP QC laboratory, and nanoforming of APIs to be used in products with a marketing authorization. A GMP inspection is expected to take place later this year.

To learn more about how Nanoform's suite of cutting-edge technologies can empower your environmental sustainability goals, contact us at commercial@nanoform.com

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